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Pharmacovigilance study on the different drugs used for the management of conjunctivitis in Bangladesh

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Abstract
At present, pharmacovigilance (PV) study is one of the key ways to improve and ensure drug safety and patient's health care in the whole world including Bangladesh. Very limited systematic studies have been conducted on PV in Bangladesh.
The overall purpose of this study was to assess treatments of conjunctivitis patients in Bangladesh. Both primary and secondary data were collected for this study from two different hospitals in Dhaka, Bangladesh. Result shows that, the number of drugs used in conjunctivitic patients were moxifloxacin (30%), olopatadine (10%), fluorometholone+ gentamicin (10%), hypromellose (5%), ketotifen (10%), rupatadine (20%), dexamethasone + tobramycin (10%), flunarizine (5%). There was different adverse drug reactions (ADRs) like blurred vision, redness of eye, itching eye, burning of eye, pain in eye, tearing, swelling of eye, hypersensitivity.
Among 210 patients, 25 patients were found to be affected with blurred vision (12%), 20 patients with redness of eye (10%), 20 patients itching eye 10%, 15 patients burning of eye (7%), 10 patients pain in eye (5%), 5 patients tearing (3%), 5 patients swelling of eye (3%) and 2 patients hypersensitivity (1%) etc. In this study we have found that moxifloxacin (30%) was most frequently prescribed antibiotic and rupatidine (20%) was most common antihistamine. The commonly observed ADR were blurred vision and redness of eye.

Keywords: Pharmacovigilance, drugs, management, conjunctivitis

1. Introduction

Currently, Pharmacovigilance (PV) study is consider as most effective way to promote and assure drug safety and patient health care in all over the world. It can be defined as the science, study, practice and activities relating to the diagnostic, evaluation, assessment, perception and prevention of adverse effect of drugs on any other drugs related problems. PV plays very useful and effective role to promote patient care and patient safety in respect to the use of drug by providing information about effective assessment of risk benefit profile of medicines. (Rahman *et al*. 2006) [1]

At present, it concerns have been widened to include vaccines, herbal, traditional and complementary medicines, blood products, biological and other medicinal devices. It helps to make good decision for patient taking medicines regarding the benefits and risk of treatment.

The systems are followed for pharmacovigilance mainly as, The Prescription Event Monitoring systems (PEM), Record Linkage Systems and Rase Control Studies. (Rahman, *et al*. 2008) [2]

At present time, WHO, International Society of Pharmacovigilance, FDA and other organizations are include in pharmacovigilance study. (Rahman, *et al*. 2008) [2]

The common sources which are provide information for pharmacovisilance are spontaneous reporting of adverse reactions from health care professionals, clinical trials and epidemiological studies published global medical literature and pharmaceutical industries (Rahman, *et al*. 2008) [2]

The improvement of pharmacovigilance plans is very useful at the time of product launch or when a safety risk is recognize during product marketing (Ruhoy, *et al*. 2008) [3]

Pharmacovigilance programmes required very potent links with regulators to assure that Authorities are well illuminated on safety issues in daily practice that may be incidental to future regulatory practice. Regulators understand that pharmacovigilance plays a central and special role to ensure safety of medicine. Pharmacovigilance programs required adequate support to accomplish their objectives (Rahman *et al*. 2007) [4].

Conjunctivitis means inflammation of the conjunctiva of the eye. Broadly it can be defined as a common condition that causes redness, itchiness and watering of the eyes and inflammation of the thin layer of tissue that covers the front of eye. At first it occurs on one eye but it affects both eyes after a few hours or days. Most of the time conjunctivitis affected the eye in the morning (Richards, *et al*. 2010) [5].

It is shown that there are several types of conjunctivitis, such as –Allergic conjunctivitis, Bacterial conjunctivitis, viral conjunctivitis and Neonatal conjunctivitis.

Allergic conjunctivitis is inflammation of the conjunctiva during allergy. Allergic conjunctivitis occurs by several allergens including dust mites, pollen, smoke, perfumes and Peru balsam. Some cosmetics and eye drops are also responsible for allergic conjunctivitis (Langley and JM. 2005) [6].

Bacterial conjunctivitis can causes the rapid conjunctival redness, excessive swelling of the eyelid. At first it affects one eye, but it can occur both eyes within 2-5 days. Bacterial

conjunctivitis is generally occurring by *staphylococci, streptococci*. Some chlamydial organisms are also responsible for bacterial conjunctivitis (Jacobs, *et al*. 2015) [7].

Viral conjunctivitis can cause the pinkness of the conjunctiva, which is the main cause for the ciliary infection of Iris (Iritis). Most of the viral conjunctivitis is associated with upper respiratory tract infection and common cold. Generally it affects one eye but spread easily to the other with a few days. Although it is imputed that the Herpes simplex virus is mainly responsible for viral conjunctivitis, but at present we know that some other viruses such as adenoviruses, enteroviruses are also responsible for viral conjunctivitis (Mark, *et al*. 2014).

Chemical conjunctivitis is mainly chemical eye injury caused by an acidic or alkali compounds getting in the eye. Acidic burns are less bad than alkali burns. A mild burn can be cause of very painful, toxic and unhealthy chemical conjunctivitis. Chemical conjunctivitis can cause the irritation and redness of the conjunctiva (Bielory, *et al*. 2008) [9].

Neonatal conjunctivitis mainly occurs in newborn babies (neonates) who are under 28 days old. This infective conjunctivitis can be cause of necrosis or progressive eye infection. It can lead to permanent damage the child's vision, if it is not treated in due time. If an infective conjunctivitis is found in a new born baby, it must be referred without delay for treatment and special assessment. Most of the baby can recover the infective conjunctivitis if properly treated, but around one in five babies with infective conjunctivitis may develop pneumonia. This is really a life-threating condition for newborn baby and may require special assessment and treatment (Isenberg, *et al.* 2002) [19].

However, prevention is better than cure. If we can know the main causes and symptoms of the conjunctivitis we can safe from this conjunctivitis, even we can prevent also if unfortunately or unconsciously it will affect our eyes.

Most of the conjunctivitis caused by viral and bacterial infection. Allergies, irritants, dryness of the eye and several acidic and basic substances which are harmful for the eyes can be causes of conjunctivitis.

The most common viruses which are responsible for viral conjunctivitis are – Adenoviruses (responsible for Adenoviral Keratoconjunctivitis), Herpes simplex viruses (responsible for Herpetic Keratoconjunctivitis), Enteroviruses such as Enterovirus 70 and Coxsackievirus A24 (responsible for acute hemorrhagic conjunctivitis). The most common bacteria which are responsible for bacterial conjunctivitis are *Staphylococcus aureus, Streptococcus pneumoniae* and *Haemophilus influenzae*. In rare case, Neisseria gonorrhoeae or N. meningitides are also can be responsible for bacterial conjunctivitis (Yanoff *et al*. 2008) [12].

The major symptoms of the conjunctivitis are redness, itchiness, watering of the eyes and inflammation of the thin layer of front of eyes. Sometimes pain of eyes, distributed vision, photophobia can be occur. In serious condition the eyelids may become swollen, the eyes may feel sticky and gritty; they often stuck together with gluey material after sleep (Rose. 2007) [15].

However, if any of those symptoms is found in human, it is very urgent to seek medical assistance instantly and admit him in a hospital, clinic or any other health Centre if required.

Methodology

Study Locations

The study was conducted in two different hospitals of Dhaka in Bangladesh. The names of the hospitals include Dhaka eye Hospital and Islamic eye hospitals.

The protocol of this research has been approved by the administrative offices of both hospitals. These hospitals were chosen in terms of different factors such as availability of patients, affordability and accessibility of treatments for low income people, and modernized treatment facilities.

Data Collection

Both primary and secondary data were collected for this study. Primary data were collected through structured questionnaire survey, analysis of clinical histories and key informant interviews. On the other hand, secondary data were collected from a range of scientific and the information section of each hospital.

Primary Data Collection

Structured Questionnaire

A structured questionnaire survey was among 210 conjunctivitis patients in the study of the hospitals, Patients receiving and completing their first interviewed face to face asses various types of ADRs among the patients. WHO cluster sampling method was applied for the representatives of the sample.

Clinical History Analysis

Clinical history were analyzed in detail for a range of information such as personal history, diagnosis, treatment biophysical characteristics, prescription and drug used to manage the adverse effects were collected from the patient's medical records.

Secondary Data Collection

Secondary data were collected through a range of literature around the world based on the study objectives. Additionally, different information on conjunctivitis data base and histories of Bangladesh were collected from the study hospitals to assess the existing cancer patients and their historical background.

Data Categorization and Analysis

All data collected through structured questionnaire survey were analyzed by using Microsoft Excel and presented both graphical.

Results and Discussion

Demographic Information

Gender

The percentage of male and female respondents of conjunctivitis affected patients of both study hospitals. From the results of the survey and interviews, it has been reported that the male mainly affected by the conjunctivitis. Female are also affected by those disease. Bangladesh, male are mainly working outside their houses due to the lifestyles are very different than females. Now days, female are also working for their livelhoods and they are also exposed to various diseases including conjunctivitis. It has mentioned in Figure 1.

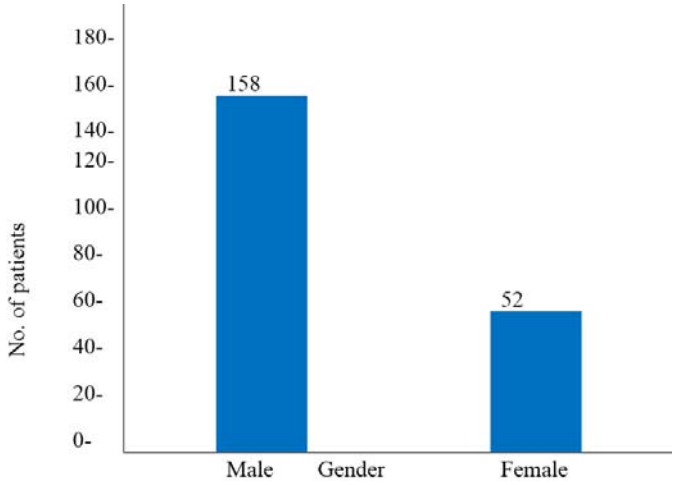


Fig 1: Gender

Area of residence

Most of the respondents came from rural areas (80%), where as the rest of them (20%) were the residents of urban areas (Figure 2). It can be explained that the urban people may have less interests to get the treatment at the government hospitals and have high preference to get facilities from the private hospitals. Majority of respondents from urban areas were in the last Stage of their conjunctivitis. On the other hand, most of the respondents from rural areas do not have ability to spend much for their treatment in private hospitals.

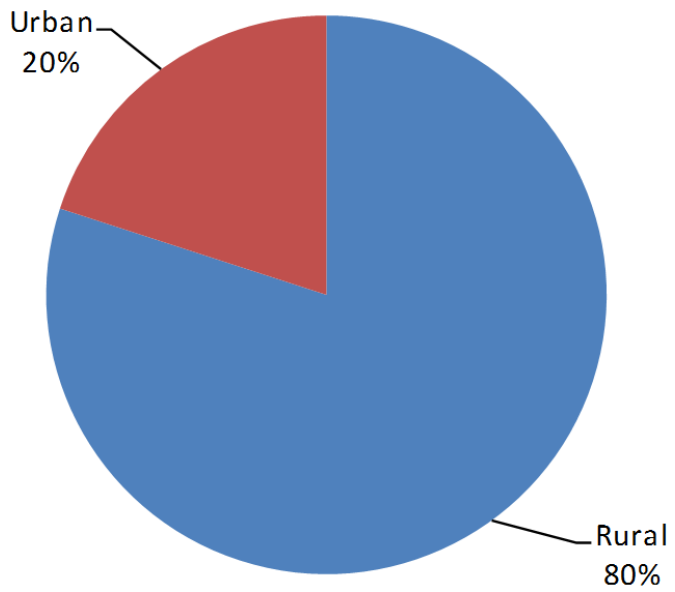


Fig 2: Area of residence

Age of the patients

Among the respondents, 90% of their age ranged from 31-70 years who were affected by conjunctivitis (Figure 3). The rest of the respondents 10% included two groups of 20-30 and 71-80.

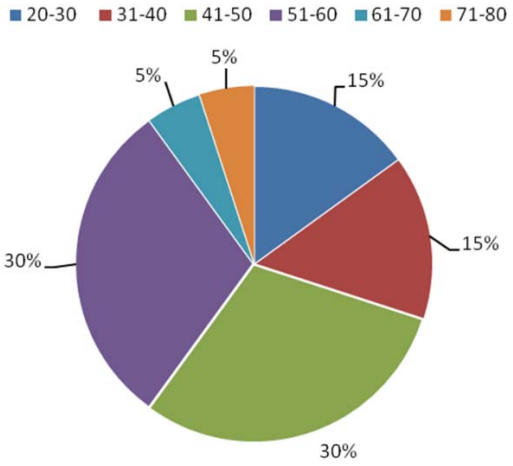


Fig 3: Age of the conjunctivitis patients

Occupations of the conjunctivitis patients

Almost one third of the respondents were farmers 30% by occupations. Other occupations

Include service- holder 20%, labor 15%, and business 10%, and driving 5% and Housewife 20%.Which are indicated in Table 1 and Figure 4.

Table 1: Occupations of the patients

Occupations of the patient	Percentage
Driving	5%
Labor	15%
Business	10%
Service holder	20%
Farmer	30%
Housewife	20%

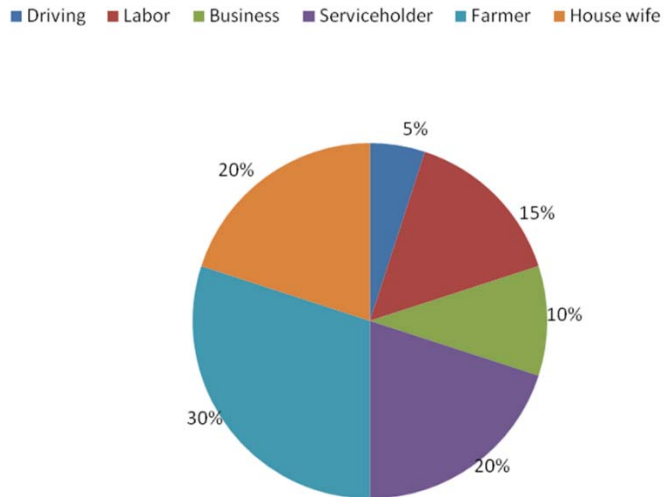


Fig 4: Occupation of the conjunctivitis patients

Social class of patients

Shows that majority of the patients 60% are poor, 20% of patients are upper middle class, 15% are lower middle class and 5% are rich conjunctivitis in this study (Figure 5).

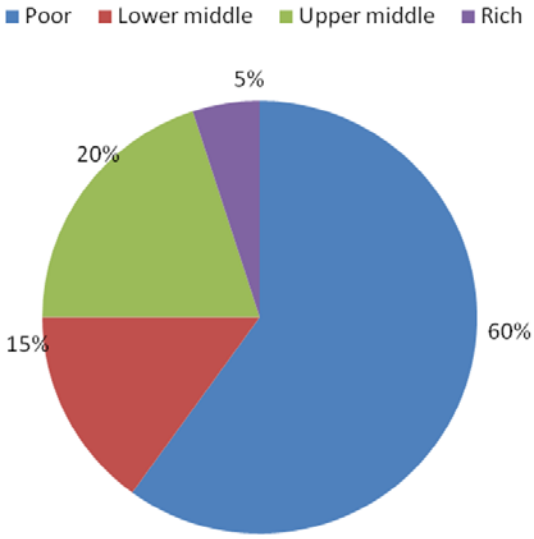


Fig 5: Social class of conjunctivitis patients

Risk Factors

Presence of conjunctivitis substances like Pollens, Mounds in presence of dry and hot climate, dust and family history of atopy. A pregnant female who has sexually transmitted disease like harps, Chlamydia during raises the risk of passing it on to her baby. Among the respondents, 40% patients had affect the mounds in presence of dry and hot climate, 30% patients of them had pollents, 25% had them dust and 5% had them family history of atopy (Figure 6).

Public Health England advises that you do not need to stay away from work or school if you or your child has conjunctivitis, unless you are feeling particularly unwell.

If there are a number of cases of conjunctivitis at one school or nursery, you may be advised to keep your child away from the school until their infection has cleared up.

Generally, adults who work in close contact with others, or share equipment such as phones and computers, should not return to work until the discharge has cleared up.

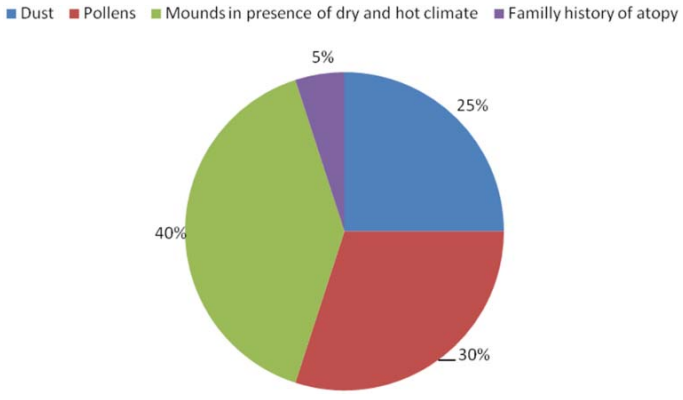


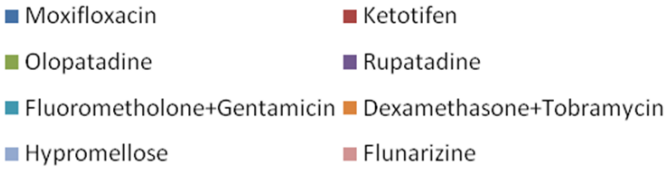
Fig 6: Risk Factors of conjunctivitis patients

Number of drugs used conjunctivitis treatment

Moxifloxaci patients were given the drugs about 30%, Olopatadin 10%, Fluorometholone+Gentamicin 10%, Hypromellose 5%, Ketotifen 10%, Rupatadine 20%, Dexamethasone+Tobramycin 10%, Flunarizine and 5%.It is shown in Table 2 and Figure 7.

Table 2: Drugs are used for conjunctivitis treatment

Drugs are used for conjunctivitis treatment	Percentage of patients
Moxifloxaci	30%
Olopatadin	10%
Fluorometholone+Gentamicin	10%
Hypromellose	5%
Ketotifen	10%
Rupatadine	20%
Dexamethasone+Tobramycin	10%
Flunarizine	5%



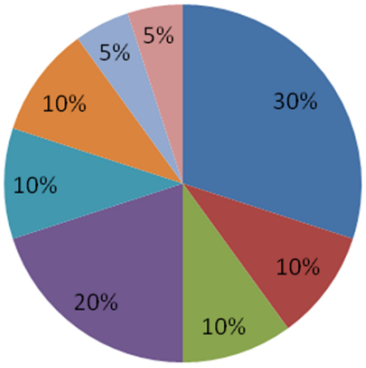


Fig 7: Number of drugs used conjunctivitis treatment

Major Adverse Drug Reaction (ADR)

Among 210 conjunctivitis patients a total number of 25 patients were affected with blurred vision (12%), 20 patients with redness of eye (10%), 20 patients itching of eye (10%), 15 patients with burning of eye (7%), 10 patients with pain in eye (5%), 5 patients with tearing (3%), 5 patients with swelling of eye (3%), 2 patients with hypersensitivity 1% etc. Table 3 is representing adverse drug reaction.

Table 3: Adverse Drug reaction

ADR	Number of patients Affected	Percentage of patient Affected
Blurred Vision	25	12%
Redness of eye	20	10%
Itching of eye	20	10%
Burning of eye	15	7%
Pain in eye	10	5%
Tearinga	5	3%
Swelling of eye	5	3%
Hypersensitivity	2	1%

Conclusions

This study has been conducted in two different hospitals in Dhaka, Bangladesh among the Conjunctivitis patients to assess the ADR. Results on socio-economic status of the conjunctivitis patients shown that, 95% respondents were low and middle income people. Majority of the respondents (80%) came from rural areas for their treatment. Result show that among 10 Conjunctivitis patients, were affected by Redness of eye (85%), 189 patients in Burning (50%), 179 patients in Tearing (30%), 168 patients in Changing vision (50%), 137 patients in Hypersensitivity (30%), 126 patients in Optic nerve Damage (10%), 95 patients in Blurred vision (45%), 74 patients in Itching eyes (35%), 32 patients in Lid edema (15%) and 21 patients in Keratitis Conjunctivitis (10%). Multiple adverse reactions were found in most of the patients except few patients with strong religious beliefs. Other ADRs include Burring. Some risk factors such as Dust, Pollens, which were Mounds in presence of dry and hot climate by 40% patients, 30% patients, had the Pollens. Other risk factors include Family history atopy (25%) due to the dust (5%). The study also suggested to practice and generates the evidence through the practitioners of health care sectors and also it will inspire confidence and trust among public in Bangladesh and other parts of the world with similar contexts.

Competing interests

The authors declare that they have no competing interests.

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