

## COSMETOVIGILANCE: The Study of Prevalence of Adverse Cutaneous Reactions of Cosmetics in a Tertiary Hospital

M Anusha<sup>1</sup>, K c Radhika rani<sup>2</sup>, B. Vasundara Devi<sup>3\*</sup>, P. Venkata ramana<sup>4</sup>

<sup>1</sup>Post graduate, <sup>2</sup>Professor, <sup>3</sup>Professor and Head of Department pharmacology, <sup>4</sup>Professor Department of Dermatology Sri Venkateswara Medical College, Tirupati, Dr NTR University of Health Sciences, Vijayawada, Andhra Pradesh-517501, India.

Corresponding Author: B. Vasundara Devi

### Abstract

#### Background

“Cosmetovigilance is a recent concept of public health surveillance on cosmetic products with a public health objective. It is the ongoing and systematic monitoring of the safety of cosmetics in terms of human health. Cosmetovigilance refers to post marketing surveillance of undesirable adverse effects due to the use of cosmetic products. The purpose of cosmetovigilance is to collect, detect, monitor and analyse the adverse effects in consumers to identify potential health risks, thus guaranteeing further strengthening of safety for consumers.

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

**Materials and methods:** This is a prospective study done in Sri Venkateswaramedical college, Tirupati. Data is collected since July 2018 till August 2019 from Department of Dermatology in SVRRGGH regarding Cosmetovigilance.

**Results:** In our Annual study on Cosmetovigilance, 6,100 patients have been observed in Department of Dermatology, out of which 90 patients are detected with contact dermatitis. In that 35 females and 55 males has been detected due to usage of several cosmetic products.

**Conclusion:** Cosmetovigilance is a new concept of safety monitoring of cosmetic products. It may be considered as an important component of public health activities.

**Key words:** Cosmetovigilance, Adverse reactions, Cosmetic products, Dermatology,

Date of Submission: 02-03-2020

Date of Acceptance: 17-03-2020

### I. Introduction

A cosmetic is defined as any preparation that is intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for the purpose of cleansing, enhancing appearance giving a pleasant smell or protection, and includes any article intended for use as a component of cosmetic.

Gazette notification G.S.R 426(E) divides cosmetics into 4 gross categories: skin products (it is further subdivided into 10 subcategories: products for skin care, cleansing, removal of body hair, body hair bleach, deodorants, shaving products, products for makeup, perfume, products for sun, and self-tanning and others), hair and scalp products (4 subcategories: cleansing and care products, products for hair colouring, hair styling products, and other products for hair and scalp care), nail and cuticle products (nail polish and remover, nail hardening, and products for oral hygiene (tooth care, mouth wash and breath spray and other products for oral hygiene). Unlike drugs, cosmetics are not thought to change body structure or function. However, the distinction between drugs and cosmetics is sometimes not clear.

Cosmetovigilance is a recent concept of public health surveillance on cosmetic products with a public health objective. It is the ongoing and systematic monitoring of the safety of cosmetics in terms of human health. Cosmetovigilance refers to post marketing surveillance of undesirable adverse effects due to the use of cosmetic products. The purpose of cosmetovigilance is to collect, detect, monitor and analyse the adverse effects in consumers to identify potential health risks, thus guaranteeing further strengthening of safety for consumers. Common allergens that can produce skin reactions including formaldehyde, thiomersal, fragrance mix, Para-phenyldiamine, high level of heavy metals (lead, zinc, cadmium) and other preservatives. These ingredients are frequently found in nail polish, kajal, kumkum, sticker bindi, perfumes, hair dyes, shampoos, foundation, mascara and lipsticks. A recent study noted that several common allergens and irritants are found in children's skin care products and additionally were labelled as “dermatologically tested” and “hypoallergic”. Limited information has been published about adverse effects of cosmetic products in the general population. The number of reported adverse reactions due to cosmetics is very low, probably because of underreporting.

In a previous study conducted most common complaint was itching(70.9%), dryness of skin(63.3%) and burning sensation in skin(50%). Face and hands were the most frequently affected location(7). Misbranded and spurious cosmetics are defined as per provision of Drugs and Cosmetics Act 1940 and Drug and Cosmetics rule 1945. Cosmetics are called misbranded if it contains an unprescribed colour, inappropriate labelling or contains false/misleading product information. Cosmetics are labelled as spurious when its name resembles another cosmetic; the product resembles another cosmetic or if manufacturer information is misleading/fictitious or does not exist, which can deceive customers.

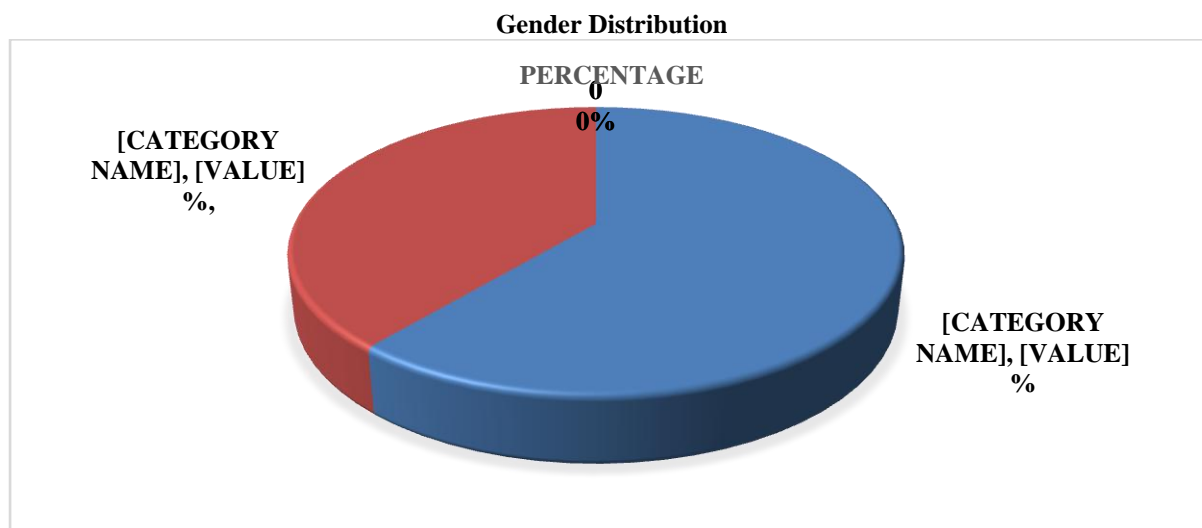
The EU Cosmetics Regulation (EC) No. 1223/2009 has created the approach to the management of serious unwanted effects caused by the use of cosmetics. The previous requirements of Directive 76/768/EEC regarding the inclusion of undesirable effects information for the public have been kept in the regulation. However, new requirements have been added on the reporting of serious undesirable effects.

## II. Methods

This is a prospective study done in Srivenkateswara medical college, Tiupati. Data is collected since July 2018 till August 2019 from Department of Dermatology in Srivenkateswaramedical college. Patients were observed after obtaining their consent. Study protocol was approved by the Institutional Ethical Committee of Srivenkateswaramedical college. Total OPD cases in Department of Dermatology was 6,100, among 6,100 OPD cases, Contact Dermatitis cases were 90. Among 90 Contact dermatitis cases; 35 were females(38.8%) and 55 were males(61.1%). Data was entered in MS Excel 2010. Prevalence of cases has been calculated.

## III. Results

In our Annual study on cosmetovigilance, 6,100 OPD patients have been observed for adverse reactions in Department of Dermatology out of which 90 patients are detected with contact dermatitis. In that 35 females and 55 males has been detected due to usage of several products. The prevalence of these cases is 1.47%. Among several cases most common are Hair dye(para-phenylenediamine (PPD) (0.49%), Bindi dermatitis (p-tertiary butyl phenol (0.16%), body lotions (0.32%). Adverse drug reactions due to cosmetic products: Hair dye reactions (0.49%), red skin rash, skin itching, burning sensation eyes, lips, hands and feet, skin itching. Dermatitis due to body lotion (0.32%) are rash or bumps on the skin. Kumkum/sticker Bindi dermatitis (0.16%); erythema, white spot

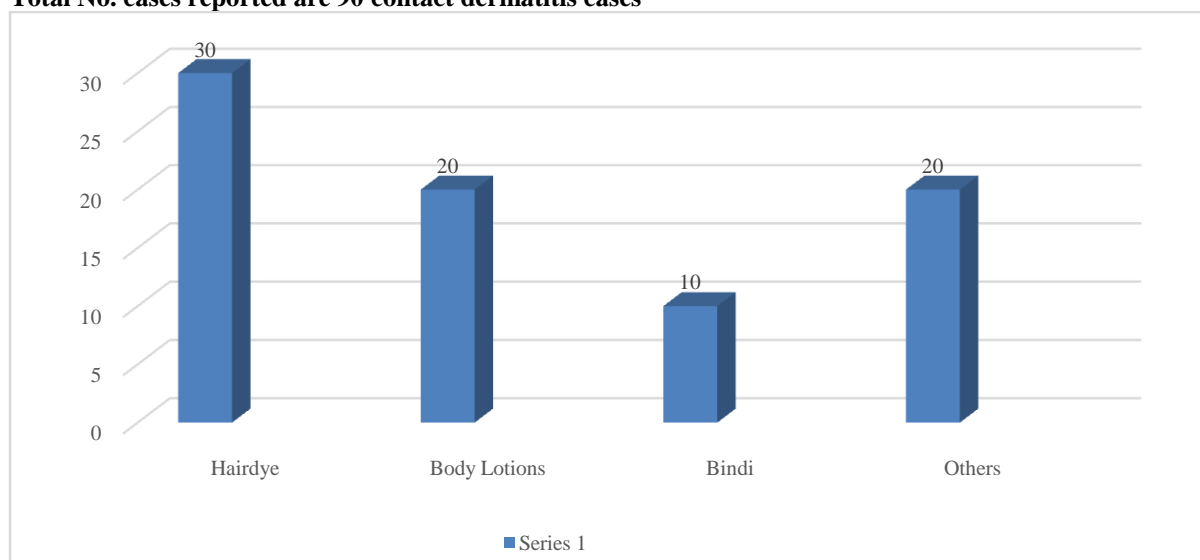


**Fig 1:** Out of 90 Contact Dermatitis Cases, 35(38.8%) were Females and 55(61.1%) were Males.

**Table 1. Incidence according to product category**

Product category	No. of persons	Percentage
Hair dye	30	0.49%
Body Lotions	20	0.32%
Bindi	10	0.16%
others	20	0.32%

**Total No. cases reported are 90 contact dermatitis cases**



#### **IV. Discussion**

In the present study out of 90 patients 35 cases were female and 55 cases were male having contact dermatitis due to usage of cosmetics. In our study hairdye users show high incidence of adverse effects with mean age of 20-40 years. In a recent survey study conducted in Ethiopia with 600 participants, 61% of them reported that they experienced adverse effects (i.e. allergic reaction, acne, hirsutism) with the cosmetics they use. A wide-scale study from Europe conducted between 2005 and 2007, a total of 102,689 consumers contacted the consumer department, including 842 (0.82%) who reported skin reactions. Hair dyes containing ammonia causing skin cancers and sindoor contains exceeded limit of lead mainly reported in India. The adverse reactions due to cosmetics are Hair dye (para-phenylenediamine (PPD) (0.49%), Bindi dermatitis (p-tertiary butyl phenol (0.16%), body lotions (0.32%). Majority of adverse reactions are reported due hair dye usage in between the age group of 20-40 yrs. In a study with patients of contact dermatitis cases, most of the patients reported adverse reactions to cosmetic products. Cosmetic product-related adverse effect identification and analysis is mainly industry driven. Although lots of efforts are made by manufacturers, potential conflict of interest may bias the findings, but manufacturers are responsible for the product safety before they are marketed. Many adverse reactions due to cosmetic products are under reported, this can be reduced by proper cosmetovigilance reporting & prevention of usage of the undesirable cosmetics. Adverse reactions due to cosmetics increasing now a days. Currently, reports can be made through the FDA's MedWatch online system or through a hotline. The data are then collected under the Center for Food Safety and Applied Nutrition adverse event reporting system and analysed by experts.

#### **V. Conclusion**

Cosmetovigilance is a new concept of safety monitoring of cosmetic products. It may be considered as an important component of public health activities. As postmarketing surveillance of cosmetics become widespread globally, problems related to these products can be identified and solved, and thus safety can be achieved. Physicians and primary care practitioners have an important role to recognize ADRs induced by cosmetic products, and thus encourage patients for ADR reporting. Increasing awareness on this new concept will be a valuable remark on global public health. Cosmetovigilance makes it possible to rule out or to control potentially hazardous ingredients by early identification and analysis. Our study an education and training programmes for health professionals, consumers and appropriate authorities and monitoring system that is efficient and reliable includes all necessary measures.

#### **References**

- [1]. Frequently Asked Questions (FAQ's) – Cosmetics Import Registration. [Last accessed on 2018 Jan 06].
- [2]. Guidelines on Registration of Import of Cosmetics. [Last accessed on 2018 Jan 06].
- [3]. Moretti, Ugo Velo, Giampaolo É. Cosmetovigilance: The Beautiful Risk. *Drug Safety* 2008; 31(5): 437-439.
- [4]. Vigan M, Castelain F. Cosmetovigilance: Definition, regulation and use "in practice" *Eur J Dermatol.* 2014;24:643–9.
- [5]. Carmen Di Giovanni, Vincenzo Arcoraci Loredana Gambardella and Lidia Sautebin, *Pharmacological Research*, Volume 53, Issue 1, January 2006, Pages 16-21.
- [6]. Lazzarini R, Hafner MFS, Rangel MG. Evaluation of the presence of allergens in children's products available for sale in a big city. *An Bras Dermatol* 2018;93:457-9.

- [7]. Groot AC, Nater JP, Lender R, Rijcken B. Adverse effects of cosmetics and toiletries: A retrospective study in the general population. *Int J Cosmet Sci.* 1987;9:255-9.
- [8]. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Government of India, Ministry of Health and Family Welfare (Department of Health) (As Amended up to the 31st December, 2016).
- [9]. European Commission. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products (Recast).
- [10]. Heidi Søsted, Allergic contact dermatitis to hair dye ingredients, Gentofte Hospital. DK-Copenhagen, University of Copenhagen, Denmark Tryktforum for Nordic dermato venereology. Supplementum no.13. vol 12.January 2007. ISSN 1402-2917.
- [11]. Bilal AI, Tilahun Z, Osman ED, Mulugeta A, Shekabdulahi M, Berhe DF. Cosmetics use-related adverse events and determinants among Jijiga town residents, Eastern Ethiopia. *Dermatol Ther (Heidelb)* 2017;7:143-53. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available from: <https://www.fda.gov/Safety/MedWatch/default.htm>. [Last accessed on 2018 Dec 17].
- [12]. Sportiello L, Cammarota S, de Portu S, Sautebin L. Notification of undesirable effects of cosmetics and toiletries. *Pharmacol Res* 2009;59:101-6

B. Vasundara Devi, etal. "COSMETOVIGILANCE: The Study of Prevalence of Adverse Cutaneous Reactions of Cosmetics in a Tertiary Hospital." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 19(3), 2020, pp. 19-22.