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Short Communication

Cosmetovigilance: A Paradigm Shift in Terminology and Concept

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INTRODUCTION

Cosmetics are articles intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetics.[1] While Cosmesis is the science of preservation, restoration, or bestowing of bodily beauty.[2]

History of Cosmesis is as old as human civilization. Various archaeological evidences point towards the use of cosmetics by the Egyptian and Greek civilizations. The Egyptians used oils, wax and milk for cosmesis. The people of Arabian Peninsula have used perfumes for thousands of years as documented in the annals of history.[3] Al-Kindi wrote a book on perfumes which he named 'Book of the Chemistry of Perfume and Distillations' in the 9th century. Cosmetics can be used to mark the culture, class, religion, or other social group to which a person belongs.[4]

In the medical context, cosmetic surgery is known since ages. Sushruta, the father of Indian surgery, performed aesthetic nose and ear surgeries on patients. Currently, cosmetic surgery is defined as any invasive procedure where the primary intention is to achieve what the patient perceives to be a more desirable appearance and where the procedure involves changes to bodily features that have a normal appearance on presentation to the doctor.[5]

Aesthetic creation of artificial and simulated limbs made from silicone or PVC, has grown in popularity. Prosthetics, such as artificial hands, can now be made to mimic the appearance of real limbs, complete with freckles, veins, hair, fingerprints, and even tattoos. Custom-made cosmeses are generally more expensive, costing thousands of US dollars depending on the level of detail. Cosmeses are attached to the body using an adhesive, suction, form-fitting, stretchable skin, or a skin sleeve.[6] Today, cosmesis is a big pharma business! The global cosmetic industry was worth USD 465 billion in 2014 and is expected to reach USD 675 billion by 2020.[4]

The rampant use of cosmetics in large number of populations led to the notice of various adverse effects in consumers and as occupational hazards. Like Pharmacovigilance[7] and Materiovigilance[8], Cosmetovigilance should deal with the safety of cosmetics with a public health objective. Cosmetovigilance is need of the time to protect the end consumers of the cosmetic pharmaceutics (cosmetoceutics) and personal care products from cosmetic related adverse reactions. These adverse reactions can produce a variety of acute and long-term consequences over the health of consumers. Adverse reaction related to Cosmetoceutics and Personal Care Products (CPCPs) is any response which is noxious and unintended, including the lack of efficacy.

Definition of Cosmetovigilance

Since cosmetovigilance is not defined scientifically, we propose the following definition after thorough research: "Cosmetovigilance is a discipline of pharmaceutical science and aesthetic art related to detection, assessment, monitoring and prevention of adverse effects of Cosmetoceutics and Personal Care Products (CPCPs)".

Misbranded cosmetics are those cosmetics which contain an unprescribed color, inappropriate labeling, or contains false/misleading product information. Cosmetics are labeled as spurious when its name resembles another cosmetic, product resembles another cosmetic and manufacturer information is misleading or fictitious which does not exist and is utilized to deceive customers.

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Need of Cosmetovigilance

CPCPs including toiletries and skin-care products quite frequently cause adverse reactions ranging from skin irritation to allergic reactions. CPCPs are commonest cause for hospital referrals in patients of allergic contact dermatitis. It is estimated that 1.3% of population is allergic to a cosmetic or cosmetic ingredient.[9]

Between July 2009 and May 2011, over 1,600 undesirable effects were reported. In 1% to 4% of cases, the undesirable effects were considered serious. The most frequently reported cosmetic products were make-up, moisturizers, hair care products and soaps. The most frequently identified allergens were isothiazolinones and fragrance ingredients. A new allergen group was identified namely co-polymers/cross-polymers.[10]

Harmful effects of Cosmetics

I. Heavy metal toxicity

Cosmetics (lipsticks, lip glosses, eye shadows, and henna hair dye) contain impurities such as high level of heavy metals (lead, zinc, and cadmium) leading to heavy metal toxicity.[1] Mercury compounds are easily absorbed from skin causing allergic reaction and it's accumulation in body leads to neurotoxicity. Some ingredients including heavy metals and toluene used in cosmetics enter into the environment and pose threat to ecosystem.[11, 12]

II. Topical steroid-dependent face (TSDF)

Topical corticosteroids abused as "fairness cream" can lead to many adverse effects such as atrophy of skin, hirsutism, acne, perioral dermatitis, and telangiectasia. Prolonged and indiscriminate use can lead to development of Topical Steroid-Dependent Face (TSDF) characterized by severe rebound erythema, burning and scaling of the face on attempted stoppage of the topical corticosteroids after prolonged use. TSDF leads to successive use of more and more potent topical corticosteroids to avoid rebound effects associated with the withdrawal condition known as steroid addiction. Long-term use of potent topical corticosteroids may also lead to systemic side effects such as adrenal suppression and cushingoid appearance.[13]

III. Reproductive health and birth defects of the toxic trio

The presence of formaldehyde, phthalates, and toluene (the toxic trio) in the work environment play a role in the risk of reproductive health effects for cosmetologists. Studies shows that there is a significant increase in premature birth and an increased risk of pregnancy disorders when hairdressers were compared to a referent group of teachers and salesclerks where the only occupational difference were exposure to the toxic trio.[14] Hairdressers and cosmetologists have a slightly increased risk of having an infant with small gestational age. Reproductive disorders in relation to low birth weight were examined and found an increased risk of having infant with low birth weight; three of these studies showed a significant increase.[15] Case studies on toluene exposures have found increased incidences of urogenital, gastrointestinal, and cardiac anomalies among children of mothers who were exposed to organic solvents, such as toluene.[16] Associations were found between pregnant women who inhaled formaldehyde, phthalates, and toluene and adverse reproductive outcomes such as intrauterine growth retardation and premature delivery.[16] Hairdressers report premature ovarian failure five times more frequently than women in non-cosmetologist occupations.[15]

IV: Miscellaneous ingredients of cosmetics and adverse effects

Following table provides other ingredients of cosmetics which pose harm to the human body.

Table 1. Cosmetics, Ingredients and adverse reactions

COSMETICS	INGREDIENTS	REACTION
Perfumes/ Fragrances	Coumarin, methyl eugenol	Allergic reactions, Skin irritation, Contact dermatitis, carcinogenic.[9]
Moisturizers		Irritation, exfoliation.[9]
Skin lightening /depigmenting agents	hydroquinone (HQ)	Mutagenicity and ochronosis[9]
Black henna	p-phenylenediamine (PPD)	Stinging sensations, erythematous rash, swelling, blisters, and surface oozing. sneezing, runny nose, cough, and shortness of breath.[9]
Sun-screening agents	Benzophenones, dibenzoylmethanes, para-aminobenzoic acid (PABA), and cinnamates [active ingredients or additives]	Irritant, allergic, phototoxic, or photoallergic reactions.[9]
Shampoos and conditioners	formalin, parabens, hexachlorophene, triclosan, and fragrances	Eye irritation.[9]
Hair straightening (relaxing) with pressing oils/metal combs/ tongs		Hair-shaft breakage and scarring alopecia.[9]
Hair bleaches	Hydrogen peroxide, Ammonium Persulfate	Skin irritation, temporary skin discoloration, pruritus Type I and IV allergic contact reactions, generalized urticaria, asthma, syncope, and shock Asthma in hair technicians Fertility disorders and adverse pregnancy outcomes in female technicians.[9]
Hair Spray	Dibutyl phthalate	Linked to reproductive issues in humans if the mother is exposed while pregnant and has been banned for use by the European Union[17] and certain phthalate esters have been shown to cause reproductive toxicity in animal models.[18]
Eye shadows	Talc, mica, sericite, magnesium stearate, colorants, preservatives	Irritant contact dermatitis.[9]
Kajal	Lead compounds--minimum (Pb_3O_4) and galena (PbS) Zincite (ZnO), Magnetite (Fe_3O_4) Amorphous carbon	Contact dermatitis Harmful for pregnant women.[1]
Mascara	Carbon black or iron oxide, Polymer, Preservative, Thickening waxes, Oils (lanolin, mineral oil), Paraffin, Petrolatum, Castor oil, Carnauba wax & candelilla wax	Infection, particularly *Pseudomonas aeruginosa* corneal infections due to multiple reuses of applicator and reinsertions into the tube between uses.[9]
Nail paints	Dissolved >suspended pigments Toluene	Nail plate discoloration and allergic contact dermatitis.[9] Toluene enters the environment when materials like fingernail polish, paints, paint thinners, and adhesives are used. It rapidly mixes with the air and individuals who work with paint, lacquer, or dyes have greater exposures to toluene via dermal and respiratory routes.[19] Toluene inhalation during pregnancy has led to neonatal effects, including intrauterine growth retardation, premature delivery, congenital malformations, and postnatal developmental retardation.[16]
Hair removal techniques		Allergic and photoallergic reactions.[9]
Shaving		Skin irritation, cuts in skin, ingrown hair.[9] (pseudofolliculitis)
Sticker bindis	Polyvinylchloride (PVC) & adhesive material (P-tertiary butyl phenol (PTBP), Epoxy resins, dispersible blue 124, dispersible blue 106, nickel, thiomersal & gallate mix	Dermatitis.[1]

Start of Cosmetovigilance in the World

Cosmetovigilance was first started in the year 1999 in France. Active surveillance made the detection of emerging noxious agents possible. Vitamin K[3] (used as an ingredient in cosmetic products) which caused sensitization was identified and subsequently banned in cosmetics. Active surveillance led to greater awareness of risk of PPD (p-phenylenediamine) sensitization from temporary black tattoos. Active surveillance was able to contribute to new regulation on hair dyes. Sensitisation to octocrylene due to photosensitization from ketoprofen gel was detected.[10]

European resolution in 2006 laid the ground-work for Cosmetovigilance system based on case notifications. European Council recommended that each member states should implement a system to record undesirable effects of cosmetic products with a view to protecting human health. Following the resolution, cosmetovigilance systems were created in Belgium, Norway, Sweden, Denmark, Germany and Italy.[10] Dutch health authorities conducted pilot project to list undesirable effects of cosmetic products and to identify the suspicious agents involved. Cases were reported by general practitioners, dermatologists and consumers. Public campaigns in mass media were done to attract attention and enhance community participation.

In United States a consumer can report a cosmetic related problem to FDA. The consumers report information to help the FDA to monitor the safety of cosmetics in the market. In Mercosur countries (Argentina, Brazil, Paraguay, Uruguay, and Venezuela) cosmetic companies/importer are requested to evaluate and to keep cosmetovigilance report. In Europe, Germany and Sweden have a formal cosmetovigilance system while others have informal one

Cosmetic Regulations in India

In India, cosmetics are regulated as per Drugs and Cosmetics Act 1940 and Rules 1945. Part-XIII deals with regulations of import and registration of cosmetics. Part-XIV deals with the manufacture of cosmetic for sale or distribution. Part-XV regulates labeling, packing and standards of cosmetics.

India is the fourth largest cosmetic market in Asia pacific region after Japan, China & South Korea. Import of cosmetics tested on animals is prohibited as per section 135 B of Drugs and Cosmetics Act 1940.

In India very little attention has been given to the adverse reactions related to cosmetic products in the past. Unwanted or adverse reactions due to cosmetic products are either very low or go unnoticed due to lack of proper organized reporting system. Hence the requirement of an organized reporting agency is imperative.

REFERENCES

1. Sarma P, Kumar H, Medhi B. Cosmetovigilance in India: Need of the day. Indian J Pharmacol 2017; 49:341-3
2. Dorland's Medical Dictionary. 25th ed. Philadelphia: W.B. Saunders Co.; 1995
3. Levey, Martin (1973), "Early Arabic Pharmacology," E.J. Brill: Leiden
4. Cosmetics Use-Related Adverse Events and Determinants among Jigjiga Town Residents, Eastern Ethiopia. Dermatol Ther (Heidelb) 2017; 7:143-53
5. Dean NR, Foley K, Ward P. Defining cosmetic surgery. Australasian Journal of Plastic Surgery. 2018; 1(1): 115-125
6. Sansoni, Stefania & Wodehouse, Andrew & McFadyen, Angus & Buis, Arjan. The Aesthetic Appeal of Prosthetic Limbs and the Uncanny Valley: The Role of Personal Characteristics in Attraction. International Journal of Design 2015; 9: 67 - 81.
7. SZ Rahman and A. Rana. 14th Annual Conference of Society of Pharmacovigilance, India – A Report. J Pharmacovig Drug Safety 2015; 12 (1): 52-54
8. Rahman, SZ. Concept of Materiovigilance in Unani Medicine. Bangladesh Journal of Medical Science 2019, 18(1): 5-6.
9. Nigam PK. Adverse reactions to cosmetics and methods of testing. Indian J Dermatol Venereol Leprol 2009; 75:10-19.
10. Cosmetovigilance: definition, regulation and use “in practice”. Eur J Dermatol 2014; 24(6): 643-9.
11. Rahman SZ, Khan RA, Gupta V, Uddin M. Pharmacoenvironmentology--a component of pharmacovigilance. Environ Health. 2007; 6:20 (Online). doi:10.1186/1476-069X-6-20
12. Rahman SZ, Khan RA. Environmental Pharmacology – A New Discipline. Indian J Pharmacol. 2006; 34: 1–2
13. Kumar S, Goyal A, Gupta YK. Abuse of topical corticosteroids in India: Concerns and the way forward. J Pharmacol Pharmacother 2016; 7:1-5
14. Henrotin, Jean-Bernard; Picot, Cyndie; Bouslama, Myriam; et. al. Reproductive disorders in hairdressers and cosmetologists: A meta-analytical approach. Journal of Occupational Health 2015; 57 (6): 485–96
15. Gallicchio, L; Miller, S; Greene, T; Zacur, H; Flaws, JA. Premature ovarian failure among hairdressers. Human Reproduction 2009; 24 (10): 2636–41
16. Donald, J. M; Hooper, K; Hopenhayn-Rich, C. Reproductive and developmental toxicity of toluene: A review". Environmental Health Perspectives 1991; 94: 237–44
17. V. M; Powers, M; Liu, J. Occupational Chemical Exposures Among Cosmetologists: Risk of Reproductive Disorders. Workplace Health & Safety 2013; 61 (12): 522–8, quiz 529
18. Hubinger, Jean C. A survey of phthalate esters in consumer cosmetic products". Journal of Cosmetic Science 2010; 61 (6): 457–65
19. Public Health Statement for Toluene. Agency for Toxic Substances and Disease Registry. January 21, 2015