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Flaremetry measurement of blood-aqueous barrier breakdown after canaloplasty combined with phacoemulsification versus phacoemulsification in patients with secondary open angle glaucoma

Ocena szczelności bariery krew–ciecz wodnista metodą flarymetrii u chorych na jaskrę wtórną otwartego kąta po zabiegu kanaloplastyki z fakoemulsyfikacją i po zabiegu fakoemulsyfikacji

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Abstract: Purpose: To evaluate the safety of canaloplasty with phacoemulsification compared to phacoemulsification in patients with pseudoexfoliative glaucoma and pigmentary glaucoma with respect to flaremetry measures.

Material and methods: Fifty-four eyes of patients with secondary open angle glaucoma who underwent canaloplasty with phacoemulsification (Group 1) or phacoemulsification (Group 2) due to the cataract and uncontrolled glaucoma were enrolled. Flare was measured using the Laser Flare Meter Kowa FM-600 at baseline, and postoperatively – on day 7, as well as at 1, 3, 6, and 12 months. Other assessed outcome measures were intraocular pressure, number of glaucoma medications and adverse events.

Results: There was no significant difference in flare between Groups 1 and 2 at baseline (17.9 $\pm$ 7.9 ph/ms vs. 16.3 $\pm$ 6.0 ph/ms, $p = 0.32$). Similarly, there were no differences in flare between the groups at 1 week ($p = 0.65$) and 1 month ($p = 0.25$) postoperatively. The mean flare at 3, 6 and 12 months postoperatively was significantly lower in Group 1 ($p<0.01$). Postoperative intraocular pressure was lower in Group 1 at all measurement points ($p<0.001$). The number of antiglaucoma medications significantly decreased from baseline at all timepoints ($p<0.001$) only in eyes after phacocanaloplasty.

Conclusion: Phacocanaloplasty is a safe option for lowering intraocular pressure in patients with secondary open angle glaucoma as it ensures blood-aqueous barrier integrity. Flaremetry analyses demonstrated that combined surgery offers as high safety profile as the one of phacoemulsification.

Key words: canaloplasty, glaucoma, flare.

Abstrakt: Cel: ocena bezpieczeństwa zabiegu kanaloplastyki z fakoemulsyfikacją w porównaniu do bezpieczeństwa zabiegu fakoemulsyfikacji z użyciem flarymetrii u chorych na jaskrę pseudoeksfoliacyjną i jaskrę barwnikową.

Materiał i metody: badaniem objęto 54 oczu u chorych na jaskrę wtórną otwartego kąta, którzy z powodu zaćmy i współistniejącej niekontrolowanej jaskry zostali zakwalifikowani do zabiegu kanaloplastyki z fakoemulsyfikacją (grupa 1.) lub do zabiegu fakoemulsyfikacji (grupa 2.). Ocena flare była dokonywana przed operacją, a także po 7 dniach oraz po 1, 3, 6 i 12 miesiącach od operacji z użyciem Flare Meter Kowa FM-600. W badaniu oceniano także ciśnienie wewnątrzgałkowe, liczbę stosowanych leków przeciwjaskrowych oraz powikłania pooperacyjne.

Wyniki: nie wykazano istotnej statystycznie różnicy ($p = 0.32$) w przedoperacyjnej wartości flare między grupą 1. (17,9 $\pm$ 7,9 ph/ms) a grupą 2. (16,3 $\pm$ 6,0 ph/ms). Nie było także istotnych statystycznie różnic w wartości flare między grupami w 1. tygodniu ($p = 0.65$) oraz w 1. miesiącu od zabiegu ($p = 0,25$). Średnia wartość flare była istotnie mniejsza w grupie 1. w 3., 6. i 12. miesiącach od zabiegu ($p<0,01$). Tylko w grupie 1. średnia liczba stosowanych leków przeciwjaskrowych była istotnie statystycznie mniejsza w każdym pooperacyjnie badanym przedziale czasu w porównaniu z liczbą leków stosowanych przedoperacyjnie ($p<0,001$).

Wnioski: fakokanaloplastyka oceniana w aspekcie szczelności bariery krew–ciecz wodnista jest bezpiecznym zabiegiem pozwalającym obniżyć ciśnienie wewnątrzgałkowe u chorych na jaskrę wtórnie otwartego kąta. Ocena wyników flarymetrii wykazała, że zabieg łączony ma równie wysoki profil bezpieczeństwa jak zabieg fakoemulsyfikacji.

Słowa kluczowe: kanaloplastyka, jaskra, flare.

The authors declare no conflict of interest/ Autorzy zgłaszają brak konfliktu interesów w związku z publikowaną pracą

Introduction

The aim of contemporary glaucoma surgery is to improve the insufficient aqueous humour outflow in order to achieve adequate hypotensive effect with minimum destruction of ocular structures, high level of safety and the least possible impairment of quality of life. Canaloplasty is a relatively new, nonpenetrating glaucoma surgery, which aims at restoring the natural aqueous outflow pathway. It involves a circumferential catheterisation and viscodilation of Schlemm's canal combined with tension suture placement. Since glaucoma is often concomitant with cataract, there is a new trend to combine glaucoma surgery with phacoemulsification and intraocular lens (IOL) implantation. It has been suggested that a wider opening of Schlemm's canal as a result of its restructuring after cataract surgery offers better intraocular pressure (IOP) reduction after combined surgery. Furthermore, numerous papers report that even phacoemulsification alone is capable of long-term IOP reduction in patients with intraocular hypertension or glaucoma (1–3). Patients with secondary open angle glaucoma (SOAG) are prone to suffer more complications after combined surgery with indirect involvement of blood aqueous barrier (BAB). The safety of canaloplasty in these patients is still not fully clear. One of non-invasive methods of assessing the level of postoperative BAB breakdown is laser tyndallometry, which provides valuable information on BAB integrity.

The aim of the study was to evaluate the flare level in the anterior chamber with respect to BAB breakdown after phacoemulsification and phacocanaloplasty to determine the safety profile of these procedures in patients with SOAG.

Material and methods

This study was conducted at the Department of Ophthalmology and Visual Rehabilitation, Medical University of Lodz in accordance with the principles set forth in the Declaration of Helsinki. The approval of a relevant Bioethics Committee was obtained (number RNN/414/12/KB). The study design was a prospective trial to compare outcomes of canaloplasty with phacoemulsification and intraocular lens implantation versus phacoemulsification with IOL implantation in subjects with SOAG. All phacocanaloplasty (PC) procedures were performed by one surgeon (PJ). Canaloplasty was performed using Visco-Canaloplasty Cannula 5 mm (DORC, The Netherlands) and Glaucolight (DORC, The Netherlands). In both groups, the post-surgical medication regimen consisted of topical non- steroidal anti-inflammatory drugs administered four times a day for up to 4 weeks; a corticosteroid drug four times a day with subsequent dose tapering for up to 4 weeks, and an antibiotic, such as fluoroquinolone, three times a day for one week or longer if clinically indicated. Flare was measured using a Laser Flare Meter FM-600 Kowa (Tokyo, Japan.) All flare readings were taken between 8 and 10 am after pupil dilatation with tropicamide eye drops 1%. Postoperative follow-up tests including a complete ophthalmic examination were performed at 1 week, and 1, 3, 6 and 12 months at minimum.

All patients gave their informed consent and were scheduled for cataract surgery or combined cataract surgery and canaloplasty. Enrolment criteria included patients eligible for cataract surgery, with a diagnosis of pigmentary and exfoliation glaucoma, at not advanced stage of glaucomatous neuropathy, either receiving the maximum tolerated medical therapy (MTMT) with an IOP $\geq$16 mmHg or recently diagnosed glaucoma with IOP $\geq$ 21 mmHg and glaucoma optic neuropathy. Exclusion criteria included primary open angle glaucoma (POAG), other SOAGs such as neovascular glaucoma and uveitic glaucoma, angle-closure glaucoma (ACG), peripheral anterior synechiae, angle recession, advanced macular degeneration and previous laser or surgical glaucoma procedures.

Results

Sixty eyes of fifty-four patients were enrolled. Of these, 30 eyes of 28 patients were treated with phacocanaloplasty (PC) with IOL implantation and 30 eyes of 26 patients were treated with phacoemulsification (Phaco) with IOL implantation. There was no significant between-group difference ($p>0.05$) in age, gender, preoperative IOP, preoperative flare, number of hypotensive medications and best corrected visual acuity (BCVA). Patient characteristics at baseline are summarized in Table I.

The successful placement of a tensioning suture into Schlemm's canal was achieved in 24 eyes (80.0%) and that group was included in further statistical analysis. Subsequently, we performed an analysis of flare. There was no significant difference in baseline flare value between groups ($p = 0.32$) (tab. II). Due to technical problems with measuring flare in the first day after surgery in some patients with hyphaema from Group 1, this timepoint was not included in statistical analyses, however, the mean flare value was visibly higher in Group 1 compared to Group 2. Despite a visibly higher flare in eyes from Group 1 within the first 7 days after surgery, there was no significant difference ($p = 0.65$) between groups due to high standard deviation. There was no significant difference in flare between both groups at 1 month ($p = 0.25$) after the procedures. In both groups, the mean flare decreased after surgery in the first month and the amount of reduction was similar ($p = 0.25$). The tendency towards flare reduction starting from 1 month after phacocanaloplasty was stronger in Group 1 than in Group 2. Statistically, the mean flare at 3, 6 and 12 months after surgery was significantly lower in Group 1 as compared with Group 2 ($p<0.01$).

An analysis of baseline IOP did not show significant differences between Group 1 and Group 2 ($p>0.10$). In both groups, there was a significant IOP reduction from baseline over the entire follow-up ($p< 0.05$). However, the postoperative IOP was lower in Group 1 compared with Group 2 at all measurements points (Fig. 1). Twelve months postoperatively, the IOP reduction from baseline was 44.4% in Group 1 and 17.3% in Group 2.

Prior to surgery, all patients in Group 1 were treated with eye drops. Among them, 9 eyes (37.5%) were on three or more medications. At the follow up in month 12., however, no medication was used in 15 eyes (62.5%) and only 3 eyes (12.5%) remained on two medications. In Group 1, medication use significantly decreased from baseline ($p<0.05$) at all timepoints. In Group 2, all eyes were treated with drops at baseline, including 3 eyes (10.0%) treated with 3 medications. At the follow-up in months 12., all patients still remained on topical antiglaucoma medications with no significant reduction in medications from baseline at any timepoint ($p>0.2$). Postoperative eye drops use was lower in Group 1 compared with Group 2 at all measurements points (Fig. 2).

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Characteristic/ Badana cecha	Group I/ Grupa I Number/ Liczba N = 30	Group II/ Grupa II Number/ Liczba N = 30
Number of right eyes/ Liczba oczu prawych Number of left eyes/ Liczba oczu lewych	15 (50%) 15 (50%)	14 (46.7%) 16 (53.3%)
Age/ Wiek	55–89 years/ lat Mean/ Średnia (75.46)	62–87 years/ lat Mean/ Średnia (77.26)
Sex/ Płeć Female/ Kobiety Male/ Mężczyźni	 21 (70%) 9 (30%)	 21 (70%) 9 (30%)
Best corrected visual acuity/ Najlepsza skorygowana ostrość wzroku (logMAR) Mean/ Średnia Range/ Zakres	 0.61 0.2–1.0	 0.66 0.2–1.0
Intraocular pressure (mmHg)/ Ciśnienie wewnątrzgałkowe (mmHg) Mean/ Średnia Range/ Zakres	 20.4 17–24	 18.5 16–24
Number of medications/ Liczba leków Mean/ Średnia Range/ Zakres	 2.2 1.4	 1.8 1.0–3.0
Glaucoma type/ Typ jaskry Pseudoexfoliative/ Pseudoeksfoliacyjna Pigmentary/ Barwnikowa	 22 (73.3%) 8 (26.7%)	 27 (90%) 3 (10%)

Tab. I. Patient characteristics at baseline.
Tab. I. Charakterystyka badanych grup.

Time	Group 1/ Grupa 1 Mean flare/ Średnia wartość flare (photon units/ msek) ± SD number/ liczba = 24	Group 2/ Grupa 2 Mean flare/ Średnia wartość flare (photon units/ msek) ± SD number/ liczba=30	p/ istotność statystyczna
baseline	17.9 ± 7.9	16.3 ± 6.0	p = 0.32
day 7.	35.8 ± 36.7	23.1 ± 10.6	p = 0.65
month 1.	16.7 ± 11.5	16.6 ± 6.5	p = 0.25
month 3.	12.0 ± 6.7	16.5 ± 3.8	p < 0.01
month 6.	9.6 ± 3.7	16.3 ± 5.6	p <0.01
month 12.	8.8 ± 3.9	15.0 ± 2.9	p <0.01

Tab. II. Mean flare in both groups at specific postoperative timepoints.
Tab. II. Średnia wartość flare w obu grupach w określonych przedziałach czasu.

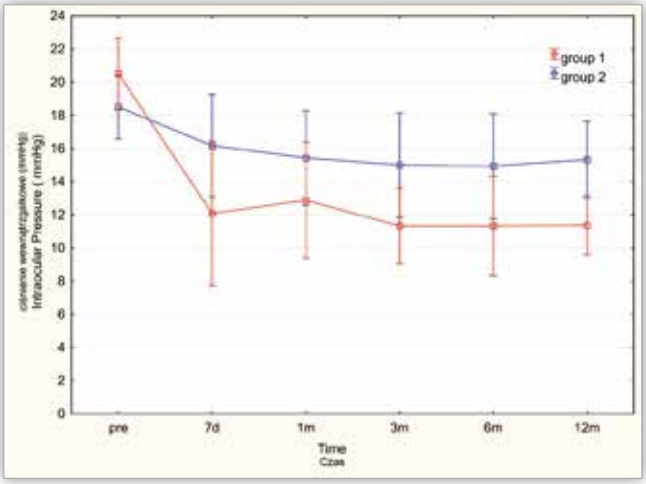

Fig. 1. Means and standard deviation for intraocular pressure in patients over the 12-month follow up.
Ryc. 1. Wykres przedstawiający średnią wartość oraz odchylenie standardowe ciśnienia wewnątrzgałkowego w 12-miesięcznej obserwacji.

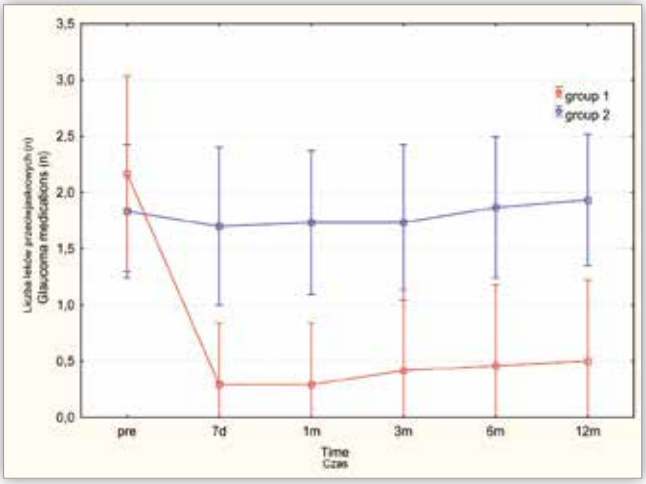

Fig. 2. Means and standard deviation for the number of glaucoma medications used by patients over the 12-month follow up.
Ryc. 2. Wykres prezentujący średnią wartość i odchylenie standardowe liczby leków przeciwjaskrowych stosowanych przez pacjentów w 12-miesięcznej obserwacji.

Complications/ Powikłania		
	Group 1/ Grupa 1. Number/ Liczba	**Group 2/ Grupa 2. Number/ Liczba**
Early postoperative complications (≤ 90 days postoperatively)/ Wczesne powikłania pooperacyjne (≤ 90 dni pooperacyjnie)		
Microhyphema/ Mikrokrwistek: < 1.0 mm layered blood/ Poziom krwi w komorze przedniej < 1.0 mm	7/30 (23.3%)	0
Hyphema/ Krwistek: ≥ 1.0 mm layered blood/ Poziom krwi w komorze przedniej ≥ 1.0 mm	10/30 (33.3%)	0
Elevated intraocular pressure (≥ 30 mmHg)/ Podwyższone ciśnienie wewnątrzgałkowe (≥ 30 mmHg)	1/30 (3.3%)	0
Descemet's detachment/ Odłączenie błony Descemeta	1/30 (3.3%)	0
Hypotony – intraocular pressure ≤5 mmHg/ Hipotonia – ciśnienie wewnątrzgałkowe ≤5 mmHg	3/30 (10.0%)	0
Shallow anterior chamber/ Spłycona komora przednia	0	0
Late Postoperative Complications (> 90 days postoperatively)/ Późne powikłania pooperacyjne (>90 dni pooperacyjnie)		
Elevated intraocular pressure (≥ 30 mmHg)/ Podwyższone ciśnienie wewnątrzgałkowe (≥ 30 mmHg)	0	0
Blebs at 12 months/ Wytorzenie pęcherzyka filtracyjnego powyżej 12. miesiąca od zabiegu	2/30 (6.7%)	0
Endophthalmitis/ Zapalenie wnętrza gałki ocznej	0	0
Hypotony – intraocular pressure ≤5 mmHg/ Hipotonia – ciśnienie wewnątrzgałkowe ≤5 mmHg	0	0
Posterior capsule opacification/ Zmętnienie torebki tylnej	3/30 (10.0%)	3/30 (10.0%)

Tab. III. Post-surgical complications regardless of severity.
Tab. III. Częstość występowania powikłań pooperacyjnych.

Most complications encountered in Group 1 occurred either intraoperatively or within the first 90 days afterwards (Tab. III). During the early postoperative period, hyphaema, defined as ≥ 1.0 mm thick blood layer in the anterior chamber, was observed in 10 of 30 eyes (33.3%). Microhyphaema, defined as < 1.0 mm thick blood layer in the anterior chamber, was observed in 7 eyes (23.3%). The IOP elevation ≥ 30 mmHg was shown in one eye (3.3%), whereas hypotony defined as IOP ≤ 5 mmHg without concomitant anterior chamber shallowing was shown in three eyes – all observed only on day 1 postoperatively. There was one case (3.3%) of Descemet detachment, which resolved spontaneously by day 7. In the late-postoperative period (> 90 days postoperatively), there were no cases of IOP elevation ≥30 mmHg or endophthalmitis. Bleb formation was observed in two eyes (6.7%).

In Group 2, there were no cases of IOP elevation ≥ 30 mmHg over the entire follow-up. Other early and late complications mentioned above, such as microhyphaema, hyphaema or hypotony did not occur in Group 2. However, all those patients required constant use of eye drops to ensure good IOP control.

Discussion

In the anterior uvea, the endothelium of the iris blood vessels and the inner layer of ciliary epithelium form the blood-aqueous barrier. However, this barrier is not complete and there is a small amount of plasma proteins identified in the aqueous humour of the anterior chamber of the eye. Physiologically, the concentration of these water-soluble proteins is about 1% of their plasma concentration. Painful or irritant stimulation within anterior segment of the eye may result in leakage of plasma proteins into the aqueous humour which is a direct result of BAB breakdown. Protein presence as a sign of BAB breakdown may be objectively quantified using Laser Flare Meter in a safe, non-invasive and efficient way (4).

Available data confirms that BAB breakdown can occur in patients with pseudoexfoliation syndrome even in unoperated eyes. These observations were based on fluorescein angiography, fluorophotometry as well as aqueous protein assay (5). There are numerous studies demonstrating that laser flare values are significantly higher in patients with pseudoexfoliative syndrome (14.3 ± 9.2 ph/ms) than in those with POAG (4.7 ± 1.6 ph/ms) or in healthy controls (4.5 ± 1.1 ph/ms) (6).

Many studies which demonstrated the associations between some glaucoma surgery and inflammation in the anterior chamber were designed to determine the risk of early and late postoperative complications in patients undergoing these procedures. Nguyen et al. demonstrated a higher flare after trabeculectomy in patients with SOAG with PEX as compared to those with POAG. They suggested that flare may contribute to a higher number of early or late complications after filtration surgery and indicated the need for close postoperative follow-up (7). Chiou et al. comparing inflammation following deep sclerectomy with collagen implant (DSCI) versus trabeculectomy in eyes with medically uncontrolled chronic open-angle glaucoma showed increased level of flare on the first day and progressive decrease in the early follow-up (8). They noted lower postoperative flare measurements after DSCI and implied that it could be related to a lack of iridectomy, irrigation or opening of the anterior chamber during deep sclerectomy. Just as many other authors, Hille et al. used laser-flare meter to

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compare the level of anterior chamber inflammation in patients with POAG after stand-alone cataract surgery and those after combined cataract and glaucoma filtration surgery. They noted that the mean flare value in the combined surgery group was significantly higher in the first two weeks after surgery (49.2 ± 92.1 in the first week, 22.3 ± 55.1 in the second week) and decreased to a level comparable to the one in the cataract surgery group in the third postoperative week (15.1 ± 35.1) (9).

To date, there have been no studies to assess the effect of canaloplasty or phacocanaloplasty on BAB breakdown in terms of postoperative safety. Therefore, we could not discuss our findings in terms of available research. In our study, the mean flare was significantly lower as compared to baseline ($p < 0.01$) at 3 to 12 months after phacocanaloplasty. There was also a significant decrease in IOP and medication use at all time points in Group 1, which did not correlate with flare reduction. In Group 2, flare decreased gradually but its reduction from baseline was not significant. Furthermore, the IOP decrease in the same group was not significant and the mean number of antiglaucoma medications was comparable to the preoperative value. This may indicate that postoperative topical medications affect the BAB.

Various systemic medications and eye drops have been shown to have an effect on protein level in the anterior chamber detected using flaremetry and other techniques. Proposed mechanisms include alterations to the BAB or aqueous humour production, resulting in either increased protein influx into the eye or decreased fluid production, thereby concentrating the proteins already present within the anterior chamber (4). Studies have demonstrated that acetazolamide and beta blockers increase laser flare photometry values (10). The effect of acetazolamide and timolol is thought to be related to decreased aqueous humour production. We suppose that the significant reduction in the number of antiglaucoma medications after phacocanaloplasty in our study could also have indirect influence on flare decrease.

The efficacy of phacocanaloplasty in patients with SOAG in our research was comparable to its efficacy in patients with OAG (11–15, 16). We found the PC to be a safe procedure with only a few complications, including hyphema (33.3% of patients) and microhyphaema (23.3% of patients) as the most common ones. Other studies reported hyphaema to occur in 16 to 59% of patients after PC (11, 16, 17). According to the literature, hyphaema seems to be a significant positive prognostic indicator in terms of IOP reduction as it results from blood reflux from distal outflow pathways into the anterior chamber (16, 18). A rare complication (3.3% of patients) was Descemet detachment, which resolved spontaneously, as reported by other authors (11, 14, 16).

In conclusion, our study demonstrated that PC is a safe option for lowering IOP in patients with PXG and PG as it does not impair BAB integrity. However, further clinical investigations are required. Furthermore, these results need to be confirmed in a longer follow-up and a larger patient sample.

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