ORIGINAL RESEARCH PAPER

Ophthalmology

A STUDY ON SIDE EFFECTS OF TOPICAL GLAUCOMA MEDICATIONS, IT'S TOLERABILITY AND PATIENT SATISFACTION IN WESTERN RAJASTHAN

KEY WORDS: Glaucoma, IOP, tolerability.

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ABSTRACT

Aim- To compare the tolerability of prescribed topical glaucoma medications by determining frequency and bothering of side effects, satisfaction with their medication in glaucoma patients.

Methodology- A study was conducted on 105 clinically diagnosed patients of glaucoma with age above 21 years. Patients with Congenital / developmental glaucoma, Concurrent infectious / non-infectious conjunctivitis, keratitis, uveitis in either eye, Clinically significant ocular disease were excluded. A detailed evaluation of all the patients was done including visual acuity, intraocular pressure by NCT and detailed funduscopy.

Result- Most commonly affected age group was 51 - 60 years (25.71%), Male female ratio was 1.69:1, the topical antiglaucoma medications available majority of patients used Beta Blockers, Prostaglandin Analogue with (26.67%) each, total 105 patients on topical antiglaucoma drugs 26 (24.76%) patients were dissatisfied with medication side effects leading to noncompliance.

Conclusion- Glaucomatous patients have tended to do not fulfill adequately the drug treatment, as demonstrated by the found rates of noncompliance. Extra effort needs to be done by health care providers to educate our patients about the nature of glaucoma, glaucoma susceptibility, importance of treatment, follow-up visits, and effect of treatment on prognosis.

Introduction

Glaucoma is defined as a multifactorial optic neuropathy with a characteristic loss of optic nerve fibres presenting as classical optic nerve head features and correlating visual field changes. Earlier intraocular pressure was considered to be the sole factor in the causation of glaucoma, the role of intraocular pressure in the current definition is only one of the causative factors responsible for the disease. Primary open angle glaucoma is the second most common cause of blindness all over the world. The lowering of the IOP could be achieved either by topical use of antiglaucoma drugs or surgery.[1]

The topically antiglaucoma drugs cross the cornea and conjunctiva to reach their sites of action. Intraocular pressure, fundoscopy, gonioscopy and visual field analysis are the investigative procedures to ascertain glaucomatous status. Dry eye and ocular surface damage are the major concerns related to this chronic, sight-threatening disease as they have an impact on parameters affecting the success of glaucoma treatment.[1]

The tear film is a key element for the quality of optical image and ocular surface health and may be altered by several conditions that disrupt the homeostasis provided by the neuroimmuno endocrine network.[2-4] Since the last decade, an increase in options for topical glaucoma therapy raised concern about compliance, persistency, side effects and complications regarding further treatments.[5-7]

The potential damage to the tear film and ocular surface by chronic and/or addition of glaucoma medications has been suggested by experimental and observational studies. Authors observed higher prevalence of symptoms, higher expression of inflammatory markers and relative reduction of some parameters of tear secretion.[8-11] Dry eye and ocular surface damage are the major concerns related to this chronic, sight-threatening disease since they may have an impact on all those parameters that affect the success of glaucoma treatment.[6-8]

Since antiglaucomatous drugs are analogs to neurotransmitters, pro-inflammatory or enzymatic mediators they may interfere in the neuroimmuno endocrine network, disrupting inflammatory and secretory actions. Moreover, benzalkonium chloride as preservative may induce inflammation or reduce secretion. Even glaucoma itself has been hypothesized to be related to dry eye and ocular surface disorder.[12-13]

Compliance is an important factor influencing the outcome of medical therapy. Whether a medication with high efficacy in large scale clinical trials can successfully exert the same effect when applied clinically depends on patients' compliance. Understanding and improvement of compliance will increase the cost-effectiveness of medical therapy. Noncompliance is deliberate or involuntary failure to comply with a doctor's direction in the administration of medications.[14-16]

MATERIALS AND METHOD

The prospective observational study was conducted at department of Ophthalmology of Mathura Das Mathur Hospital, Dr. Sampurnanand Medical College, Jodhpur, Rajasthan. with due permission from the Institutional Ethical Committee and Review Board and after taking written informed consent from patient.

The study population consist of 105 glaucoma patients who already used or started to use glaucoma medication (prospective). The patients included ranged from 21 to 90 years during period of 1 year.

EXCLUSION CRITERIA:

1. Patient refusal for study or answering questionnaire.
2. Congenital / developmental glaucoma.
3. Concurrent infectious / non-infectious conjunctivitis, keratitis, uveitis in either eye.
4. Clinically significant ocular disease (eg., severe keratoconjuntivitussicca, corneal edema) , any opacity in ocular media.
5. Progressive retinal or optic nerve disease apart from glaucoma.
6. History of acute angle closure glaucoma treated with peripheral iridotomy.
7. Regular use of any eye drops or known tear interfering systemic drugs
8. Any abnormality preventing tear break up test.
9. Use of contact lens or eye makeup on study day.
10. Any other eye surgery.

Data collected from the case notes included age at presentation, duration of symptoms if any, intraocular pressure, visual acuity, visual field results and the name of drugs prescribed. Routinely, every patient had his or her visual acuity, intraocular pressure by NCT and detailed funduscopy done at each clinic attendance.

The side effects of topical glaucoma medication were registered by asking patients to fill in a questionnaire based on "the Comparison of Ophthalmic Medications for Tolerability" (COMTOL) questionnaire. The COMTOL questionnaire was designed and validated for comparing the tolerability of topical glaucoma medications. Since the COMTOL mainly focuses on side effects of pilocarpine and timolol, the questionnaire was modified for our present purpose.

The ocular symptoms listed were burning, stinging, conjunctival hyperaemia, itching, photophobia, tearing, dryness, foreign body sensation, keratopathy, brow ache, blurred vision. The systemic symptoms listed were unusual taste, head ache, dyspnea and drowsiness.

For each side effect, the frequency of the symptoms and the severity of bother for the patient were documented.

STATISTICAL ANALYSIS:
All collected data was pooled and entered on to a excel spreadsheet and analysed using IBM SPSS statistics software version 20.

Observation
Most commonly affected age group was 51 - 60 years (25.71%), followed by age group of 61 - 70 years (24.76%), 71 - 80 years (21.90%), 41 - 50 years (15.24%).

With total of 105 patients 66(62.86%) were males and 39 (37.14%) were females. Male female ratio was 1.69:1. Mean age for males was 60.98 years and for females was 60.33 years.

From study group of 105 patients on glaucoma treatment 81 (77.14%) had POAG, 9 (8.57%) PACG, 8 (7.62%) were normotensive, 3 (2.86%) had secondary glaucoma.

Study group showed that out of the topical antiglaucoma medications available majority of patients used Beta Blockers, Prostaglandin Analogue with (26.67%) each, Alpha Agonist (17.14%), combination (BB+AA) with 23.81%, (BB+PG) with 18.10%, (BB+CAI) with 17.14%.

Table1-

Antiglaucoma Medications	Very Unsatisfied	Unsatisfied	Little Unsatisfied	Little Satisfied	Satisfied	Very Satisfied
Beta Blockers	1	1	1	4	15	5
Prostaglandin Analogue	0	1	1	4	15	7
Carbonic Anhydrase Inhibitor	0	3	0	6	2	0
Alpha Agonist	1	0	2	5	8	2
Miotics	0	1	2	0	3	0
Fixed Combination (BB+PG)	0	1	1	1	9	6
Fixed Combination (BB+CAI)	2	2	3	4	6	1
Fixed Combination (BB+AA)	1	0	2	4	13	4
Fixed Combination (BB+M)	0	0	0	3	4	2
Fixed Combination (CAI+AA)	0	0	0	0	2	1

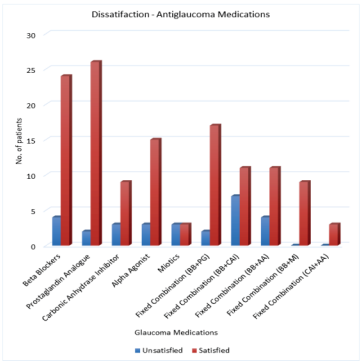

Table1 and graph1- Study group showing satisfied and unsatisfied ratio & percentage of topical antiglaucoma medications (single and fixed combination).

Table 2-

Side effects	Did Not	One day	Several day	Half the days	Almost everyday	Everyday
Ocular Burning	22	36	27	14	5	1
Ocular Stinging	39	39	17	8	2	0
Ocular Redness	31	22	46	3	1	2
Ocular Itching	26	15	41	19	4	0
Photophobia	49	24	20	7	4	1
Ocular Tearing	62	21	13	7	2	0
Ocular Dryness	47	45	7	3	3	0
Foreign Body Sensation	25	19	49	6	5	1
Keratopathy	70	7	12	14	2	0
Eyebrow Ache	81	9	13	1	1	0
Blurred Vision	6	10	69	9	8	3
Unusual Taste	74	4	16	11	0	0
Head Ache	31	35	32	7	0	0
Dysnea	68	20	9	8	0	0
Drowsiness	55	21	15	11	3	0

Table 2: Showing different side effect experience frequency to topical antiglaucoma medications with majority of patients tolerating and not much bothered with side effects.

DISCUSSION

In this study mean age of presentation was 60.74 years. Patients below the age of 60 years were 53 out of which 14 (26.42%) were unsatisfied and patients above the age of 60 years were 52 out of which 12 (23.08%) were unsatisfied, showing that patients above age of 60 years had better compliance.

In study of total 105 patients on topical antiglaucoma drugs 26 (24.76%) patients were dissatisfied with medication side effects leading to noncompliance.

Bloch et al. [17]found that 7 (64%) not adherent and 9 (31%) adherent patients interrupted their treatment because of the adverse effect ($\chi 2 = 3.53, p < 0.1$). Granström &Norell noticed the occurrence of adverse effect in 54 of 78 patients using pilocarpine, but the non-adhesion rate wasn't significantly higher between patients exhibiting adverse effect ($p > 0.20$).

Another study developed for Kass et al. [18] pointed a higher adhesion on the part of patients using timolol maleate, when compared with those making use of pilocarpine, a fact related to the lower incidence of adverse effects of timolol maleate. Similarly to Bloch et al.study, Patel &Spaeth[19]compared the presence of adverse effects in compliant and noncompliant patients, but, no significant influence for noncompliance was noticed ($\chi 2 = 1.42, p = 0.23$).

Taylor, Galbraith and Mills [20] verified that almost 10% of patients (2 in 21) left to use the eye drops due to adverse effects. In a study on the classification of barriers for adhesion to glaucoma treatment, 27% of patients told that adverse effects confused or became difficult the use of eye drops Deokule, Sadiq and Shah[21]noticed a prevalence of about 30% of adverse effects in the systemic level. Respiratory difficulty (14%), nocturnal dyspnea (7.6%), ankle edema (4%), and migraines (3.4%) were the most frequent events, suggesting that these effects could also have some contribution for noncompliance to the treatment. Sleath et al. pointed adverse effects as one of the main factors with respect to non-adhesion, being pointed by 16% of the patients.

CONCLUSION

The data analysis showed that 75% of 105 glaucoma patients in study group were satisfied or very satisfied with their eye medication. The probability of changing medication due to side effects after a visit to the ophthalmologist was 25%. The probability that the use of medication was discontinued by the ophthalmologist due to side effects after each visit to the outpatient clinic, the percentage of patients who were not satisfied with their eye drops.

The daily instillation of eye drops is the main form of treatment of glaucoma, hindering the illness advance and preventing, consequently, the loss of vision in glaucomatous. Literary review showed that glaucomatous patients have tended to do not fulfill adequately the drug treatment, as demonstrated by the found rates of noncompliance, which varied up to 24.76%. This variation could be influenced by the difficulty, on the part of the authors, in defining noncompliance, and, even, by the variance of methodologies used for the determination of the noncompliance rates.

Extra effort needs to be done by health care providers to educate our patients about the nature of glaucoma, glaucoma susceptibility, importance of treatment, follow-up visits, and effect of treatment on prognosis. Longer time has to be spent with our patients teaching them how to instill their drops. Also, simplifying treatment regimen and tailoring it to their daily routine lifestyle are a must.

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