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και Κλινική Βιοπληροφορική»

Reporting quality of randomized-controlled trials in treatment of Primary Angle Closure Glaucoma with Prostaglandin analogs from 2000 to 2024, based on CONSORT statement

Ποιότητα αναφοράς τυχαιοποιημένων κλινικών δοκιμών στη θεραπεία του πρωτοπαθούς γαυκώματος κλειστής γωνίας με ανάλογα προσταγλανδίνης από το 2000 έως το 2024, με βάση το ερωτηματολόγιο CONSORT

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A. 1. Abstract

Background

Randomized Controlled Trials (RCTs) are the backbone of medical research and the gold-standard of evidence-based medicine. However, the reporting quality of RCTs is not always up to date with research standards, affecting the strength and reliability of their results. Angle-closure glaucoma is a major cause of blindness, commonly treated with a peripheral laser iridotomy followed by topical glaucoma medications.

Objective

To evaluate the reporting quality of RCTs published from 2000 to 2024 in the treatment of Primary Angle-Closure Glaucoma (PACG) with prostaglandin analogs using the 2010 CONSORT statement checklist.

Methods

The reporting of RCTs published from 2000 to 2024 on the use of prostaglandin analogs for the treatment of PACG following a peripheral laser iridotomy was evaluated using the CONSORT 2010 checklist. CONSORT 2010 adherence scores of before and after 2010 were compared to explore possible improvements in reporting quality following the release of the revised checklist. RCTs published prior to 2010 were also evaluated using the 2001 CONSORT checklist and compared with their adherence scores under the 2010 checklist. Additionally, the relationship between the 2023 Impact Factor of the publishing journals and CONSORT adherence scores was examined as a potential determinant of reporting quality.

Results

The study was limited due to the small number of trials available. Of the 10 trials, only 2 achieved a CONSORT 2010 adherence score of >=75%. None of the comparisons yielded statistically significant results.

Conclusion

There is a need for improved adherence to reporting guidelines in trials related to the treatment of angle-closure glaucoma

Key-words: Angle-Closure Glaucoma; prostaglandin analogs; CONSORT; Randomized Controlled Trials

Α. 2. Περίληψη

Εισαγωγή

Οι Τυχαιοποιημένες Κλινικές Δοκιμές (RCTs) αποτελούν τον ακρογωνιαίο λίθο της ιατρικής έρευνας και το gold-standard στην ιατρική που βασίζεται σε αποδείξεις (evidence-based medicine). Ωστόσο, η ποιότητα αναφοράς των RCTs δεν συμβαδίζει πάντα με τα σύγχρονα πρότυπα, κάτι που μπορεί να επηρεάσει την αξιοπιστία και την ισχύ των ευρημάτων τους. Το γλαύκωμα κλειστής γωνίας είναι σημαντική αιτία τύφλωσης και συνήθως αντιμετωπίζεται με περιφερική ιριδοτομή με λέιζερ, ακολουθούμενη από τοπική φαρμακευτική αγωγή.

Στόχοι

Να αξιολογηθεί η ποιότητα αναφοράς των RCTs που δημοσιεύτηκαν από το 2000 έως το 2024 σχετικά με τη θεραπεία του πρωτοπαθούς γλαυκώματος κλειστής γωνίας (PACG) με ανάλογα προσταγλανδίνης, χρησιμοποιώντας το ερωτηματολόγιο CONSORT 2010.

Μέθοδοι

Αξιολογήθηκε η ποιότητα της αναφοράς των RCTs που δημοσιεύτηκαν από το 2000 έως το 2024 σχετικά με τη χρήση αναλόγων προσταγλανδίνης για τη θεραπεία του PACG μετά από περιφερική ιριδοτομή με λέιζερ, χρησιμοποιώντας το ερωτηματολόγιο CONSORT 2010. Συγκρίθηκαν τα σκορ συμμόρφωσης με τη CONSORT πριν και μετά το 2010 για να διερευνηθεί πιθανή βελτίωση στην ποιότητα αναφοράς μετά την έκδοση του αναθεωρημένου ερωτηματολογίου. Επιπλέον, οι RCTs που δημοσιεύτηκαν πριν από το 2010 αξιολογήθηκαν με το ερωτηματολόγιο CONSORT 2001 και τα σκορ τους συγκρίθηκαν με τα αντίστοιχα σκορ συμμόρφωσης με το CONSORT 2010. Εξετάστηκε επίσης το Impact Factor του 2023 των επιστημονικών περιοδικών ως πιθανός παράγοντας που επηρεάζει τα σκορ συμμόρφωσης με το CONSORT.

Αποτελέσματα

Η μελέτη περιορίστηκε λόγω του μικρού αριθμού διαθέσιμων δοκιμών. Από τις 10 δοκιμές, μόνο 2 πέτυχαν σκορ συμμόρφωσης με το CONSORT 2010 ≥75%. Καμία από τις συγκρίσεις δεν έδειξε στατιστικά σημαντικά αποτελέσματα.

Συμπέρασμα

Υπάρχει ανάγκη για βελτίωση της συμμόρφωσης με τις κατευθυντήριες οδηγίες σχετικά με την αναφορά στις δοκιμές που σχετίζονται με τη θεραπεία του γλαυκώματος κλειστής γωνίας.

Λέξεις- Κλειδιά: Γλαύκωμα κλειστής γωνίας, ανάλογα προσταγλανδίνης, CONSORT, Τυχαιοποιημένες Κλινικές Δοκιμές

B. Introduction

Randomised Control Trials are widely regarded the most effective and most powerful tool in clinical research. (1) In an era of constant and easily available information, it is essential to base medical decisions on accurate and high-quality data in accordance with evidence-based medicine. The three main principles that distinguish RCTs' strength from other trial designs are randomization, blinding, and inclusion in the analysis of all participants who entered in the study and were randomised into a group (2). However, poor trial design can lead to faulty results and bias (2), severely undermining the role of Randomised Clinical Trials as the cornerstone of medical research. Thus, it is critical to explore and question a trial's design and assess its quality, before the actual implementation of its results in the everyday clinical practice.

By understanding early on the significance of RCTSs and in an effort to improve their reporting quality, the CONSORT statement – Consolidated Standards of Reporting Trials- was first introduced in 1996 (3). It consisted of an initiative of academics, researchers, statisticians and editors in the biomedical field which resulted in the development of a checklist designed to provide guidelines for better reporting of RCTs (3). Soon afterwards, after a few years of experience of the implementation of the CONSORT statement, the group met again in 1999, providing the academic world with the Revised Consort Statement of 2001 (3). The revision included a checklist and a flow diagram, aiming to further improve the reporting quality of simple, two-group, parallel RCTs, and keeping up to date with the newly arisen needs of its time. It was also accompanied by a complimentary article explaining the key aspects of CONSORT (4), further promoting its best implementation. The new Consort statement was adopted by continuously more journals and editorial groups, and from early on signs of improvement of quality of RCTs were observed (5), (6).

With over a decade of experience since the introduction of the original CONSORT statement, a newly revised version was released in 2010 to address emerging needs in clinical research (7), alongside with a new complimentary explanation and elaboration article (8). This version stands to this day and is considered a highly useful tool adopted by a great number of journals. Furthermore, since the original CONSORT statement and its revised versions were mainly designed for simple, two-group, parallel RCTs, some expansions or adaptations have emerged, such as the extension to crossover randomised trials (9) and the expansion regarding the better reporting of harms (10).

Glaucoma is the leading cause of irreversible blindness worldwide. (11). It is the projected that approximately 111.8 million people will suffer from the disease in 2040 (11), (12). The two primary types of glaucoma are Primary Open-Angle Glaucoma (POAG) and Primary Angle-Closure Glaucoma (PACG) (13). While PACG is less common than POAG, PACG accounts for almost half of the cases of blindness caused by glaucoma (13), highlighting a dire need for its better control. The prevalence of the types of glaucoma differs between ethnic groups. While PACG is more common between blacks and people of Hispanic origin, PACG has a higher prevalence among Asians and Inuit populations (11), (12).

Glaucoma is a progressive optic neuropathy characterized by optic nerve cupping, retinal ganglion cell apoptosis, and subsequent vision loss (11). Intraocular pressure is one of the factors that plays a role in the pathogenesis of glaucoma, but not the only one (11). Increased IOP damages the lamina cribrosa and impairs the normal structure of the axons of ganglion cells in the retina and their metabolic support, affecting the axoplasmic transport (11). Elevated levels of IOP are considered above 21mmHg. While a higher IOP is observed at the majority of patients with the disease, there are some patients with evident glaucoma and IOP lower than 21mmHg, and others with high IOP and no clinical presence of glaucoma (11) However, lowering IOP is the only method available to halt the progression of the optic neuropathy characterizing glaucoma (11), (13). Thus, although an elevated IOP plays an important role in the pathogenesis and especially in the control of glaucoma, the disease is multifactorial that cannot be attributed solely to increased IOP.

Aqueous humor is produced by the ciliary body in the posterior chamber of the eye. It flows through the pupil into the anterior chamber, and then gets absorbed mainly by the trabecular meshwork and secondly by the ciliary body face. Certain anatomic features of the iris and the crystalline lens in patients with PACG can limit its outflow to the anterior chamber, resulting in higher pressure in the posterior chamber and in the anterior bowing of the iris, which blocks the trabecular meshwork and subsequently the outflow of aqueous humor (11, 13).

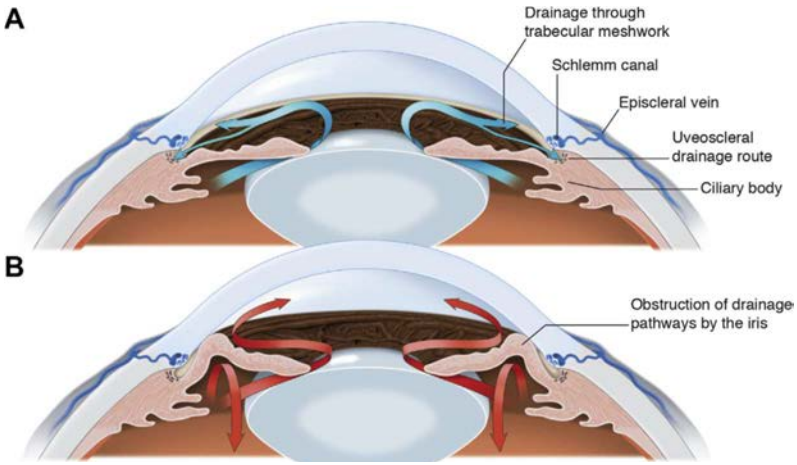

Figure 1
A: Normal Outflow of Aqueous Humor
B: Primary Angle-Closure Glaucoma
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To achieve lower levels of IOP in patients with PACG, Laser Peripherical Iridotomy (LPI) has been advocated as the first line treatment option (15), (16), (17). However, in many cases LPI alone is insufficient to achieve adequate IOP reduction. Thus, topical glaucoma medication is then added to the treatment scheme (11), (15), (17). Traditional glaucoma medications include β-blockers, which work by reducing the production of aqueous humor (11). More recent glaucoma medications include prostaglandin analogs, which increase outflow of aqueous humor directly through the ciliary body by activating matrix metalloproteases which subsequently degrade collagen in this tissue (11). While these medications have been largely tested for treatment of POAG, limited data is available on the treatment of PACG. The difference in the pathogenesis of these types of glaucoma deems it necessary for clinical research on the field of topical glaucoma medication used for PACG.

Over the last few decades, only a small number of RCTs were aimed specifically at PACG, perhaps because of its lower prevalence and its ethnic-specific presentation. While the results of those RCTs suggest that topical glaucoma medication and specifically prostaglandin analogs are effective for the treatment of PACG, the limited number of studies makes it crucial to assess their quality in order to reach safe conclusions.

Therefore, the objective of this paper is to assess the reporting quality of RCTs on the use of prostaglandin analogs for the treatment of PACG, utilizing the CONSORT statement as a framework for evaluation.

C. Methods

Data Sources

We searched in PubMed databases for RCTSs published from 2000 to 2024 about the treatment of PACG with prostaglandins. Using the "Mesh Terms" option, the search algorithm was "prostaglandin analogs [MESH] AND angle closure glaucoma [MESH]''. Then, the filter "Randomised Control Trials" was selected, and the time frame was adjusted from 2000 to 2024.

Eligibility of Studies

Randomised Control Trials in which a prostaglandin analog was compared with another topical glaucoma medication for the treatment of angle-closure glaucoma were included. Exclusion criteria were any other type of study designs, comparison of a prostaglandin analog with a surgical treatment, trials regarding other forms of glaucoma and articles not available in the English language.

Reporting assessment tool

The 2010 revised version of the CONSORT statement consists of a checklist of 25 elements, some of which with further sub-items, bringing the total to 37 elements. It is accompanied by the "2010 CONSORT Explanation and Elaboration" (8), which guided the best use of the checklist. For trials published before 2010, it was decided to evaluate them with the CONSORT 2001 checklist as well, gaining a better understanding of the quality of those articles with the information that was available at that time.

The CONSORT 2001 consists of a checklist of 22 items. However, some of those items include some unnumbered sub-items, which were separately answered. Thus, we added the following sub-items to the checklist, bringing the total to 29: 4a, "Describe extra resources added to (or resources removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites" ; 4b, "Describe the comparator in similar detail to the intervention" ; 6a, "Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial" ; 7a, "If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this difference was obtained" ; 11a, "If blinding was not done, or was not possible, explain why." ; 13a, "The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported".

Methological Evaluation

During the evaluation process, each article was reviewed according to the 2010 CONSORT checklist. The articles published before 2010 were evaluated using both the 2001 and the 2010 CONSORT version. Each item on the checklist was assigned a positive response stated as "yes" or a negative response stated as "no". For an item to have a positive response, all information stated in the sentence must be true and can be found in the article. Otherwise, the item was given a negative answer. When the item did not apply to the article, the characterization "not applicable" was assigned. That was mainly the case for clauses 3b "Important changes to methods after trial commencement (such as eligibility criteria), with reasons", 6b "Any changes to trial outcomes after the trial commenced, with reasons", 7b "When applicable, explanation of any interim analyses and stopping guidelines" and 14b "Why the trial ended or was stopped". The adherence score was calculated excluding the items with the label "not applicable".

The primary outcome measure was the CONSORT adherence percentage. A cut-off of 75% was selected based on previous CONSORT quality reports (29), (30). With an adherence percentage of >= 75% with the CONSORT statement the reporting of the trial was considered as of adequate quality. Furthermore, the reporting of trials up until 2010 was evaluated using both the 2001 and the 2010 CONSORT versions, and the two adherence scores were compared to demonstrate any differences arising from the revision of the checklist using the t-test for dependant samples. The adherence score to

2010 CONSORT from trials before 2010 was also compared to that of trials after 2010, to explore the affect of the newly revised version on the quality of published RCTs, using the chi-square statistic.

Furthermore, the Impact Factor (IF) was used to explore a possible connection between a higher IF and a better reporting quality. The 2023 IF was noted for each trial in the analysis, and the mean of those IF was used as a threshold to characterize the journals of the included trials as of high or low IF. Then, the adherence percentage to the CONSORT statement checklist was compared between those groups using the chi-square statistic. The Pearson correlation between 2023 IF and 2010 CONSORT adherence score was also calculated.

The statistical analysis was made on the IBM SPSS v.29 package.

D. Results

For the chosen algorithm, 17 results came back in the Pubmed databe. From those articles 2 were about an observational study, 3 about surgical treatment, one about open angle glaucoma as well as angle-closure glaucoma, and one article was available only in Croatian. Due to the small number of available RCTs in this field, two RCTs with crossover design were included. Although an expansion for crossover RCTs is available, the reporting quality of the two crossover trials included in this analysis were evaluated using the 2001 and 2010 versions of the CONSORT statement for simple RCTs. At the end, 10 trials matched the eligibility criteria.

CONSORT Adherence Score

The mean adherence score to the 2010 CONSORT checklist was calculated at 57,7% with SD = 16,83, minimum adherence at 33% and maximum at 81%. Only 2 studies achieved a good reporting quality of >=75%, while the remaining 8 did not. The full list of the articles included in the analysis with their adherence scores can be found at Table 1.

Article	Medical Journal	Year	Mean Compliance Score (%)
Aung et al	Ophthalmology	2000	65
Liu et al	Acta Ophthalmologica	2002	44
Chew et al	Ophthalmology	2004	75
Sihota et al	JAMA Ophthalmology	2004	41
Sakai et al	Journal of Ocular Pharmacology and Therapeutics	2005	33
Chen et al	Journal of Ocular Pharmacology and Therapeutics	2006	40
Chen et al	Journal of Ocular Pharmacology and Therapeutics	2007	60
How et al	British Journal of Ophthalmology	2009	70
Wu et al	Journal of Glaucoma	2011	68
Zhao et al	Journal of Glaucoma	2013	81

Table 1: List of Radomised Control Trials along with the CONSORT adherence score

The compliance rate for each item of the 2010 CONSORT checklist was calculated and presented in Table 2. The items that were characterised as “not applicable” in a trial were not used in the calculation of the compliance percentage. Four items, namely 3b “Important changes to methods after trial commencement (such as eligibility criteria), with reasons”, 6b “Any changes to trial outcomes after the trial commenced, with reasons”, 7b “When applicable, explanation of any interim analyses and stopping guidelines” and 14b “Why the trial ended or was stopped” were not applicable for all trials included in this analysis. Some items, such as 2a “Scientific background and explanation of rationale”, 2b “Specific objectives or hypotheses”, 4a “Eligibility criteria for participants”, 12a “Statistical methods used to compare groups for primary and secondary outcomes”, 17a “For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)”, 17b “For binary outcomes, presentation of both absolute and relative effect sizes is recommended” and 22 “Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence” were reported at all trials. Other items, such as 10 “Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions” and 21 “Generalizability (external validity, applicability) of the trial findings” at none.

	Item No	Checklist item	Compliance (%)
Title and abstract	1a	Identification as a randomised trial in the title	20
	1b	Structured summary of trial design, methods, results, and conclusions	80
Introduction	2a	Scientific background and explanation of rationale	100
	2b	Specific objectives or hypotheses	100
Methods	3a	Description of trial design (such as parallel, factorial) including allocation ratio	20
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	not applicable at 100%
	4a	Eligibility criteria for participants	100
	4b	Settings and locations where the data were collected	50
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	80
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	50
	6b	Any changes to trial outcomes after the trial commenced, with reasons	not applicable at 100%
	7a	How sample size was determined	40
	7b	When applicable, explanation of any interim analyses and stopping guidelines	not applicable at 100%
	8a	Method used to generate the random allocation sequence	40
	8b	Type of randomization; details of any restriction (such as blocking and block size)	40
	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	30
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	0
	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	40
	11b	If relevant, description of the similarity of interventions	60
	12a	Statistical methods used to compare groups for primary and secondary outcomes	100
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	70
Results	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	80
	13b	For each group, losses and exclusions after randomization, together with reasons	75
	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	not applicable at 100%
	15	A table showing baseline demographic and clinical characteristics for each group	70

	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	80
	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	100
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	100
	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	50
	19	All-important harms or unintended effects in each group	90
Discussion	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	70
	21	Generalizability (external validity, applicability) of the trial findings	0
	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	100
Other information	23	Registration number and name of trial registry	30
	24	Where the full trial protocol can be accessed, if available	0
	25	Sources of funding and other support (such as supply of drugs), role of funders	60

Table 2: Adherence per CONSORT item

Trials published before 2010 (n=8) were then compared to trials published after 2010 (n=2) regarding their adherence score to the 2010 CONSORT checklist (<75% or >75%) using chi-square statistic. Due to the small number of trials and the majority of the cells in the 2*2 table being less than 5, the Yates correction was implemented. There was no statistical difference between the two groups (p-value = 0.843).

Impact Factor

The trials were characterized as of high or low Impact Factor. The 2023 Impact Factor of the journals in which the trials were conducted was used. The threshold for low or high IF was calculated as the mean value of the IF of all trials, in this case being 5. Thus, trials published in a journal with IF <5 were labeled as “low IF”, and in journals with IF >=5 as “high IF”. Then, a comparison between high (n=3) or low (n=7) IF and a CONSORT adherence of >=75% was conducted using the chi-square statistic. Again, due to the small number of trials and the majority of the cells in the 2*2 table being less than 5, the Yates correction was implemented. There was no statistical difference between the two groups (p-value = 1).

Article	Medical Journal	2023 IF	Mean Compliance Score (%)
Aung et al	Ophthalmology	13.1	65
Liu et al	Acta Ophthalmologica	3	44
Chew et al	Ophthalmology	13.1	75
Sihota et al	JAMA Ophthalmology	7.8	41
Sakai et al	Journal of Ocular Pharmacology and Therapeutics	1.9	33
Chen et al	Journal of Ocular Pharmacology and Therapeutics	1.9	40
Chen et al	Journal of Ocular Pharmacology and Therapeutics	1.9	60

How et al	British Journal of Ophthalmology	3.7	70
Wu et al	Journal of Glaucoma	2	68
Zhao et al	Journal of Glaucoma	2	81

Table 3: 2023 IF of journals included in the study

A correlation between 2023 IF and the 2010 CONSORT adherence score was further investigated. However, there was no statistically significant correlation (Pearson correlation = 0.268, p-value = 0.454)

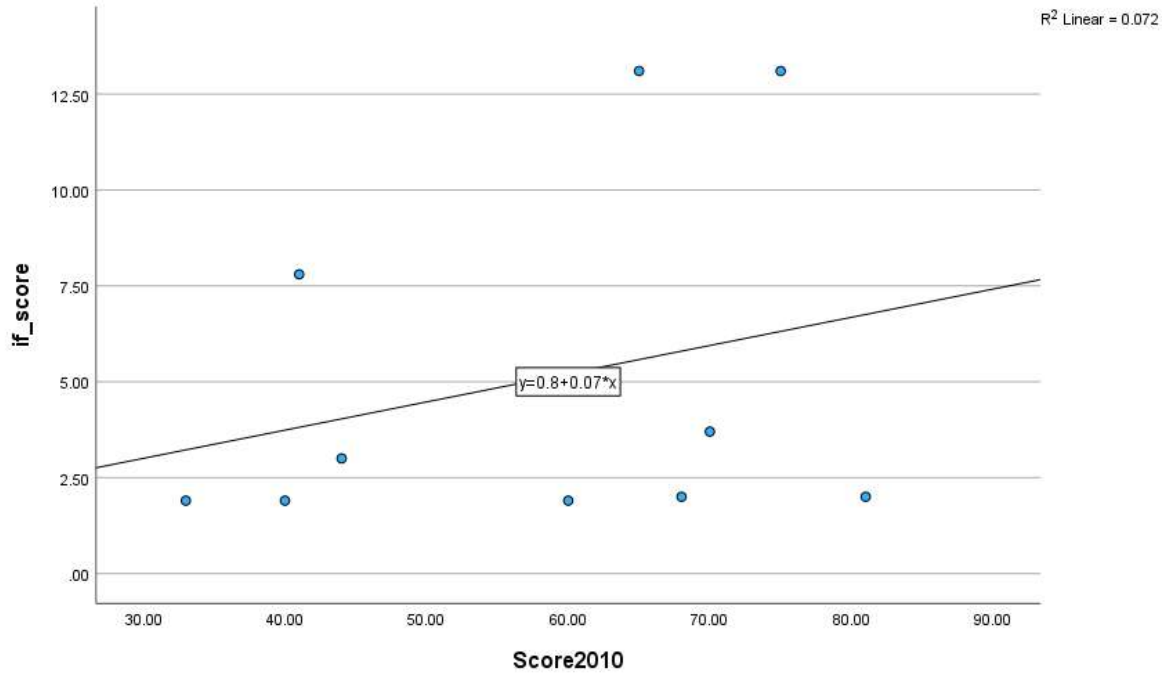

Table 4: Correlation (scatter-plot) between reporting quality and 2023 IF (Impact Factor)

CONSORT 2001 and 2010 checklist comparison

A final comparison was made for trials published until 2010 between the CONSORT adherence score to the checklist of 2001 and the revised checklist of 2010. The two scores were compared in pairs using the t-test for dependent samples. No statistical significance was observed between the two scores (p-value = 0.249).

Article	2001 CONSORT Compliance Score (%)	2010 CONSORT Compliance Score (%)
Aung et al	64	65
Liu et al	37	44
Chew et al	78	75
Sihota et al	52	41
Sakai et al	46	33
Chen et al	50	40
Chen et al	57	60
How et al	70	70

Table 5: CONSORT adherence score for trials published until 2010 using the 2001 and the 2010 checklist

E. Discussion

This study aimed to assess the reporting quality of randomized controlled trials (RCTs) on the treatment of angle-closure glaucoma with prostaglandin analogs, using the 2010 CONSORT statement. Only 10 trials were eligible for inclusion in this analysis, suggesting that it is a field with little evidence available. Among these trials, only two achieved a CONSORT adherence of more than 75%, suggesting that the reporting quality of the trials available is not up to the standards of the time and that it is falling short of contemporary standards for evidence-based medicine.

Further analysis explored whether there were improvements in reporting quality based on publication date or other factors, but no statistically significant differences were found:

- No significant differences in reporting quality between trials published before and after 2010 (the year the revised CONSORT checklist was released).
- No correlation between the 2023 Impact Factor of the journals where the trials were published and the CONSORT adherence score.
- No significant differences between adherence to the 2001 CONSORT checklist compared to the 2010 version.

This study faced limitations due to the small number of available trials, reflecting the relatively scarce evidence in this field. Prostaglandin analogs were first introduced for the treatment of angle-closure glaucoma (PACG) in the early 2000s. Preliminary studies, such as that of Aung et al. (18), suggested that topical glaucoma medications, particularly prostaglandin analogs, might be as effective for PACG as they are for primary open-angle glaucoma (POAG).

However, with PACG having a prevalence of approximately 0.5% in the global population, compared to 3% for POAG, research has mainly focused on treating POAG, resulting in a limited number of studies dedicated to PACG. This scarcity of evidence makes the reporting quality of the few available trials particularly important. Ensuring high-quality reporting is crucial, as it directly impacts the ability to assess and implement the findings of these trials in clinical practice. Thus, the study emphasizes the need for more research and better reporting standards in this underrepresented area.

F. Conclusion

Overall, the study highlights the need for improved adherence to reporting guidelines in trials related to angle-closure glaucoma medications.

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