

Study and Review of Cosmetovigilance in a Tertiary Care Hospital

Kavita Nathan^{1*}, Sekharbabu Bandar¹, Sharon Sonia S², Vijaya Bhaskara Reddy Y³, I. Chandrasekhar Reddy⁴

¹Post graduate, ²Professor, ³Professor and Head, Department Of Pharmacology, ⁴Head of Department of Dermatology. Kurnool Medical College, Kurnool, Dr NTR University Of Health Sciences, Vijayawada, Andhra Pradesh -518002, India

Corresponding Author: Kavita Nathan

Abstract

INTRODUCTION

“Cosmetovigilance” is a term related to the collection, evaluation, and monitoring of spontaneous reports of undesirable events observed during or after normal or reasonably foreseeable use of a cosmetic product. It is a Public health surveillance carried out by industry to address the safety of cosmetic products. It is recognized globally as a concept of public health to address the safety of cosmetic products.

Aim: To detect Adverse effects of Cosmetic products, and to prevent Adverse effects by taking appropriate measures in tertiary care hospital.

Materials and methods: This is a prospective study done in Kurnool medical college, Kurnool. Data is collected since September 2018 till August 2019 from Department of Dermatology in Kurnool medical college regarding Cosmetovigilance.

Results : In our Annual study on Cosmetovigilance, We have made our study in Department of Dermatology and it has been observed that out of 7,200 OPD patients, 120 patients are detected with contact dermatitis. In that 50 females and 70 males has been detected due to usage of several products.

Conclusion: Cosmetovigilance is a new concept of safety monitoring of cosmetic products. Problems related to all cosmetic products can be identified and solved, and thus safety can be achieved.

Key words: Cosmetovigilance, Cosmetics, Dermatology, ADR.

Date of Submission: 02-11-2019

Date of Acceptance: 18-11-2019

I. Introduction

Cosmetovigilance is a term related to the collection, evaluation, and monitoring of spontaneous reports of undesirable adverse effects observed during/after normal or reasonably foreseeable use of a cosmetic products. It is a Public health surveillance carried out by industry to address the safety of cosmetic products. First use in literature by Vigan (1997) to refer to the monitoring of cosmetic product safety. Cosmetovigilance was initiated by the French health products safety agency as a part of pharmacovigilance system for cosmetics. It is recognized globally as a concept of public health to address the safety of cosmetic products.

Cosmetics are defined as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced or applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. Products covered under this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colours, and deodorants, or any other substance intended for use as a component of a cosmetic product.

Regulation of cosmetics in India: Cosmetics are regulated as per “Drugs and Cosmetics Act 1940” and Rules 1945. Rule 145 and 135 - Prohibition of “Arsenic and Lead” containing compounds. Rule 135A and 145D - Prohibition of “Mercury” containing cosmetics. Rule 134A Prohibition of “Hexachlorophene” containing cosmetics. Import of cosmetics tested in animals is prohibited in India as per section 135 B of Drugs and Cosmetics Act. Rule 134 specifies cosmetic products should contain color, dye or pigment as specified by schedule Q and bureau of Indian standards.

Gazette notification G.S.R 426(E) divides cosmetics into 4 gross categories: Skin products, Hair and scalp product, Nail and cuticle product, Products for oral hygiene. With increased use of cosmetics, the rate of sensitization to many allergenic components has increased.

Undesirable effects occurring due to cosmetics; Hormonal imbalance, Skin discoloration, Infertility, cancers, can lead to Pharmacoconomics loss.

Spurious cosmetics: They are very commonly reported in Indian market. They are sold to parlors and saloons in branded bottles. High level of lead has been reported in many products. Hair technicians in saloon and parlor are at high risk of ADRs like-Hand Dermatitis, Asthma due to ammonium persulfate exposure, Fertility Disorder etc., due to cosmetics.

II. Methods

This is a prospective study done in Kurnool medical college, Kurnool. Data is collected since September 2018 till August 2019 from Department of Dermatology in Kurnool medical college. Patients were observed after obtaining their consent. Study protocol was approved by the Institutional Ethical Committee of Kurnool medical college. Total OPD cases in Department of Dermatology was 7,200, among 7,200 OPD cases, Contact Dermatitis cases were 120. Among 120 Contact dermatitis cases; 50 were females(41.66%) and 70 were males(58.34%). The privacy and the confidentiality of the data was maintained throughout the study. Data was entered in MS Excel 2010. Prevalence of cases has been calculated.

III. Results

In our Annual study on cosmetovigilance, We have made our study in Department of Dermatology and it has been observed that out 7,200 OPD patients, 120 patients are detected with contact dermatitis. In that 50 females and 70 males has been detected due to usage of several products. The prevalence of these cases are 1.66% . Out of several cases that Kurnool medical college has diagnose or treated the most common ones are Hair dye(para-phenylenediamine 0.55% (PPD), Bindi dermatitis (p-tertiary butyl phenol 0.27%), Nickle dermatitis (beauty products, artificial ornaments 0.41%).Adverse drug reactions due to cosmetic products:Hair dye reactions (0.55%);Itchy skin, red skin rash, Swollen eyes, lips, hands and feet.Kumkum/sticker Bindi dermatitis (0.27%); Itching redness, Depigmentation. Nickel dermatitis (0.41%);Rash or bumps on the skin.

TOTAL NUMBER OF CONTACT DERMATITIS CASES -120

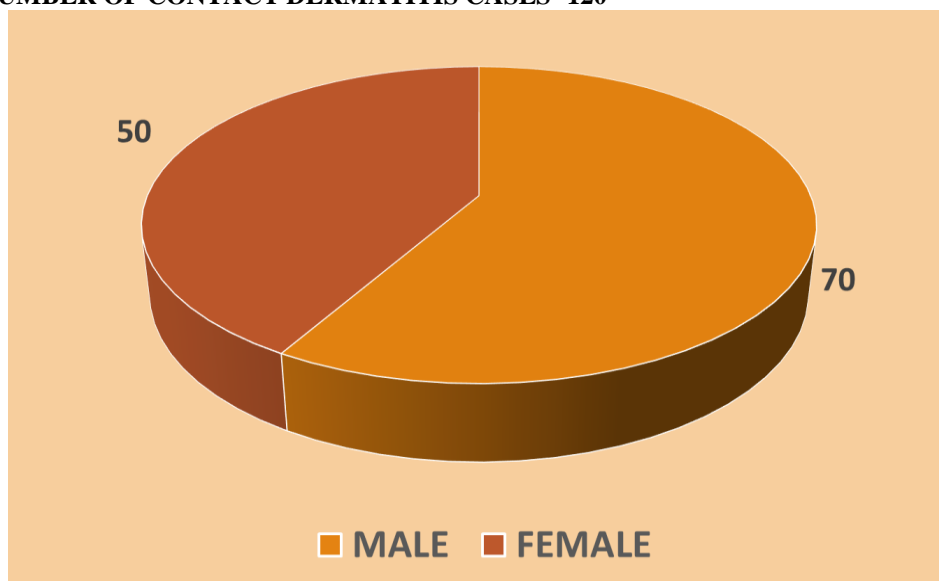


Fig 1; Out of 120 Contact Dermatitis Cases , 50 were Females and 70 were Males. Which shows majority of contact dermatitis cases found were Males.

OF THE 120 CONTACT DERMATITIS CASES

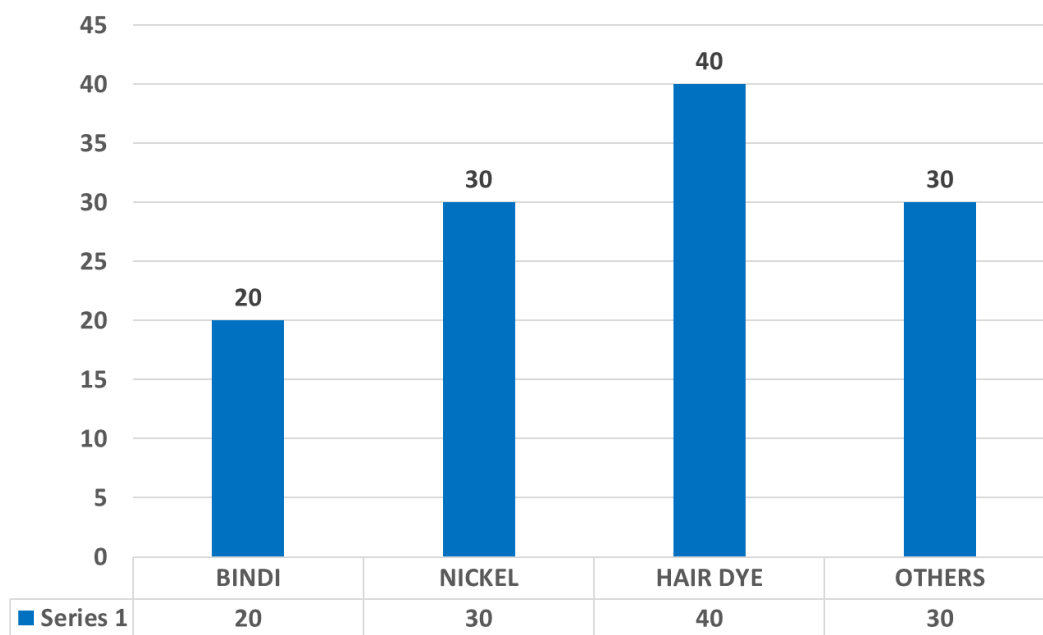


Fig 2; Graph shows Maximum Number of Contact Dermatitis were seen due to Hair Dye(40), followed by Nickel(30), Bindi(20), Others(30)

INCIDENCE

BINDI	0.27%
NICKEL	0.41%
HAIR DYE	0.55%
OTHERS	0.41%

Fig 3 Shows the Incidence of Hair Dye was Maximum i.e 0.55%

IV. Discussion

In our present study out of 120 patients, 50 Females and 70 Males found to have Contact Dermatitis due to undesirable usage of Cosmetic Products. Our data showed that the mean age of usage of Hair Dye products are 20-40 years, Other studies have shown that both adults and children are exposed to the same products, containing same allergens. In a Study done by Norwegian consumer among 1126 persons showed that 10% of those who used hair dye reported adverse effects defined as: discomfort, affliction or damage. Bindi /Kumkum is most commonly used in south part of India, Sindoor exceeded the limit of lead content in India comparative to US Samples. Nickel Products are commonly used by youngsters. Hair dye reactions (0.55%); Itchy skin, red skin rash, Swollen eyes, lips, hands and feet. Kumkum/sticker Bindi dermatitis (0.27%); Itching redness, Depigmentation. Nickel dermatitis (0.41%) Rash or bumps on the skin. Incidence of our study shows majority of contact dermatitis cases are due to Hair Dye usage. Even though cosmetic products are usually well-tolerated, undesirable effects can be seen with cosmetics. Knowledge and identification of these effects are challenging because of the lack of standardized reporting forms and validation of the reports. In our study it's been clearly shown that incidence of Adverse drug reactions due to cosmetic products is increasing day by day. This can be curtailed with proper cosmetovigilance reporting & prevention of usage of the cosmetic. It is the responsibility of manufacturers to determine what products and ingredients are safe before they are marketed, and then to collect reports of adverse reactions. These reports are entered into the national adverse drug reaction database and analyzed by expert reviewers justifying the whole cosmetovigilance system

V. Conclusion

It has been considered as an important component of public health activities. Proper use of cosmetovigilance can help to control or rule out hazardous ingredients in cosmetics. Problems related to these products can be identified and rectified. Encourage patients for ADR reporting. Increasing awareness on this new concept and thus improve our confidence on use of these agents. The process of cosmetovigilance is evolving and coming up as a strong regulatory science to protect public health and beauty and will be a valuable remark on global public health. As Post marketing surveillance of cosmetics become widespread globally,

problems related to these products can be identified and solved, and thus safety can be achieved. Our study suggests that an efficient and reliable monitoring system has to be placed, which includes all the necessary measures to protect public health, an education and training programmes for health professionals, consumers and appropriate authorities.

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Kavita Nathan* . “Study and Review of Cosmetovigilance in a Tertiary Care Hospital”. *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, vol. 18, no. 11, 2019, pp 13-16.