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Canaloplasty ab externo: retrospective 2-year follow-up results

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ABSTRACT

Aim of the study: To assess the efficacy and safety of canaloplasty (CP) alone or in combination with phacoemulsification (PCP) in the reduction of intraocular pressure (IOP) and antiglaucoma medications (meds) usage in patients with primary open angle glaucoma (POAG).

Material and methods: This retrospective study comprised 78 eyes of 75 POAG patients, who underwent CP or PCP in the period from January, 2009 to August, 2016. Intraocular pressure, number of meds, their number of eye drops and bottles, uncorrected distance visual acuity (UCVA) and best corrected visual acuity (BCVA) and number of postoperative complications were evaluated at the baseline and 1, 3, 6, 12 and 24 months after CP or PCP.

Results: The mean ±SD IOP of the CP group was 26.9 ±7.7 mmHg at the baseline and 16.9 ±6.6 mmHg ($p \leq 0.001$) at 24 months postoperatively, while in the PCP group it was 27.2 ±10.8 mmHg and 14.6 ±4.2 mmHg ($p \leq 0.001$), respectively. There was a statistically significant decrease in the mean ±SD number of meds and the number of eye drops and bottles at 24 months postoperatively in both groups compared to the baseline results. We found no statistically significant difference at any follow-up stage, when comparing the mean ±SD of IOP and number of meds between these two groups. The most common postoperative complication after CP and CPP was hyphema.

Conclusions: Canaloplasty alone or in combination with phacoemulsification is an effective and safe procedure in terms of IOP and glaucoma medications' lowering effect in POAG patients. However, PCP showed slightly better and sustainable postoperative results in comparison to CP.

KEY WORDS: glaucoma, canaloplasty, phacocanaloplasty.

INTRODUCTION

Glaucoma is one of the major factors leading to blindness worldwide [1]. The most common type of glaucoma, which accounts for 74% of all glaucoma cases, is primary open angle glaucoma (POAG) [2]. The global number of people affected by glaucoma is expected to grow to 111.8 million by 2040 due to the aging population [3]. It is well known that early diagnosis and effective reduction of the intraocular pressure (IOP), either with conservative or surgical treatment, reduces rapid progression of glaucoma-induced defects in the visual field [4-6]. Antiglaucoma medications are considered as the treatment of choice upon diagnosis of POAG. Nevertheless, in cases of ineffective conservative management or drug intolerance, surgical treatment is required [7].

Trabeculectomy remains the gold standard in the surgical treatment of glaucoma [8]. Although it has the greatest IOP-lowering effect, during the procedure the natural physiological pathway of intraocular fluid is compromised by removing part of the trabecular meshwork together with neighboring structures, forming an external fistula. This results in a higher risk of early and late severe or even sight-threatening postoperative complications, which aggravate postoperative care [9]. Therefore, minimally invasive glaucoma surgery (MIGS) techniques were introduced. They restore and improve the natural drainage system, and thus preserve long-term reduction of IOP [10].

In the recent years, canaloplasty (CP) has gained particular interest. It is a procedure in which a microcatheter is inserted into Schlemm's canal (SC) and is navigated 360° around it while dilating it together with surrounding collector channels through the injection of a viscoelastic substance. The microcatheter is then removed and the suture, which is tightened at the end of the procedure, is then placed within the canal [11].

Although CP has a smaller IOP-lowering effect, it has also been shown that it possesses a lower risk of postoperative complications when compared to trabeculectomy [12-14] and is equally effective in reducing the number of antiglaucoma medications. It becomes particularly important when we discuss about the direct medical costs that glaucoma contributes to. It has been estimated that the financial burden increases

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in relation to the severity of the disease and can reach up to $ 2511 per patient per year on average. Furthermore, glaucoma has a significant impact on patients' and their relatives' quality of life, as it affects their daily routines and results in additional indirect glaucoma-related costs [15].

As the CP shows promising results, the aim of this study was to evaluate the efficacy and safety of CP alone or in combination with phacoemulsification (PCP) in patients with POAG in terms of the IOP lowering effect, postoperative complications and reintroduction of medical therapy over a 24-month follow-up.

MATERIAL AND METHODS

Patients and selection

We performed a retrospective chart review of consecutive CP and PCP procedures in the period from January, 2009 to August, 2016 performed for POAG patients by 1 surgeon (V.J.) in the Hospital of Lithuanian University of Health Sciences, Department of Ophthalmology. The study protocol was approved by the Department of Bioethics, Lithuanian University of Health Sciences (No. BEC-MF-418, 21/05/2018). Inclusion criteria for the CP group were patients older than 18 years with POAG unsuccessfully controlled with medical therapy, and in the PCP group the additional criterion of the presence of visually significant cataract was included. Exclusion criteria were no light perception vision, prior glaucoma surgery, secondary glaucoma, congenital or juvenile glaucoma, angle-closure glaucoma.

All patients underwent a standard ophthalmic examination in an outpatient clinic performed by the same glaucoma specialist in the Department of Ophthalmology, Hospital of Lithuanian University of Health Sciences, including uncorrected distance visual acuity (UDVA) and best corrected visual acuity (BCVA) evaluation, IOP measurement, slit-lamp biomicroscopy for anterior segment evaluation, gonioscopy and indirect ophthalmoscopy for fundus assessment. Postoperative hypotony was defined as IOP 6 mmHg or lower [16]. An ophthalmic history of any previous ocular diseases, surgery or laser treatments and conservative treatment prior the operation and postoperatively was also gathered.

Surgical procedure

After initial evaluation, patients with a diagnosis of POAG were scheduled to undergo CP or PCP. All operations were performed in a single center (Department of Ophthalmology, Hospital of Lithuanian University of Health Sciences). During surgical procedures all patients were under local anesthesia. All POAG patients included in this study underwent CP using an iTRACK 250 (Ellex Medical Lasers Ltd., 3-4 Second Avenue, Mawson Lakes SA 5095 Australia) microcatheter. In the CP group, all study participants were already pseudophakic. If prior ophthalmic examination revealed opacities in the lens, concomitant standard cataract surgery was performed. The description of CP and PCP procedures has been published before in detail [17].

Postoperative care

After each procedure topical therapy with eye drop solutions was prescribed for patients: levofloxacin 4 times daily for 2 weeks and dexamethasone for 1 month, starting with 4 drops daily for 1 week and then slowly tapering it each week by 1 drop. Outpatient follow-up appointments took place 1, 3, 6, 12 and 24 months after surgery. Data about patients' IOP, visual acuity (VA), antiglaucoma medications (meds) and postoperative complications were recorded. We also looked for early postoperative complications in each patient's hospital admission records made on the day of the surgical procedure and few days after until the patient was released for the postoperative care in an outpatient setting. In our study, a complete success was defined as achieving the specific IOP without glaucoma medication, and a limited success was defined as those cases with the postoperative use of one or more antiglaucoma medications.

Statistical analysis

Descriptive statistics (mean, SD, count, percent, etc.) were used to summarize the data. In this study, the primary endpoints included the mean IOP and meds, the number of eye drops and bottles used at each follow-up visit. The secondary endpoints included postoperative complications. Comparisons of IOP, meds count, and VA were made against baseline at each follow-up point using non-parametric Mann-Whitney U criteria or Wilcoxon's signed-rank tests, as appropriate. For the assessment of the correlation of IOP values with age, duration of glaucoma and number of antiglaucoma medications at baseline, Pearson correlation coefficient (r) values were calculated. The difference in the rate of postoperative complications between groups was evaluated using the Pearson chi-square test. Two-tailed p values less than 0.05 were considered statistically significant. IBM SPSS software platform (version 25.0) was used for the statistical analysis of the data.

RESULTS

Demographics

A total of 78 eyes of 75 patients, who underwent CP (n = 32) or PCP (n = 43) in the period from January 2009 to August 2016 were included in this study. The CP group consisted of 16 males (50%) and 16 females (50%), who had previously undergone cataract surgery, with a mean age of 72.4 ±7.5 years and 71.1 ±12.1 years (p = 0.7), respectively (Table I). The group of patients who underwent combined surgery consisted of 21 males (49%) and 22 females (51%) with a mean age of 67.8 ±6.6 years and 69.9 ±9.2 years (p = 0.2), respectively. The mean time of glaucoma diagnosis on the day of the operation was 7.66 ±5.13 years and 6.20 ±6.29 years (p = 0.054) in the CP and PCP groups, respectively.

Change in intraocular pressure

In the CP group, 32 eyes were included. One of them (3.1%) was diagnosed with stage I glaucoma, 13 eyes (40.6%) with stage II glaucoma, 18 eyes (56.3%) with stage III glaucoma at the time of the operation. Figure 1 shows that

the mean baseline IOP was 26.9 ±7.7 mmHg and it decreased to 15.7 ±6.9 mmHg ($p < 0.001$) at the 1st month, to 15.5 ±5.3 mmHg ($p < 0.001$) at the 3rd month, to 15.1 ±5.2 mmHg ($p < 0.001$) at the 6th month, to 16.2 ±5.4 mmHg ($p < 0.001$) at the 12th month and to 16.9 ±6.6 mmHg ($p < 0.001$) at the 24th month postoperatively. Therefore, after CP the decrease of the mean IOP from baseline to the 24th postoperative month was 37.2%. In this group we also found a statistically significant increase in IOP at the 12th month (16.2 ±5.4 mmHg) compared to IOP at the 6th month (15.1 ±5.2 mmHg) postoperatively ($p = 0.025$) but it always remained within normal IOP limits.

In the PCP group, 46 eyes met the inclusion criteria. On the day of the operation, 4 eyes out of 46 (8.7%) were diagnosed with stage I glaucoma, 20 eyes out of 46 (43.5%) with stage II glaucoma and 22 eyes out of 46 (47.8%) with stage III glaucoma. The mean baseline IOP in this study group was 27.2 ±10.8 mmHg and it decreased to 14.5 ±5.6 mmHg ($p < 0.001$) at the 1st month, to 13.4 ±4.6 mmHg ($p < 0.001$) at the 3rd month, to 14.2 ±4.2 mmHg ($p < 0.001$) at the 6th month, to 14.3 ±4.2 mmHg ($p < 0.001$) at the 12th month and to 14.6 ±4.2 mmHg ($p < 0.001$) at the 24th month postoperatively (Figure 1). Therefore, we found that the decrease in the mean IOP from baseline to 24 months after PCP was 46.3%.

There was no statistically significant baseline IOP difference between CP and PCP groups ($p = 0.472$). After 24 months the initial IOP decreased more after PCP (Δ IOP 12.7 mmHg) than after CP (Δ IOP 10.0 mmHg). Furthermore, the postoperative IOP was lower in the PCP group at all follow-up visits when compared to the CP group but this difference was not statistically significant (at all visits $p > 0.05$).

At 2 years, 33.3% of eyes that underwent CP reached ≤ 18 mmHg with no medication and an additional 50% did so with one or more antiglaucoma medications (Table II). In the PCP group, 66.7% of eyes reached ≤ 18 mmHg with no medication and an additional 23.3% achieved limited success (Table III). Figure 2 shows Kaplan-Meier survival plots for cumulative failure rates of the CP and PCP groups using the failure criterion of an IOP > 18 mmHg on two successive visits throughout the 24-month follow-up. The chi-square approximations for logrank and Wilcoxon tests comparing the failure proportions of both study groups demonstrated a significantly lower cumulative failure rate in the PCP group compared with the CP group ($p = 0.013$).

Table I. Demographics and preoperative (baseline) characteristics of study participants

Characteristics	CP ($n = 32$)	PCP ($n = 46$)	*p*-value
Age	71.75 ±9.96	68.89 ±8.06	0.178
Sex			
Males, *n* (%)	16 (50.0)	22 (47.8)	0.850
Females, *n* (%)	16 (50.0)	24 (52.2)	
Duration of glaucoma	7.66 ±5.13	6.20 ±6.30	0.054
UDVA logMAR	0.42 ±0.59[1]	0.67 ±0.47[1]	**0.003**
BCVA logMAR	0.33 ±0.58	0.34 ±0.38	0.126
IOP	26.93 ±7.69	27.23 ±10.82	0.472
Meds			
Antiglaucoma medications, *n*	3.09 ±0.89	2.98 ±1.00	0.705
Antiglaucoma medication eye drops, *n*	3.88 ±1.23	3.59 ±1.00	0.319
Antiglaucoma medication bottles, *n*	2.44 ±0.76	2.17 ±0.74	0.104

[1]*p-values below 0.05.*

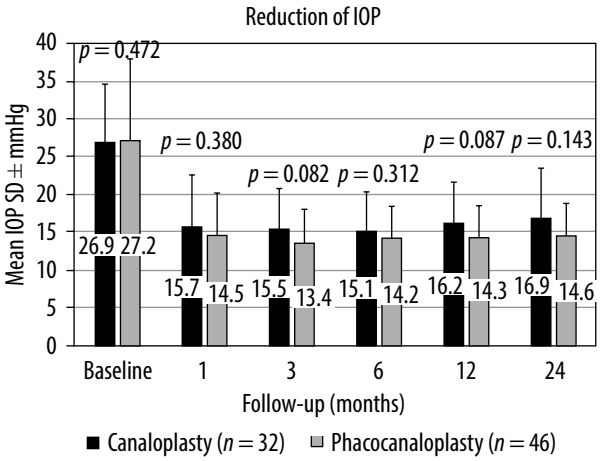

Figure 1. Reduction of mean intraocular pressure from baseline throughout the 24-month follow-up period

Table II. Success rates in the CP group ($n = 32$)

Success type	1 month	3 months	6 months	12 months	24 months
Complete success					
≤ 21 mmHg	18.3%	25%	16.7%	25.0%	12.5%
≤ 18 mmHg	4.4%	14.3%	16.7%	33.3%	33.3%
≤ 15 mmHg	63.9%	57.9%	55.6%	28.6%	35.7%
Limited success					
≤ 21 mmHg	69.1%	64.5%	73.3%	58.3%	70.8%
≤ 18 mmHg	83%	75.2%	73.3%	50%	50%
≤ 15 mmHg	23.5%	31.6%	34.4%	54.7%	48.3%

Table III. Success rates in the PCP group ($n = 46$)

Success type	1 month	3 months	6 months	12 months	24 months
Complete success					
≤ 21 mmHg	0%	0%	33.3%	50%	0%
≤ 18 mmHg	31.9%	77.8%	80%	72.7%	66.7%
≤ 15 mmHg	42.7%	68.2%	33.3%	29.6%	30.8%
Limited success					
≤ 21 mmHg	0%	4.2%	55.6%	42.6%	90%
≤ 18 mmHg	55.6%	9.7%	8.9%	19.9%	23.3%
≤ 15 mmHg	44.8%	42%	55.6%	63%	59.2%

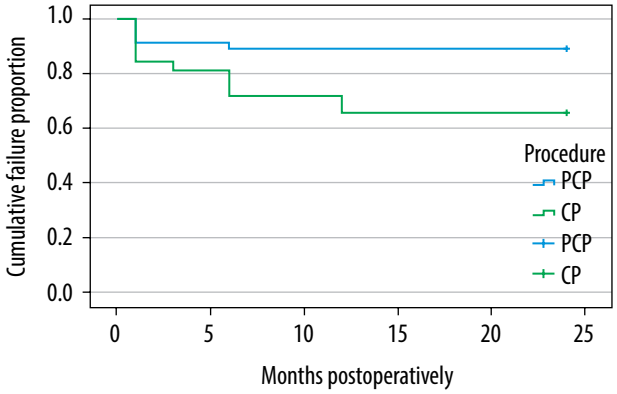

Figure 2. Kaplan-Meier plot of the cumulative probability of failure for the CP and PCP group. Failure was defined as IOP > 18 mmHg on two subsequent visits

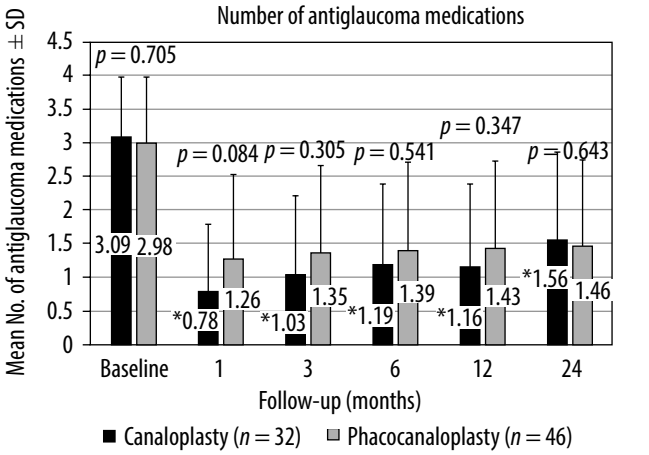

Figure 3. Reduction of mean number of antiglaucoma agents from baseline throughout the follow-up period

Change in glaucoma medication usage

Figure 3 shows that the number of meds postoperatively decreased statistically significantly from a mean of 3.09 ±0.89 and 2.98 ±1.00 preoperatively to 1.56 ±1.29 ($p < 0.001$) and 1.46 ±1.28 ($p < 0.001$) at the 24th postoperative month in the CP and PCP group, respectively. However, in the former group there was a statistically significant increase in the mean number of antiglaucoma medications at the 3rd ($p = 0.046$), 6th ($p = 0.006$), 12th ($p = 0.008$), and 24th postoperative month ($p < 0.001$) compared to 0.78 ± 1.04 at the 1st postoperative month. There was a slight increase in the PCP group as well but it was not statistically significant (all $p > 0.05$).

In our study we also looked at the changes of the number of meds eye drops and bottles. We found a statistically significant decrease in the number of antiglaucoma medication eye drops from a mean of 3.88 ±1.24 and 3.59 ±1.24 preoperatively to 1.75 ± 1.48 ($p < 0.001$) and 1.63 ±1.47 ($p < 0.001$) at the 24th postoperative month in the CP and PCP group, respectively (Figure 4). In the CP group, there was a statistically significant increase in the number of antiglaucoma medication drops at the 3rd ($p = 0.040$), 6th ($p = 0.006$), 12th ($p = 0.031$) and 24th postoperative month ($p = 0.002$) compared to 0.97 ±1.28 at the 1st postoperative month. There was a slight increase in the PCP group as well but it was not statistically significant (all $p > 0.05$).

Furthermore, our study results show that postoperatively the number of meds bottles also decreased statistically significantly from a mean of 2.4 ±0.8 and 2.2 ±0.7 preoperatively to 1.2 ±0.2 ($p < 0.001$) and 0.9 ±0.1 ($p < 0.001$) at the 24th postoperative month in the CP and PCP group, respectively (Figure 5).

Changes in the distribution of meds and the number of eye drops and bottles preoperatively and at the 24th postoperative month in both groups are shown in Figures 6 and 7.

Postoperative complications

In the early postoperative period (≤ 90 days), hyphema was the most frequently observed complication in both CP and PCP groups ($n = 14$ and $n = 12$ [$p = 0.143$], respectively). The patients in the CP group had a higher incidence of hypotony than those in the PCP group ($n = 2$ vs. $n = 1$ [$p = 1.0$], respectively), whereas the latter group had a higher incidence of corneal edema ($n = 3$ vs. $n = 2$ [$p = 1.0$]), choroidal detachment ($n = 4$ vs. $n = 1$ [$p = 0.643$]) and iridocyclitis ($n = 2$ vs. $n = 1$ [$p = 1.0$]) compared to the CP group. A trabecular cut by suture was found in a single eye two days after CP.

In the late postoperative period (> 90 days), only 1 patient in the CP group had iridocyclitis.

Change in visual acuity

Patients in the CP group had a statistically significantly better mean baseline UDVA (0.42 ±0.59 logMAR) compared to the patients in the PCP group (0.67 ±0.47 logMAR)

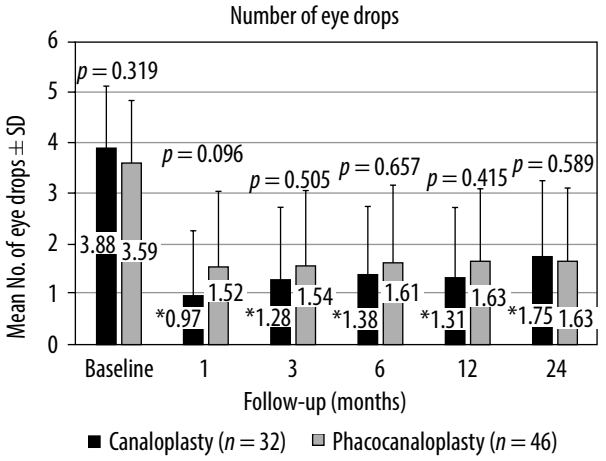

Figure 4. Reduction of mean number of antiglaucoma agents' eye drops from baseline throughout the follow-up period

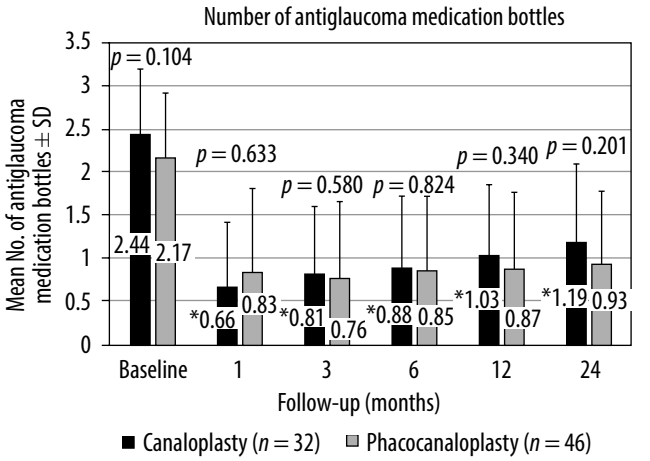

Figure 5. Reduction of mean number of antiglaucoma agents' bottles from baseline throughout the follow-up period

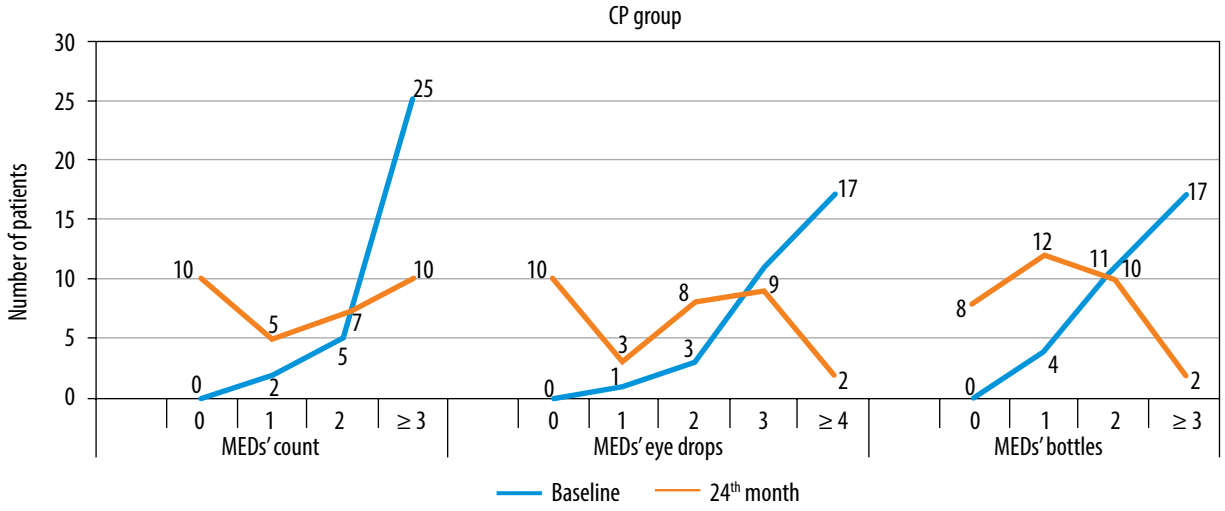

Figure 6. Overview of conservative glaucoma treatment at baseline and the 24th postoperative month in the CP group

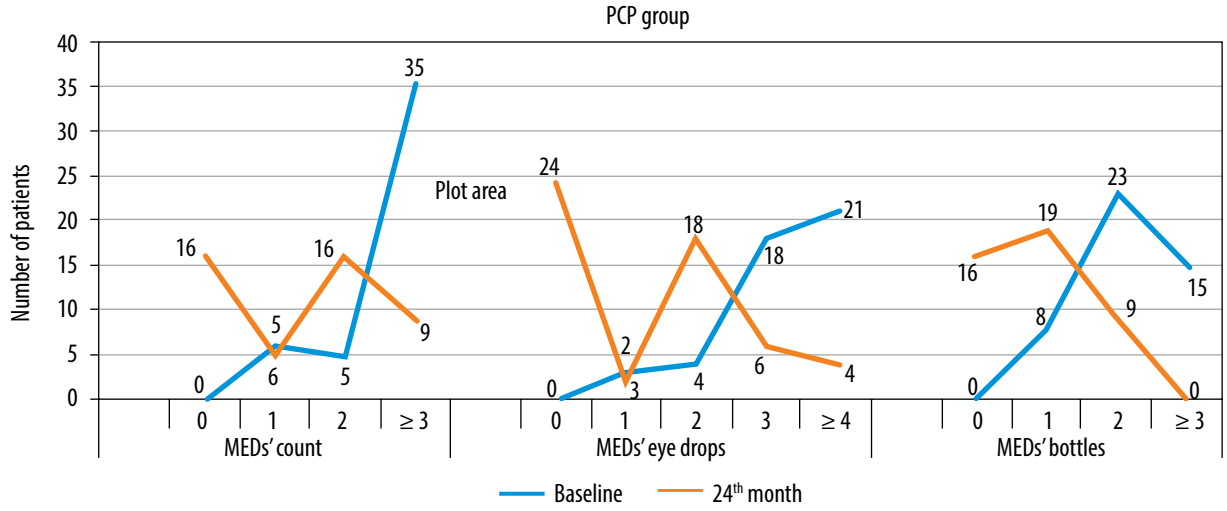

Figure 7. Overview of conservative glaucoma treatment at baseline and the 24th postoperative month in the PCP group

($p = 0.003$). In the PCP group UDVA increased statistically significantly to 0.34 ±0.39 logMAR after 1 postoperative month ($p < 0.001$). In the other study group, where subjects with pseudophakic eyes underwent CP alone, we did not find any statistically significant change from mean baseline UDVA at any 24-month follow-up time after CP.

The mean baseline BCVA was 0.33 ±0.58 logMAR and 0.34 ±0.38 logMAR in the CP and PCP groups, respectively ($p = 0.126$). In the PCP group BCVA increased statistically significantly to 0.21 ±0.31 logMAR after 1 postoperative month ($p = 0.007$). We did not find any statistically significant difference between the baseline and postoperative BCVA in the CP group at any follow-up point (all $p > 0.05$).

Associations between change in IOP and other parameters

Interestingly, a positive correlation between the change in IOP and patients' age was found in the CP group ($p = 0.005$). The older the study participant, the greater was the postoperative IOP reduction found. In the PCP group, no significant association between IOP values and patients' age, duration of glaucoma or number of antiglaucoma medications at baseline was found (all $p > 0.05$).

DISCUSSION

Our study results confirmed that CP alone or in combination with phacoemulsification effectively lowers IOP in patients with POAG for 24 months. The average baseline IOP dropped by 37.2% and 46.3% after a two-year postoperative follow-up in the CP and PCP group, respectively. In both of our study groups we also found a significant reduction of antiglaucoma medications at the 24th postoperative month. This statistically significant IOP and antiglaucoma medication usage decrease is consistent with previously published studies.

We compared our results with a prospective, multi-center, interventional study of 109 eyes of 109 adults with POAG published by Bull *et al.* [18]. They found that the mean baseline IOP in group 1 (CP) dropped by 33% and in group 2 (PCP) by 40% after a 24-month follow-up. In our study, we found a slightly larger reduction of mean baseline IOP after 24 months of follow-up. Our results also showed a slightly larger mean reduction of antiglaucoma agents by 1.5 compared with Bull *et al.*'s result of 1.2 in both groups.

The international multi-center prospective open-label surgical study of 127 eyes of 127 patients with POAG published by Lewis *et al.* [19] showed slightly different results. There was a smaller reduction of the mean IOP in both groups, by 6.9 mmHg in the CP group and 9.7 mmHg in the PCP group from baseline to two years postoperatively compared to our results, which showed a mean IOP reduction by 10 mmHg and 12.6 mmHg, respectively. They also reported a slightly larger decrease in the number of antiglaucoma medications.

We also looked into another retrospective study published by Khaimi *et al.* [20]. In their study, the postoperative CP efficacy results were evaluated after gathering information from 277 eyes affected by POAG. They found a reduction in IOP from 21.1 ±7.2 mmHg at baseline to 13.3 ±4.1 mmHg at 24 months in the CP group and from 18.1 ±5.6 mmHg to 14.7 ±4.4 mmHg in the PCP group, respectively. They also reported a statistically significant decrease in the number of antiglaucoma medications, which was also found in both CP (from a mean baseline of 2.2 ±1.3 to 0.5 ±0.8 mmHg at 24 months) and PCP (from 2.0 ±1.1 preoperatively to 0.6 ±0.9 mmHg at 24 months) groups. In comparison, our study results showed a slightly larger reduction of a mean baseline IOP but a marginally smaller decrease in mean number of antiglaucoma drugs after 24 months of follow-up.

Vastardis *et al.* [21] published another retrospective cohort study, where they reported results of a 12-month follow-up. Their study showed that the mean baseline IOP dropped only by 5.9 mmHg in the CP group and by 4.9 mmHg in the PCP group after 12-month follow-up. They also reported a statistically significant decrease in the number of antiglaucoma medications by 2.4 in both CP and PCP groups. In our study, there was a notably larger decrease of mean baseline IOP as well as smaller reduction of mean number of antiglaucoma agents after 12 months.

In our study, PCP showed a slightly better IOP-lowering effect by 2.7 mmHg compared to CP. A significant reduction of IOP by 9.57 mmHg after PCP was also found in the most recent study published by Kozera *et al.* [22]. This might be partially explained by the effect of cataract surgery alone. It has been shown that phacoemulsification alone can reduce the IOP by 7.6 mmHg in patients with POAG [22]. Several theories exist which try to explain the mechanism behind it. Some argue that cataract surgery acts similarly as parasympathomimetics, which have an effect on the position of the choroidal and corneal-scleral trabecular lines [23, 24]. Others emphasize a possible improvement of water flow through the trabecular meshwork and SC [23], as well as enhancement of uveoscleral outflow [25] or decrease in aqueous humor production [26] after performing phacoemulsification.

To the best of our knowledge this is the first study presenting a significant decrease of numbers of antiglaucoma medication eye drops and bottles after CP and PCP. At the 24th postoperative month 31.35% and 52.17% of POAG patients' eyes were on no antiglaucoma medications in the CP and PCP group, respectively. This may indicate an improved quality of life for a considerable number of patients, who do not need to allocate time in their daily routine for applying eye drops. Furthermore, the results of our study indicate a significant reduction in the number of antiglaucoma medication bottles, and thus potentially a smaller financial burden for POAG patients. However, future studies are required to analyze these relationships in greater detail.

In addition to high efficacy, our study results demonstrate that CP and PCP are safe surgical procedures with a relatively low number of mainly mild postoperative complications. However, in some eyes there developed choroidal detachment, which is an extremely rare complication [27]. It is thought that this might happen in eyes with postoperative hypotony caused by some subconjunctival filtration [16]. Nevertheless,

more extensive research on the possible mechanism behind it is needed to support this.

The main limitation of our study was its retrospective type of analysis and the fact that the data were gathered from the patients' charts.

CONCLUSIONS

In conclusion, CP and PCP are both effective and safe procedures but PCP showed better results in terms of IOP control in POAG patients after 24 months. Future studies may analyze postoperative results prospectively and include the analysis of rate of progression of changes in the visual field. An analysis of the reduced number of eye drops of antiglaucoma medications and its impact on quality of life might also be performed together with calculations of the possible economic benefit of CP and PCP to patients after a significant reduction in the number of bottles of antiglaucoma medications.

DISCLOSURE

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Department of Bioethics, Lithuanian University of Health Sciences (No. BEC-MF-418, 21/05/2018).

The authors declare no conflict of interests.

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