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ORIGINAL RESEARCH

Surgical Management of Primary Congenital Glaucoma: Results of a Nationwide Descriptive Study in France (CONGLAU)

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Purpose: Childhood glaucoma is rare but severe, with no recognized standard surgical procedure. We conducted a retrospective, observational, multicenter study describing surgical practices for primary congenital glaucoma (PCG) in France.

Patients and methods: This study was conducted between 2013 and 2018 using data from PCG patients aged <4 years at 16 reference centers in France. Intraocular pressure (IOP) (baseline [pre-surgery], 1 month, 1 year), initial surgical procedure, antimitotic (mitomycin C [MMC]) use, secondary intervention(s), and surgical success (complete, relative, or failure) were recorded.

Results: Overall, 116 eyes (83 patients) were included. The most common surgeries were trabeculotomy (31.0%) and trabeculotomy combined with trabeculectomy (20.7%). A further 11 other types of surgery were performed for <10% of eyes. Median IOP was reduced in each surgical group at 1 month (the largest median reduction being for combined trabeculotomy/non-perforating deep sclerectomy [−60%]) and at 1-year (the largest median reduction being for trabeculectomy [−55%]). Anti-glaucomatous treatment was administered in 30.4% of cases, most commonly for trabeculectomy (66.7%). Complete and relative surgical success were observed for 21.5% and 33.6% of surgical procedures overall, with complete success most common for trabeculotomy (47.1%). When MMC was used (51.8% of surgical procedures overall, excluding trabeculotomy), surgery was less successful (complete success 3.6% *versus* 40.8%) and further interventions were more common.

Conclusion: There was a trend towards better effectiveness of angle-based surgery (eg, trabeculotomy). The findings suggest that MMC may not be essential in first-line PCG surgery.

Keywords: childhood, glaucoma, observational, primary, surgery

Introduction

Childhood glaucoma is rare but severe and occurs from birth until adolescence. It has has multiple etiologies, each of which can have a significant impact on the clinical approach and decision-making process, and compared to adults, childhood glaucoma occurs at a lower incidence and is frequently linked to substantial visual loss. The Childhood Glaucoma Research Network classification provides a logical and systematic framework for standardizing nomenclature in childhood glaucoma, and has been adopted by the American Association of Ophthalmology and the European Glaucoma Society.[1] Factors for accurate diagnosis include raised intraocular pressure (IOP), defects in the visual field, and alterations in the cornea, optic nerve, and ocular size.[2]

Primary congenital glaucoma (PCG) is the most common form of pediatric glaucoma in Western Europe, with an incidence of approximately 1/18,500 births,[3] and typically presents at birth or in the first few weeks of life. PCG may arise in the absence of any associated acquired or pre-existing conditions. It is caused by angle dysgenesis due to a genetic maldevelopment of the outflow pathway structures (trabecular meshwork) in the iridocorneal angle before and/or after birth, which impairs aqueous humor outflow and results in elevated IOP. The classical signs of PCG include photophobia, tearing, and blepharospasm, with progressive corneal enlargement and haze also being commonly reported. Diagnosis and prompt

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management are crucial, and untreated PCG can lead to buphthalmos and subsequently to irreversible optic nerve damage and severe visual impairment.[4] While most cases of PCG occur sporadically, approximately 10 to 40% occur in individuals with an inherited predisposition,[2] with autosomal recessive inheritance being most common.[5] Accurate diagnosis typically relies on examination under general anesthesia for an assessment of IOP, corneal diameter, axial length, and angle structures using gonioscopy. Following diagnosis, medical treatment alone is usually insufficient for long-term control of IOP,[4] and surgical treatment is usually required to prevent vision loss but varies considerably between countries and between centers within the same country. Unlike glaucoma surgery in adults, there is no recognized standard surgical procedure for PCG, which can depend on factors such as surgeon expertise, available resources, and patient demographics.[3,6] Trabeculotomy with or without trabeculectomy is often described in the literature.[7]

In the context of gaps in the existing literature, including a lack of comparative data, national registry-based approaches, or effectiveness of mitomycin, the objective of this study, sponsored by the French health authorities, was to characterize the treatment procedures used for PCG in reference centers in France and their effectiveness at 1-year post-surgery, including an evaluation of the effect of mitomycin.

Methods

Design and Patients Studied

This multicenter, observational study was conducted between 2013 and 2018 as part of a public National Clinical Research Hospital Program (PHRC-N) (ID-RCB 2012-A00929-34) in pediatric patients from 16 reference centers in France following approval from the PHRC ethics committee. The study complied with International Organization for Standardization standards (Clinical Investigation of Medical Devices for Human Subjects) and was performed according to the ethical framework of the Declaration of Helsinki and the International Council for Harmonization guidelines for Good Clinical Practice (GCP). Each patient's parent(s) or legally approved representative(s) provided written informed consent prior to inclusion.

Male or female patients aged <4 years for whom an ophthalmological examination under general anesthesia was planned to confirm a diagnosis of PCG were eligible. All patients who were eligible were to be enrolled successively in each center. Pediatric patients with secondary glaucoma or who had already received an intervention for PCG were excluded.

Recorded Data

For each patient, an electronic case report form was completed by qualified study center staff to record baseline data (age, unilateral or bilateral glaucoma, sex), IOP (baseline, 1 month, and 1 year), initial surgical procedure performed and complications during 1-year follow-up, antimitotic (mitomycin C [MMC]) use (Yes/No) (further detail regarding the application of MMC was not available), secondary intervention(s) (none, needling, or new surgery), and surgical success (complete, relative, or failure). The definition of complete surgical success was a 1-year post-surgical reduction in IOP ≥30% after a single surgical procedure and without associated medical treatment. The definition of relative surgical success was a 1-year post-surgical reduction in IOP ≥30% after one or more surgical procedures and with or without associated medical treatment. Surgical failure was defined as a post-surgical reduction in IOP <30% at 1 year after one or more surgical procedures and with or without associated medical treatment.

Statistical Analysis

The primary objective was to describe the reduction in IOP at 1-year post-surgery for each type of initial surgical procedure. Secondary objectives included a description of IOP results at 1 year with or without MMC, the number of repeat procedures (overall and with or without MMC), the number of anti-glaucomatous treatments (overall and with or without MMC), and the surgical success (overall and with or without MMC).

A formal calculation of sample size was not conducted since there was no statistical hypothesis. Only descriptive statistics are presented (continuous data included the number of non-missing observations [n], mean, standard deviation [SD], median, minimum, and maximum; categorical data included the number of non-missing observations [n], count, and percentage of each modality). IOP distribution (baseline, 1 month, and 1 year) was described using boxplots. SAS® software, version 9.4 (SAS Institute, North Carolina, USA) was used.

Results

Patients and Baseline Characteristics

Of 250 eyes (125 patients) initially screened, 134 eyes were not included in the analysis. The factors leading to exclusion were: not PCG (60 eyes), missing diagnosis (25 eyes), lost to follow-up (30 eyes), missing IOP data (19 eyes) (Supplementary Figure 1). In total, therefore, 116 eyes (83 patients) were included in the evaluations.

Unilateral glaucoma was diagnosed in 50 (60.2%) patients and bilateral glaucoma in 33 (39.8%) patients (Table 1). At the time of surgery, mean±SD age was 6.1±5.7 months, with slightly more male (53.0%) than female (47.0%) patients.

Types of Initial Surgery and 1-Year Follow-up for Complications

A range of initial procedures were performed, including separate or combined angle (goniotomy, trabeculotomy, viscocanalostomy) and filtering (non-perforating deep sclerectomy [NPDS], STAAR Aquaflow™ device, and trabeculectomy) surgery (Table 2). Except for a single center where various surgical procedures were used, the same procedure was used in each center for all eyes. Overall, the most common types of surgery were trabeculotomy (36 eyes, 31.0%), and trabeculotomy combined with trabeculectomy (24 eyes, 20.7%). All other types of surgery were performed for <10% of eyes and as such are considered to be exploratory. No complications were reported until the end of the 1-year period of follow-up.

Efficacy of Initial Surgery

At baseline, depending on the surgical group, mean±SD IOP ranged from 13.5±3.6 mmHg to 19.6±4.5 mmHg (Table 3). At 1-month post-surgery, median IOP was reduced in each surgical group with median (min, max) reduction being largest for combined trabeculotomy/NPDS (−60% [−75, −17]), followed by trabeculectomy (−50% [−81, 50] and trabeculotomy (−41% [−81, 179]). The lowest median relative IOP reduction was for combined trabeculotomy/viscocanalostomy/NPDS (−20% [−47, 50]). At 1-year post-surgery, the effectiveness of surgical procedure in terms of IOP reduction differed to the evaluation at 1 month, with median reduction being largest for trabeculectomy (−55% [−77, 9]), followed by NPDS (−48% [−71, 6]) and trabeculotomy (−46% [−80, 38]), and lowest for both combined trabeculotomy/trabeculectomy (−17% [−78, 157]) and NPDS/STAAR Aquaflow device (−17% [−42, 10]).

Regarding further interventions, new surgery was performed in 34.3% of cases overall, most commonly following initial trabeculectomy (in 71.4% of cases) and trabeculotomy/trabeculectomy (52.6%), and less commonly after combined trabeculotomy/NPDS (12.5%) and trabeculotomy/viscocanalostomy/NPDS (14.3%) (Table 3). Needling was

Table 1 Patient Characteristics

	Patients N=83
Number of operated eyes	116
Glaucoma	
Unilateral, n (%)	50 (60.2%)
Bilateral, n (%)	33 (39.8%)
Gender	
Male, n (%)	44 (53.0%)
Female, n (%)	39 (47.0%)
Age at initial surgery (months)	
Mean (SD)	6.1 (5.7)
Min, max	0, 24

Abbreviations: Max, maximum; min, minimum; N, number of patients; n (%), number (%) of patients in subgroup; SD, standard deviation.

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Table 2 Type of Initial Surgical Procedure (All Eyes)

Type of Surgery	Operated Eyes N=116
Trabeculotomy, n (%)	36 (31.0)
Trabeculotomy/Trabeculectomy, n (%)	24 (20.7)
NPDS/STAAR Aquaflow™ device, n (%)	11 (9.5)
Trabeculotomy/NPDS, n (%)	10 (8.6)
NPDS, n (%)	10 (8.6)
Trabeculectomy, n (%)	9 (7.8)
Trabeculotomy/Viscocanalostomy/NPDS, n (%)	8 (6.9)
Other[a], n (%)	8 (6.9)
Total, n (%)	116 (100)

Notes: [a]Other performed surgeries were as follows: STAAR Aquaflow™ collagen drainage implant (n=2 eyes, both with MMC), trabeculotomy/NPDS/STAAR Aquaflow™ Collagen drainage implant (n=2 eyes, 1 with MMC, 1 without MMC), trabeculotomy/viscocanalostomy (n= 1 eye, with mitomycin), NPDS/STAAR Aquaflow™ collagen drainage implant/viscocanalostomy (n=1 eye, MMC use not known), NPDS/viscocanalostomy (n=1 eye, with MMC), goniotomy (n=1 eye, without mitomycin).
Abbreviations: N, number of eyes; n (%): number (%) of eyes in subgroup; NPDS, non-penetrating deep sclerectomy.

performed in the event of failure of filtration as the initial intervention, at the discretion of the surgeon rather than by a standard protocol, and of note, needling was always performed following NPDS/STAAR device (in 100% of cases) and was frequent after combined trabeculotomy/NPDS (75.0%), combined trabeculotomy/viscocanalostomy/NPDS (71.4%) and NPDS alone (55.6%); no needling was performed following trabeculotomy and trabeculectomy.

Anti-glaucomatous treatments were administered in 30.4% of cases overall, most commonly for trabeculectomy (in 66.7% of cases) and combined trabeculotomy/trabeculectomy (52.2%), and less frequently for combined NPDS/STAAR device (0%), combined trabeculotomy/NPDS and NPDS alone (20.0% each) (Table 3).

Complete and relative surgical success were observed for 21.5% and 33.6% of surgical procedures overall (Table 3). Complete success was most commonly reported for trabeculotomy (in 47.1% of cases), followed by trabeculotomy/trabeculectomy (22.7%). Relative success was most commonly reported for NPDS alone (80.0%), followed by trabeculectomy (50.0%) and combined trabeculotomy/NPDS (44.4%). Surgical failure at 1 year was most frequent for trabeculotomy/viscocanalostomy/NPDS (71.4% of cases), NPDS/STAAR device (70.0%), trabeculotomy/trabeculectomy (63.6%), and trabeculotomy/NPDS (55.6%), although these high rates could be influenced by the relatively small sample size for some subgroups.

Mitomycin Use

MMC was used in 51.8% of surgical interventions, although all trabeculotomies alone were performed without MMC (Figure 1). Most or all other types of surgery were performed with MMC (from 57% of combined trabeculotomy/trabeculectomy to 100% of combined trabeculotomy/viscocanalostomy/NPDS).

Efficacy parameters for MMC-augmented surgery vs surgery performed without MMC are shown in Figure 2, and IOP data for each type of surgery with and without mitomycin are presented in Figure 3. A detailed description of all efficacy parameters (IOP, secondary interventions, anti-glaucomatous treatment, and surgical success) is also provided for each type of initial surgery performed with MMC in Supplementary Table 1 and without MMC in Supplementary Table 2. A decline from baseline IOP (overall) was observed at 1 month post-surgery that was similar with and without MMC (Figure 2A). Similar findings were observed for each type of surgery (Figure 3). When MMC was used, the largest median IOP reduction was noted for combined trabeculotomy/NPDS (−63%), followed by NDPS alone (−41%), trabeculectomy (−35%), and NPDS/STAAR device (−34%). When MMC was not used, the largest median IOP reduction was obtained following trabeculectomy alone (−70%), combined trabeculotomy/trabeculectomy (−54%), goniotomy (−45%, only 1 eye), trabeculotomy/NPDS (−43%, only 1 eye), trabeculotomy (−41%), and NPDS (27%).

Table 3 Intraocular Pressure, Secondary Interventions, Anti-Glaucomatous Treatment, and Surgical Success (All Eyes)

			Type of Surgery								
			Trabeculo N=36	**Trabeculec N=9**	**Trabeculo/ Trabeculec N=24**	**Trabeculo/ visco/ NPDS N=8**	**Trabeculo/ NPDS N=10**	**NPDS N=10**	**NPDS/ STAAR N=11**	**Other N=8**	**Total N=116**
IOP (mmHg)	Baseline	N	36	9	24	8	10	10	10	8	115
		Mean (SD)	19.5 (7.0)	16.3 (3.7)	14.2 (7.3)	17.8 (6.9)	18.2 (5.5)	19.6 (4.5)	13.5 (3.6)	19.4 (8.6)	17.4 (6.7)
		Median	20	16	13	20	20	20	13	22	17
		Min, max	9, 33	12, 22	6, 31	4, 26	9, 26	13, 28	8, 20	4, 28	4, 33
	1 month	N	35	9	24	8	9	9	11	8	113
		Mean (SD)	12.2 (9.6)	8.8 (4.8)	9.6 (3.0)	13.9 (4.9)	8.6 (4.1)	11.0 (4.4)	8.6 (3.4)	9.3 (2.9)	10.5 (6.3)
		Median	10	8	9	14	8	10	9	9	9
		Min, max	5, 51	3, 18	5, 16	6, 21	5, 18	6, 20	4, 16	5, 14	3, 51
	Evolution at Month 1	N	35	9	24	8	9	9	10	8	112
		Mean (SD)	−7.4 (11.1)	−7.6 (6.3)	−4.6 (7.8)	−3.9 (4.6)	−10.7 (4.7)	−8.2 (6.6)	−4.6 (3.7)	−10.1 (9.0)	−6.8 (8.3)
		Median	−7	−8	−3	−4	−12	−5	−5	−13	−7
		Min, max	−23, 29	−14, 6	−17, 9	−9, 2	−16, −2	−20, 0	−11, 0	−20, 1	−23, 29
	1 year	N	36	9	24	8	10	10	11	8	116
		Mean (SD)	10.5 (4.3)	9.2 (5.3)	11.3 (6.0)	13.3 (7.0)	10.6 (5.6)	10.4 (2.9)	10.7 (2.1)	9.5 (1.8)	10.7 (4.7)
		Median	9	9	10	11	10	10	12	9	10
		Min, max	5, 24	4, 22	5, 28	6, 24	3, 19	8, 17	7, 13	7, 12	3, 28
	Evolution at Year 1	N	36	9	24	8	10	10	10	8	115
		Mean (SD)	−9.0 (6.5)	−7.1 (6.7)	−2.9 (9.4)	−4.5 (9.0)	−7.6 (7.6)	−9.2 (5.8)	−2.9 (2.8)	−9.9 (8.3)	−6.7 (7.7)
		Median	−9	−7	−2	−4	−5	−9	−3	−12	−6
		Min, max	−22, 2	−16, 6	−21, 11	−19, 5	−17, 3	−20, 1	−7, 1	−19, 3	−22, 11
IOP (%)	Relative change At Month 1	N	35	9	24	8	9	9	10	8	112
		Mean (SD)	−32.0 (52.5)	−42.6 (39.1)	−10.6 (55.9)	−13.0 (32.3)	−54.2 (20.3)	−40.1 (24.0)	−32.7 (22.4)	−38.0 (38.1)	−29.8 (45.3)
		Median	−41.0	−50.0	−21.0	−20.0	−60.0	−31.0	−34.0	−55.0	−39.0
		Min, max	−81, 179	−81, 50	−73, 129	−47, 50	−75, −17	−74, 0	−65, 0	−71, 25	−81, 179
	Relative change At Year 1	N	36	9	24	8	10	10	10	8	115
		Mean (SD)	−42.4 (21.7)	−40.8 (34.9)	1.4 (65.8)	−7.7 (63.8)	−36.9 (34.8)	−44.1 (21.5)	−18.9 (17.2)	−33.7 (48.3)	−27.7 (44.5)
		Median	−46.0	−55.0	−17.0	−20.0	−29.0	−48.0	−17.0	−55.0	−38.0
		Min, max	−77, 9	−80, 38	−78, 157	−73, 125	−85, 20	−71, 6	−42, 10	−68, 75	−85, 157

(*Continued*)

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Table 3 (Continued).

			Type of Surgery								
			Trabeculo N=36	**Trabeculec N=9**	**Trabeculo/ Trabeculec N=24**	**Trabeculo/ visco/ NPDS N=8**	**Trabeculo/ NPDS N=10**	**NPDS N=10**	**NPDS/ STAAR N=11**	**Other N=8**	**Total N=116**
Secondary Intervention			**N=34**	**N=7**	**N=19**	**N=7**	**N=8**	**N=9**	**N=10**	**N=5**	**N=99**
	None	n (%)	22 (64.7)	2 (28.6)	8 (42.1)	1 (14.3)	1 (12.5)	1 (11.1)			35 (35.4)
	Needling	n (%)			1 (5.3)	5 (71.4)	6 (75.0)	5 (55.6)	10 (100.0)	3 (60.0)	30 (30.3)
	New surgery	n (%)	12 (35.3)	5 (71.4)	10 (52.6)	1 (14.3)	1 (12.5)	3 (33.3)		2 (40.0)	34 (34.3)
Anti-glaucomatous Treatment			**N=36**	**N=9**	**N=23**	**N=8**	**N=10**	**N=10**	**N=11**	**N=8**	**N=115**
	No	n (%)	25 (69.4)	3 (33.3)	11 (47.8)	6 (75.0)	8 (80.0)	8 (80.0)	11 (100.0)	8 (100.0)	80 (69.6)
	Yes	n (%)	11 (30.6)	6 (66.7)	12 (52.2)	2 (25.0)	2 (20.0)	2 (20.0)			35 (30.4)
Surgical success			**N=34**	**N=8**	**N=22**	**N=7**	**N=9**	**N=10**	**N=10**	**N=7**	**N=107**
	Complete	n (%)	16 (47.1)	1 (12.5)	5 (22.7)			1 (10.0)			23 (21.5)
	Relative	n (%)	8 (23.5)	4 (50.0)	3 (13.6)	2 (28.6)	4 (44.4)	8 (80.0)	3 (30.0)	4 (57.1)	36 (33.6)
	Failure	n (%)	10 (29.4)	3 (37.5)	14 (63.6)	5 (71.4)	5 (55.6)	1 (10.0)	7 (70.0)	3 (42.9)	48 (44.9)

Abbreviations: N: number of eyes; n: number of non-missing observations; SD: standard deviation; NPDS: non-perforating deep sclerectomy; STAAR: STAAR Aquaflow™ Collagen drainage implant; trabeculec: trabeculectomy; trabeculo: trabeculotomy; visco: viscocanalostomy.

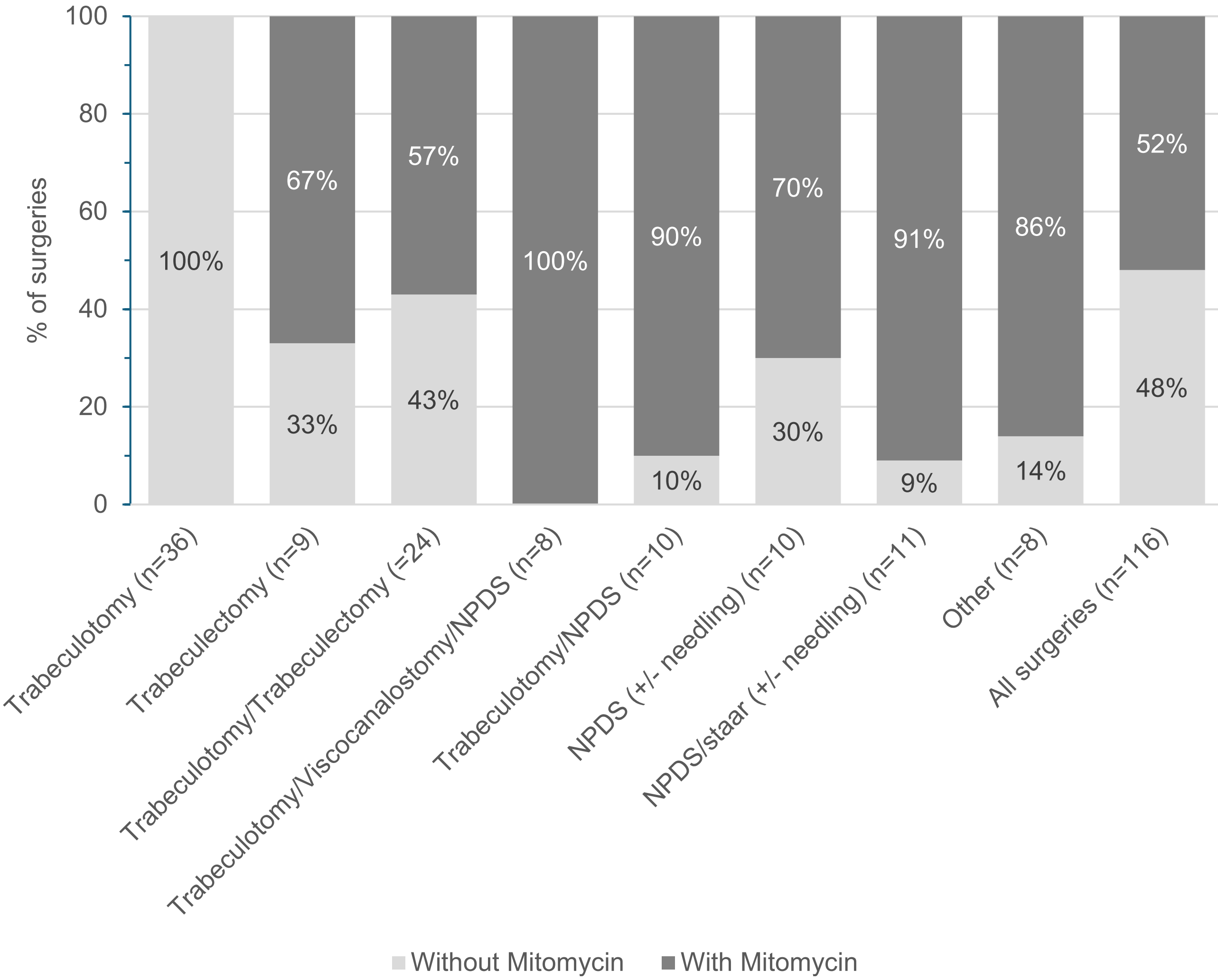

Figure 1 Use of mitomycin by type of first surgery.

The effectiveness of each surgical procedure (with or without MMC) in terms of IOP reduction was largely confirmed at 1-year post-surgery. When MMC was used, the largest median IOP reduction at 1 year was for NPDS alone (−43%), followed by combined trabeculotomy/NPDS (−33%), trabeculectomy alone (−31%), and combined trabeculotomy/viscocanalostomy/NPDS (−20%). For trabeculotomy/trabeculectomy with MMC, there was a median increase in IOP of 56% at 1 year. When MMC was not used, the largest median IOP reduction was obtained following trabeculectomy alone (−63%), followed by NPDS alone (−57%), combined trabeculotomy/trabeculectomy (−48%), trabeculotomy alone (−46%), and goniotomy (−45%, only 1 eye). For combined trabeculotomy/NPDS (evaluated in a single eye), there was no change at 1 year.

Further interventions were more frequently performed following initial surgery with MMC (86.5% of procedures) compared to surgery without MMC (41.3%) (Figure 2B). Procedures with the lowest reintervention rate were trabeculotomy (without MMC, 64.7%) and combined trabeculotomy/trabeculectomy (42.1% overall, 60.0% without MMC and 30.8% with MMC). When MMC was used, new surgery was most commonly performed after initial trabeculectomy (80.0%) or combined trabeculotomy/trabeculectomy (61.5%) and was less common after combined trabeculotomy/NPDS (12.5%) or trabeculotomy/viscocanalostomy/NDPS (14.3%). Needling was frequently performed following surgery augmented with MMC (100% of NPDS/STAAR device, 75.0% of trabeculotomy/NPDS, 71.4% of trabeculotomy/viscocanalostomy/NPDS, and 66.7% of NPDS) (Supplementary Table 1 and Supplementary Table 2).

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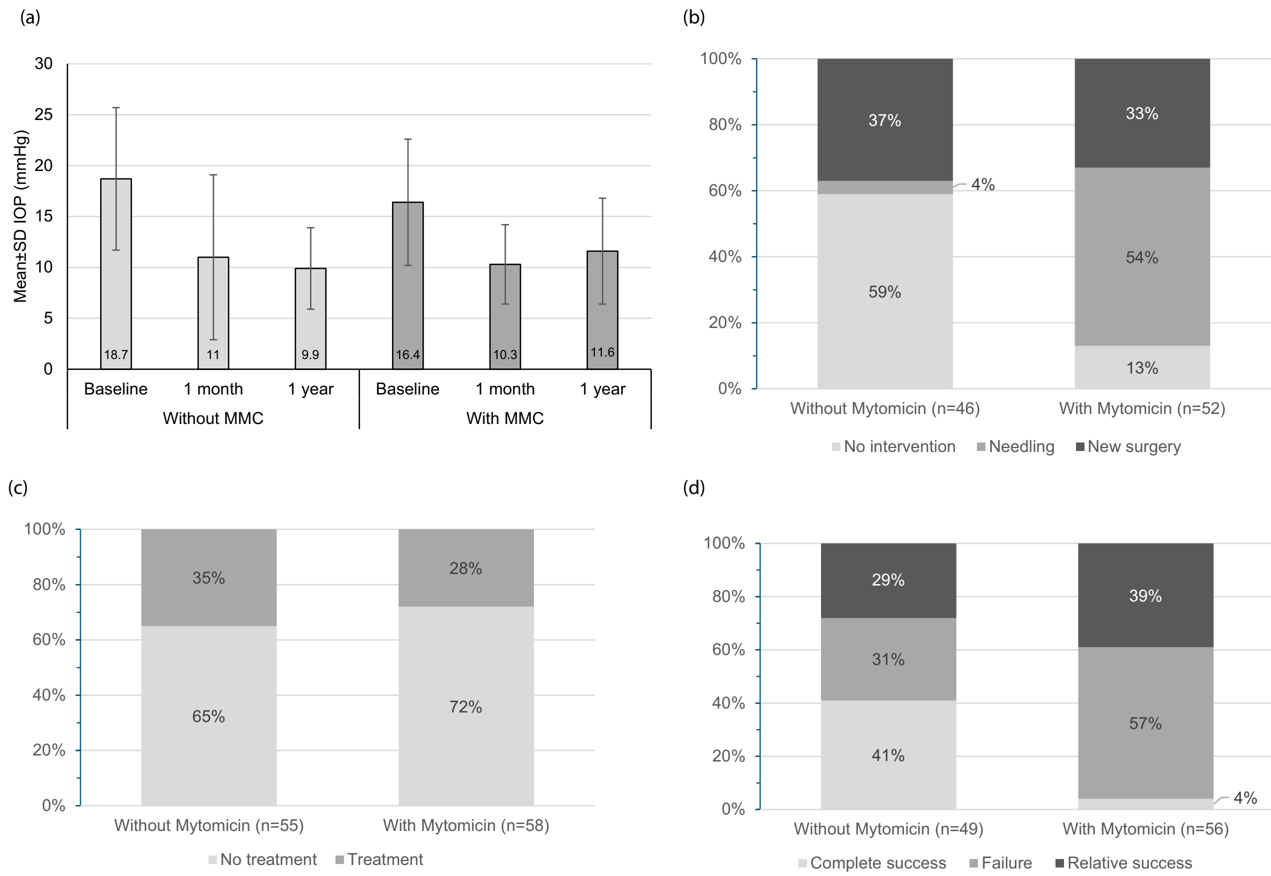

Figure 2 Comparison of efficacy endpoints by use of mitomycin (**a**) IOP by use of mitomycin (**b**) New intervention (new surgery or needling) by use of mitomycin.(**c**) Anti-glaucomatous treatment intake by use of mitomycin (**d**)Surgical success by use of mitomycin.
Note: Data are mean±SD.

Anti-glaucomatous treatments were administered slightly less frequently after surgery with MMC (in 27.6% of cases) than without (34.5%) (Figure 2C). Procedures requiring the most local anti-glaucoma treatment at 1 year were trabeculectomy alone (66.7%, both with and without MMC) and combined trabeculotomy/trabeculectomy (58.3% with MMC and 50.0% without MMC). No anti-glaucomatous treatment was administered following combined NPDS/STAAR device surgeries (both with and without MMC) (Supplementary Tables 1 and 2).

Procedures performed without MMC had a higher complete success rate than those with MMCs (40.8% vs 3.6%, respectively) at 1 year (Figure 2D). Also, a higher overall success rate (complete and relative) was noted for surgeries without MMC than those with MMC (69.4% vs 42.9%). For procedures performed with MMC, complete success at 1 year was only reported for 15.4% of trabeculotomy/trabeculectomy, while surgical failure was reported following 76.9% of trabeculotomy/trabeculectomy, 71.4% of trabeculotomy/viscocanalostomy/NPDS, 70% of NPDS/STAAR device, and 50% of both trabeculectomy and trabeculotomy/NPDS (Supplementary Tables 1 and 2), although as mentioned earlier these high rates could be influenced by the relatively small sample size for some subgroups. For procedures without MMC, trabeculectomy (50.0%, only 1 eye) and trabeculotomy (47.1%) had the highest complete success rate at 1 year. Surgical failure was most commonly reported following trabeculotomy/NPDS (100.0%, only 1 eye), followed by trabeculotomy/trabeculectomy (50.0%) and trabeculotomy (29.4%). No surgical failure was reported at 1 year for trabeculectomy or NPDS without MMC.

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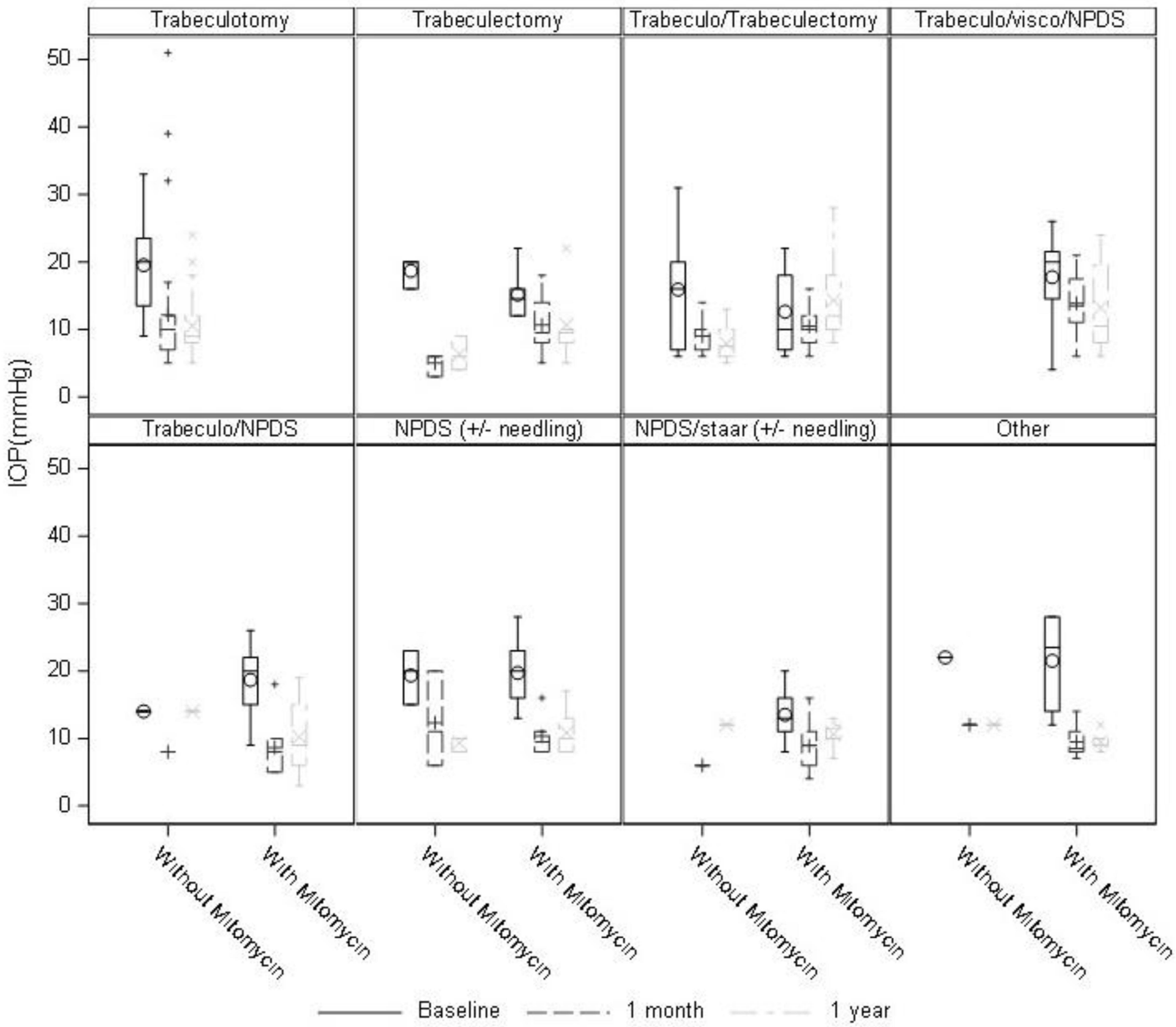

Figure 3 Intraocular pressure by type of first surgery and use of mitomycin.
Abbreviations: NPDS, non-perforating deep sclerectomy; STAAR, STAAR collagen drainage implant; visco, viscocanalostomy.

Discussion

In this observational study using data collected from 83 patients (116 eyes) following initial surgery between 2013 and 2018, we assessed the management of PCG at 16 reference centers in France. The European Glaucoma Society recognizes pediatric glaucoma management as particularly complex, owing to both the disease characteristics and the inherent challenges in examining and treating young patients. It advises that treatment be tailored to the primary condition and the underlying cause of raised IOP.[8] Surgery is almost always indicated in PCG, with initial surgical interventions including early goniotomy, trabeculotomy, and filtration surgery, and repeat surgery is frequent.

Surgical Procedures

Although a range of surgical procedures was used in the different centers, for all centers the same procedure was used consistently with the exception of one center where a range of procedures was used. The most common surgical intervention was trabeculotomy, followed by (in descending order) trabeculotomy/trabeculectomy, NPDS-STAAR, NPDS, and trabeculotomy/NPDS, trabeculectomy, and trabeculotomy/viscocanalostomy/NPDS. Therefore, *ab externo* angle-based surgery (trabeculotomy alone or combined with trabeculectomy or NPDS with or without canalostomy) was the most widely used technique, accounting for 78 eyes (67.2%) overall. These findings reflect the World Glaucoma Recommendations for the initial PCG surgical procedure.[1] Surgical procedures with filtration are usually considered to be second-line after failed angle-based surgery, and in our study 37 eyes (32.1%) were initially operated on using filtering surgery. Surgical techniques for primary open-angle glaucoma may have been used at some centres more accustomed to performing this type of procedure in adults rather than angle-based surgery.

Comparison of IOP results at 1 Year According to Surgical Procedure

Complete surgical success (ie, a reduction in IOP ≥30% at 1 year after a single surgical procedure and without associated medical treatment) was observed for 16/34 (47.1%) eyes following trabeculotomy and for 5/22 (22.7%) eyes following trabeculotomy/trabeculectomy, confirming the pertinence of first-line angle-based or trabecular surgery. Filtration surgery was less successful, with only 2/18 (11.1%) eyes showing complete surgical success (ie, for trabeculectomy and NPDS), which could reflect differences in pediatric versus adult eyes, surgeon experience, or case severity. However, the surgeons were the designated contacts for each center and therefore qualified in these techniques, and the cases were likely to have been comparable, and so it is reasonable to surmise that filtration surgery was less efficient than angle-based surgery. In considering cumulative complete and relative surgical success rates, NPDS showed 90% success, followed by trabeculotomy (70.6%), trabeculectomy (62.5%), trabeculotomy/NPDS (44.4%), trabeculotomy/trabeculectomy (36.3%), NPDS-STAAR (30%), and lastly the triple surgical technique of trabeculotomy/viscocanalostomy/NPDS (28.6%). Our findings are aligned with those reported historically: traditional goniotomy and trabeculotomy *ab externo* (incising 2 quadrants) have shown success rates from 30% to 65% and 40 to 80%, respectively, varying from 10% to 94%,[1,9] and success rates of 50% to 87% for trabeculectomy performed for PCG.[10]

Comparison of IOP results at 1 year According to Surgical Procedures and Use of Mitomycin

With the exception of trabeculotomy, mitomycin was widely used. At 1 year, there was a clinically important difference between the success of surgery performed without mitomycin (40.8%) and with mitomycin (3.6%). When considering cumulative complete and relative surgical success rates, surgery without mitomycin was more successful than with mitomycin (69.4% *versus* 42.9%). Accordingly, the surgical failure rate was higher for procedures performed with mitomycin (57.1%) than without mitomycin (30.6%). Furthermore, surgical procedures with mitomycin were associated with a larger number of secondary interventions (cumulative total of 86.5%) *versus* procedures without mitomycin (cumulative total of 41.3%). However, these findings remain speculative since they could be confounded by less complex surgery (which could be associated with higher success rates) being performed without MMC.

These findings should therefore be interpreted with caution, since in our study trabeculotomy (angle-based surgery) was associated with a better outcome than filtration surgical techniques. However, it appears that the systematic use of mitomycin in adult filtration surgery for glaucoma may not be needed in pediatric surgery for PCG. The rate of success for trabeculectomy without adjunctive anti-metabolites in children has been reported to vary widely (around 35% to 92.3%).[10–14] The use of adjunctive anti-metabolites has been associated with short-term success from 55% to 95%, although these outcomes vary depending on the form of glaucoma, demography and clinical profile of the pediatric population, and the criteria used to define success.[15–20] With extended follow-up, success rates decreased (between 55% to 60%).[16,21] However, some studies have reported no difference in success rates with or without mitomycin in children[6,22,23] while others have shown that younger age and aphakia following congenital cataract surgery are associated with an increased risk of trabeculectomy failure when adjunctive metabolites are used.[15,19]

Choosing to perform trabeculectomy with anti-metabolites in children requires careful judgment. Age plays a crucial role—older children tend to have better outcomes, partly due to their ability to follow post-operative instructions such as monitoring for bleb leaks and having sutures released. They are also better able to recognize and report symptoms of bleb-related infections, which improves the chances of receiving timely and effective treatment. The high risk of bleb-related infections has led to caution being recommended regarding the use of mitomycin as an adjunct in pediatric trabeculectomy,[18] and with the development of drainage devices it has been suggested that these might be a better option for pediatric patients than the use of mitomycin in conjunction with trabeculectomy.

Comparison of Tenonectomy to Use of Mitomycin

In addition to the use of mitomycin to enhance efficacy, the potential impact of removing the Tenon's layer—and its associated fibroblasts—is frequently considered. Data have been reported from a pediatric study comparing conventional trabeculectomy with mitomycin to that with tenonectomy.[24] Patients who underwent tenonectomy had significantly lower IOP from 1-month post-surgery through 2 years, reported less use of medication use from 3 months, and statistically showed less failure (30% *versus* 55%) and less bleb encapsulation (3% *versus* 25%) at 2 years. Although longer average survival time was reported in the tenonectomy group (16.6 months) compared to those who did not undergo tenonectomy (11.6 months), no difference in surgical success was observed with or without additional glaucoma medication.[24,25]

Limitations of the Study

While this study was observational and descriptive in nature, and therefore subject to inherent limitations, the findings offer important insights into real-world clinical practices used for PCG in reference centers in France. The relatively small number of patients within each surgical group as well as the heterogeneity of the patient population limit the ability to conduct formal statistical comparisons and affect the overall robustness of the data. Additionally, differences in the severity of PCG between groups and the absence of baseline data constrain the interpretation of variations in IOP outcomes across procedures (IOP was measured at diagnosis and during follow-up using the same methodology at each center but was not controlled between centers in this observational study). As such, the findings should be considered within the context of the variability in surgical approaches (eg, NPDS/STAAR was mainly performed at a single centre), patient characteristics, method of MMC application, and IOP measurement, and it should be noted that these data provide a description of surgical practices rather than a formal comparison of the different surgical techniques used in the reference centres. However, the study holds significant value by capturing real-world treatment patterns for PCG across expert reference centers in France, providing a meaningful contribution to the understanding of current clinical management in this rare condition.

Conclusion

This observational study in French reference centers highlighted a wide range of surgical management procedures for PCG. All centers except one performed the same procedure consistently, considering it to bring the best result for their pediatric patients. There was a trend towards better effectiveness of angle-based surgery, and the use of an anti-fibroblast product may not always be necessary in first-line PCG surgery.

Abbreviations

GCP, Good Clinical Practice; IOP, Intraocular pressure; MMC, Mitomycin C; n, Number of non-missing observations; NPDS, Non-perforating deep sclerectomy; PCG, Primary congenital glaucoma; PRHC-N, National Clinical Research Hospital Program; SD, Standard deviation.

Data Sharing Statement

Individual data supporting the results presented in this article, along with the study protocol, will be available to researchers who provide a methodologically sound proposal, upon request to the Corresponding Author.

Ethics Approval and Informed Consent

The protocol received approval from the National Clinical Research Hospital Program ethics committee, and the study complied with International Organization for Standardization standards (Clinical Investigation of Medical Devices for Human Subjects) and was performed according to the ethical framework of the Declaration of Helsinki and the

International Council for Harmonization guidelines for Good Clinical Practice (GCP). Each patient's parent(s) or legally approved representative(s) provided written informed consent form prior to inclusion.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; agreed on the journal to which the article was submitted; and agree to be accountable for all aspects of the work.

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