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ORIGINAL ARTICLE

A Non-Inferiority Study of Combination of Latanoprost and Timolol Formulation to Their Separate Use in Drug-Naive Primary Open Angle Glaucoma and Ocular Hypertension Nigerian Patients (RCT 93803536 Nigeria Clinical Trial Registry)

Une Étude De Non-Infériorité De La Combinaison De La Latanoprost Et Du Timolol Par Rapport À Leur Utilisation Séparée Chez Des Patients Nigérians Atteints De Glaucome À Angle Ouvert Primaire Naïfs Aux Médicaments Et D'hypertension Oculaire. {RCT 93803536 (Registre Des Essais Cliniques Du Nigeria)}

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ABSTRACT

BACKGROUND: Control of intraocular pressure continues to be the mainstay of the management of primary open-angle glaucoma. It is also one of the key factors to consider in the diagnosis and risk of conversion of ocular hypertension to glaucoma (POAG). Medical management of IOP control is central to the treatment of POAG especially in resource-poor countries.

AIM: This study aimed to demonstrate the non-inferiority of a fixed combination of front-line drugs in the medical management of glaucoma (latanoprost and timolol) compared to concomitant use of the same drugs.

METHODOLOGY: It was a double-blind, randomized clinical trial (RCT) in which 116 sequentially consenting participants 40 years and above were recruited and randomized to receive either a fixed combination (group A) or a concomitant combination of latanoprost and timolol (group B). The study was carried out across two tertiary centers in southwest Nigeria.

RESULTS: One hundred and fifteen (115) patients were analysed, 58 in group A and 57 in group B. The mean age of participants was 57.9 (± 11.5) years. There were 51 (44.3%) females. Primary open-angle glaucoma (POAG) was the diagnosis in 88 (76.5%) of the participants. No statistically significant difference between the two groups at recruitment.

Mean IOP reduction from baseline to day 28 was -17.30 ± 7.8 (95% CI: -15.37 to -19.15), and -14.59 ± 6.1 (95% CI: -12.98 to -16.19) for groups A and B. Group A thus had a 54.97% IOP reduction from baseline values while group B had 51.81% ($p = 0.770$).

The mean intergroup difference (MeD) in IOP reduction ($\mu\text{A} - \mu\text{B}$) between the two groups on day 28 was 2.05 ± 5.74 (95% CI: 0.6 – 1.61) $p=0.04$.

CONCLUSION: The study was able to demonstrate a non-inferiority relationship between the fixed combination dosage form of latanoprost and timolol as compared to the concomitant dosage forms. **WAJM 2023; 40(12): 1285 - 1290**

KEYWORDS: Glaucoma, Ocular hypertension, IOP control, Nigerians, Latanoprost, Timolol, Ocular hypotensives, Fixed-combination, Drug-naïve

RÉSUMÉ

CONTEXTE: Le contrôle de la pression intraoculaire reste le pilier de la prise en charge du glaucome à angle ouvert primaire. C'est également l'un des principaux facteurs à considérer dans le diagnostic et le risque de conversion de l'hypertension oculaire en glaucome (POAG). La gestion médicale du contrôle de la pression intraoculaire est essentielle dans le traitement du POAG, surtout dans les pays à ressources limitées.

OBJECTIF: Cette étude visait à démontrer la non-infériorité d'une combinaison fixe de médicaments de première ligne dans la gestion médicale du glaucome (latanoprost et timolol) par rapport à l'utilisation concomitante des mêmes médicaments.

MÉTHODOLOGIE: Il s'agissait d'un essai clinique randomisé en double aveugle dans lequel 116 participants consécutifs âgés de 40 ans et plus ont été recrutés et répartis de manière aléatoire pour recevoir soit une combinaison fixe (groupe A) soit une combinaison concomitante de latanoprost et de timolol (groupe B). L'étude a été menée dans deux centres tertiaires du sud-ouest du Nigeria.

RÉSULTATS: Cent quinze (115) patients ont été analysés, 58 dans le groupe A et 57 dans le groupe B. L'âge moyen des participants était de 57,9 ($\pm 11,5$) ans. Il y avait 51 (44,3%) femmes. Le glaucome à angle ouvert primaire (POAG) a été diagnostiqué chez 88 (76,5%) des participants. Aucune différence statistiquement significative entre les deux groupes au moment du recrutement.

La réduction moyenne de la pression intraoculaire entre le début et le jour 28 était de $-17,30 \pm 7,8$ (IC à 95% : -15,37 à -19,15) et de $-14,59 \pm 6,1$ (IC à 95% : -12,98 à -16,19) pour les groupes A et B. Le groupe A a ainsi présenté une réduction de 54,97 % de la PIO par rapport aux valeurs initiales tandis que le groupe B a enregistré 51,81 % ($p = 0,770$).

La différence moyenne intergroupes (DMI) dans la réduction de la PIO ($\mu\text{A} - \mu\text{B}$) entre les deux groupes au jour 28 était de $2,05 \pm 5,74$ (IC à 95% : 0,6 – 1,61) $p = 0,04$.

CONCLUSION: L'étude a pu démontrer une relation de non-infériorité entre la forme posologique fixe de latanoprost et de timolol par rapport aux formes posologiques concomitantes. **WAJM 2023; 40(12): 1285 - 1290**

MOTS-CLÉS: Glaucoma, Hypertension oculaire, Contrôle de la PIO, Nigérians, Latanoprost, Timolol, Hypotenseurs oculaires, Combinaison fixe, Patients naïfs aux médicaments

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