Review Article

Int Jou Hea Bio Sci, 5(2), 2024, 12-17

International Journal of Health care and Biological Sciences

Content available at www.saap.org.in Online ISSN: 2582-7499

Open Access

A BRIEF ARTICLE ON COSMETOVIGILENCE THE ONGOING AND SYSTEMATIC MONITORING OF SAFETY AND ADVERSE EFFECTS OF COSMETICS

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Article History

Received on: 15-03-2024
Revised on: 26-04-2024
Accepted on: 11-05-2024

Abstract

Cosmetovigilence is the study of cosmetic products from a public health perspective. The Saudi Food and Drug Authority has assumed responsibility for regulating cosmetic items and issuing recommendations to ensure their safety due to the drastic growth of beauty products in Saudi Arabia. Addressing the safety of cosmetic goods is widely recognized as a public health concept. In tertiary care hospitals, identify potentially dangerous impacts from cosmetic goods and take appropriate action to prevent them. The goals of this text are to cater to the demands of dermatologists, scientists, cosmetic chemists, and formulators who have to grasp a variety of topics in order to develop innovative, successful skin care products for a particular market. In addition to chemicals, physical and biological risk factors also manifest in the skin, which is the biggest organ in the body.

Keywords: Cosmetics, Cosmetovigilence, skincare products, health care products, awareness, appearance.

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DOI: https://doi.org/10.46795/ijhcbs.v5i2.613

1. Introduction

Definition of Cosmetics:

Cosmetics are defined by their intended use, as "articles intended to be rubbed, poured,sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance"

Definition of Cosmetovigilence:

Cosmetics Act, 1940 is an Act of the parliament of India which regulates the import, manufacture and distribution of drugs in India. The drugs and cosmetics sold in India are safe, effective and conform to state quality standards. (1) In the Middle East, beauty and personal care trade is growing twice as faster than any other part of the world. But the study revealed that exposure to various chemical substances present in cosmetics poses a health risk. It can vary from mild hypersensitivity response to serve anaphylactic reaction or after the prolonged use of cosmetics.(2) Headache, dizziness,tiredness, and nausea were the frequency reported adverse reactions associated with prolonged exposure to heavy makeup. Nearly 1-3% of the population is allergic to ingredients in cosmetics.(14)Furthermore, SFDA assigned a unified call center number to enquire about the safety of food, drugs, and cosmetics.(1)

2. Applications and uses of Cosmetics:

- Cosmetics have been in use since ages for improving the appearance of the person wearing them. Makeup is designed to enhance your appearance.
- Beauty cosmetics can make a drastic change in a person's features, as they enhance the bestfeatures and cover the blemishes. People use lotions and creams to cleanse the skin deeply.
- This is not possible with regular soap and water. Deep cleansing opens the skin pores and removes other underlying pollutants. Blocked pores lead to the formation of acne and beauty cosmetics prevent this from happening.
- People use makeup, because it gives them a better appearance than natural. This increases

3. Materials and methods

Study design and settings:

A cross-sectional study was conducted, from January to March 2019, among the generalpopulation living in the metropolitan area in the Eastern Province of Saudi Arabia. The
metropolitan area is formed by three main neighbouring cities: Dammam, Dhahran, and Khobar. Study questionnaires were distributed in public as well at working places such as schools, colleges, hospitals, companies, and shopping malls(3). Participants were requested to read the information about the study and to agree with the informed consent before proceeding to items in the questionnaire.

Study population and sampling:

Residents of Dammam metropolitan region were included in the study irrespective of their nationality and gender or age persons who have a habit of using any categories of cosmetic products and who ready/write either English or Arabic were included in the study.

Data extraction and analysis:

The selected publications, articles, and reports were meticulously reviewed and analysed. Thecontent of each source was carefully examined to extract pertinent information, including statistical data, case studies, adverse event reports, regulatory updates, and emerging concerns (4). Comparative analysis was performed to identify commonalities, discrepancies, and emerging trends within the collected data.

Data validation:

To ensure accuracy and reliability, a rigorous process of cross-referencing and verification was employed. The extracted information was validated by comparing it with multiple sources and corroborating it with established scientific knowledge and regulatory guidelines in Cosmetovigilence.(5)

Data collection:

The questionnaire for data collection was adopted and modified from previous studies for the cosmetic utilisation behaviours and adverse reactions. US FDA Med watch ADR reporting forms for the consumers were used as the primary reference for the development of AR section. The questionnaire was translated into Arabic; a back-translation method was used to confirm the phase validity of the original questionnaire.

Statistical analysis:

Data management and analysis were carried out using SPSS Statistics. Descriptive statistics (frequency and percentage) were used to summarise demographic characteristics, the pattern of cosmetic use, and adverse events. Logistic regression model was used to assess the determinants of the occurrence of cosmetics-related adverse events among the respondents. Variables that found significant in the univariate analysis were entered into multivariable logistic regression. Adjusted odds ratio (AOR) and it's 95% confidence and statistical significance of predictors.(6)

Literature search:

A comprehensive search was conducted to identify relevant research articles, review articles, regulatory documents, guidelines, and other online resources related to Cosmetovigilence. Databases, such as PubMed, Google Scholar, and regulatory agency websites, were utilised to obtain a wide range of scholarly and authoritative sources.

Pattern identification:

The validated information was further analysed to identify emerging patterns in Cosmetovigilence. This involved scrutinising the data for recurring adverse reactions/undesirable effects, safety concerns, emerging risks, and regulatory gaps. Patterns were recognised through the observation of consistent trends or associations within thecollected data (7).

Documentation:

The findings obtained from the analysis were carefully documented, including the identified patterns, relevant statistical data, and supporting evidence. The documentation served as a comprehensive record of the study's results, allowing for transparency, reproducibility, and future reference.(7)

Classification of cosmetics

Cosmetics broadly categorised into four types:

- Skin cosmetics
- Hair cosmetics
- Nail cosmetics
- Cosmetics for hygiene purpose

Skin cancer:

The abnormal growth of skin cells most often develops on skin exposed to the sun. But this common form of cancer can also occur on areas of your skin not ordinarily exposed to sunlight.PAHs, in association with exposure to the sun can cause various cancers of the skin among bricklayers and tilers: these include malignant epithelioma, carcinomas and even the much- feared malignant melanoma (carcinogenic or mutagenic agents).

Symptoms of skin cancer:

Skin cancer develops primarily on areas of sun-exposed skin, including the scalp, face, lips, ears, neck, chest, arms and hands, and on the legs in women. But it can also form on areas thatrarely see the light of the day – your palms, beneath your fingernails or toenails, and your genital area. Skin cancer affects people of all skin tones, including those with darker complexations(8). When melanoma occurs in people with dark skin tones, it's more likely to occur in areas not normally exposed to the sun, such as the palms of the hands and soles of the feet.

Treatment for Skin cancer:

Freezing: Your doctor may destroy actinic keratosis and some small, early skin cancers by freezing them with liquid nitrogen (cryosurgery). The dead tissue sloughs off when it thaws.

Excisional surgery**:** This type of treatment may be appropriate for any type of skin cancer.

Your doctor cuts off(excuses) the cancerous tissue and a surrounding margin of healthy skin. A wide excision –

removing extra normal skin around the tumour – may be recommended in some cases.

Mohs surgery: This procedure is for larger, recurring or difficult-to-treat skin cancers, which may include both basal and squamous cell carcinomas. It's often used in areas where it's necessary to conserve as much skin as possible, such as on the nose.

Radiation therapy**:** Radiation therapy uses high-powered energy beams, such as X-rays, to kill cancer cells. Radiation therapy may be an option when cancer can't be completely removed during surgery.

Chemotherapy: In chemotherapy, drugs are used to kill cancer cells. For cancers limited to the top layer of skin creams or lotions containing anti-cancer agents may be applied directly to the skin. Systemic chemotherapy can be used to treat skin cancers that have spread to other parts of the body.

Rosacea:

Rosacea is a chronic skin disease that affects more than 16 million Americans. The cause of rosacea is still unknown, and there is no cure. However, research has allowed doctors to find ways to treat the condition by minimising it's symptoms. There are four subtypes of rosacea. Symptoms of Rosacea:

Rosacea symptoms are different between each subtype.

- Flushing and redness in the centre of your face.
- Visible broken blood vessels.
- Swollen skin.
- Sensitive skin.
- Stinging and burning skin.
- Dry, rough, and scaly skin.

Treatment of Rosacea**:**

Treatment for rosacea focuses on controlling signs and symptoms. Most often this requires a combination of good skin care and prescription drugs(9).

Hair cosmetics:

Hair cosmetics are also an important tool for increasing patients adhesion to scalp treatments, according to the diversity of hair types and ethnicity. True described them as "preparations intended for placing in contact with the hair and scalp, with the purpose of cleansing, promoting attractiveness, and/or protecting them in order to maintain them in good condition"

Examples of Hair Cosmetics: Shampoos, Conditioners, Hair straighteners, permanent waves and hair sprays.

Nail Cosmetics:

The nail as an anatomic structure protects the terminal phalanx of the digit from injury. Historically, it has served as a tool for protection and for survival(10). As civilizations developed, it attained the additional function of adornment. Nail beautification is a big industry today, with various nail cosmetics available, ranging from nail hardeners, polishes, extensions, artificial/sculpted nails, and nail decorations. Example of Nail Cosmetics: Nail polish, Vanish paint, Hypoallergenic Nail polish, Nail Hardeners, Nail polish Remover, French Nail Manicure, Nail Adornment, Artificial Nails,etc.

Cosmetovigilence: need of the hour:

In today's fast-paced world, the cosmetics industry stands at a unique juncture of innovation, diversity, and increasing consumer demand. With a constant stream of novel products and evolving consumer preferences, the realm of beauty and personal care has never been more dynamic. Yet, within this dynamic landscape, the obligation for Cosmetovigilence emerges asa cornerstone of responsible product stewardship (9).

Several key factors converge to emphasize the pressing need for Cosmetovigilence in today'slandscape:

Scientific advancements and research:

Ongoing scientific research and advancements in dermatology, toxicology, and other related fields contribute to the need for Cosmetovigilence. New findings, studies, and evidence regarding the safety and efficacy of cosmetic ingredients or products may necessitate the monitoring and evaluation of their impact on consumer health. Cosmetovigilence ensures that scientific knowledge is translated into practical measures for consumer safety(12).

Public awareness and consumer expertations:

Increasing consumer awareness and concerns about product safety have also fueled the need for Cosmetovigilence. Consumers expect transparency, accurate labelling, and safe products. Monitoring adverse events and implementing measures to ensure safety help build consumer trust in cosmetic products and the industry.

Global market and supply chains:

Cosmetics are often produced and distributed on a global scale, with ingredients sourced from various regions. Cosmetovigilence ensures that potential risks associated with cosmetics are monitored throughout the entire supply chain, including the identification of unsafe ingredients, detection of counterfeit products, and addressing safety cincerns related manufacturing, packaging, or distribution processes(7).

Rapidly evolving industry:

The cosmetic industry is dynamic, with new ingredients, formulations, and products constantly being introduced. Cosmetovigilence is necessary to keep up with these changes and assess the safety of new ingredients and products before they are marketed; it helps identify potential risks associated with emerging trends or innovations in the cosmetic industry.

Regulatory compliance:

Regulatory authorities enforce safety guards and regulations to protect consumers. Cosmetovigilence data is crucial for assessing compliance with these regulations, identifying gaps, and taking appropriate actions to ensure that cosmetic products meet the required safety standards. It helps in developing and updating regulations to address emerging risks.

Consumer safety and adverse reactions:

Consumer safety stands as the foremost motivation behind Cosmetovigilence. Cosmetic products intimately

interact with the skin, hair, nails, and various body areas. Although most cosmetics maintain a high safety standard, the potential for adverse reactions and other safety issues exists. Cosmetovigilence plays a pivotal role by systematically gathering and scrutinising data on adverse reactions, discerning patterns, evaluating the seriousness and frequency of incidents, and uncovering underlying causes. This meticulous analysis serves to enhance product safety and pre-emptively mitigate risks, ultimately safeguarding consumers from potential harm. (14).

Diving deep:the ever-present challenge of chemicals in cosmetics:

Cosmetics, an integral part of our daily routines, contribute to our sense of well-being, selfexpression, and personal grooming. While most cosmetics are rigorously tested and provensafe for use, a subset of these products contains chemicals and harmful agents that can potentially impact out health. In this section, we delve into the realm of cosmetics and their ingredients, shedding light on the various chemicals and agents that have raised concerns in recent years. (7).

Sulfates:

Sulfates, which are formed through the reaction of sulphuric acid (H2SO4) with other substances, can be derived from petroleum or plant sources such as coconut and palm oil. These salts are commonly used as surfactants in cosmetics to create lather. However, Sulfates can cause irritation to the skin and eyes, prematurely fade hair dye, and pose a toxic threat to aquaticlife when washed away.

Parabens:

Parabens are preservatives used to maintain the freshness and hygiene of skincare and makeup products. They can be found in various items such as soaps, lotions, and cosmetics. Studies have indicated that parabens can increase oestrogen production and interface with reproductive and brain functions. Some research suggests that Parabens can penetrate the skin and mimic oestrogen, leading to excessive cell division in breast tissue and ultimately contributing to the development of breast cancer. (16)

Toluene:

Toluene, a petrochemical solvent, is commonly found in hair dyes and nail polish. It can have adverse effects on the immune system and carries a risk of birth defects and blood cancer. Pregnant women are advised to avoid using hair dyes and nail polish containing Toluene, as it can harm the developing foetus. Toluene can also effect the central nervous system, leading tosymptoms such as fatigue, headaches, nausea, and drowsiness. (16)

Polyethylene glycol (PEG):

PEG is commonly used as a thickening agent in. Skincare products like lotions, sunscreens, and shampoos. However, it has the potential to cause cancer and respiratory disorders. PEG can also strip the natural oils (sebum) from the skins triggering the sebaceous glands to produceexcessive sebum, resulting in greasy skin. (11)

Formaldehyde:

Formaldehyde is a colourless gas often used as a preservative in skincare products. It helps prevent bacterial growth and can be found in items such as nail polishes, hair straightening treatments, hair gels, nail hardeners, shampoos, deodorants, lotions, and makeup. Formaldehyde has been associated with developmental toxins, hair loss, scalp burns, asthma, and neurotoxicity. Inhalation of formaldehyde can cause dizziness and suffocation.

Hydroquinone:

Hydroquinone is utilised in skincare products for its skin lightening properties, targeting pigmentation issues such as acne scars, freckles, melasma, age spots, and post-inflammatory hyperpigmentation. However, hydroquinone is a known carcinogen. Prolonged use can result in skin whitening as it significantly reduces melanocytes, the cells responsible for producing melanin. (8)

Counterfeit cosmetics and safety risks:

Counterfeit cosmetics are fraudulent or imitation beauty products that are designed to mimic genuine and reputable brands. These counterfeit products are often produced and distributed without the authorization or approval of the original brand or regulatory authorities. They are sold with the intent to deceive consumers into believing they are purchasing legitimate and safe cosmetics.The problem of counterfeit cosmetics has grown significantly in recent years, and it poses several substantial challenges:

Safety concerns:

Counterfeit cosmetics often contain harmful and undisclosed ingredients. These substances canrange from toxic heavy metals like lead and mercury to harmful allergens and microbial contaminants. The use of such products can lead to serious health issues, including skin reactions, allergies, infections, and even long-term health risks like organ damage or cancer.

Consumer deception:

Counterfeit cosmetics are packaged to closely resemble genuine products, making it difficult for consumers to distinguish between real and fake items. Consumers may inadvertently purchase counterfeit cosmetics, believing they are buying genuine, safe products. (9)

Lead:

One of the more common ingredients found in counterfeit cosmetics at 5 to 19 times above the legal level. Health effects are reported to be human developmental toxicity, reproductiveissues, and organ system toxicity within the kidneys, liver, sensory organs, and the cardiovascular system.

Mercury:

Mercury is a possible human development toxicant, can lead to nervous system toxicity, as well as immune and respiratory toxicity. This is recognised by many institutions as a toxic chemical. Mercury is particularly

hazardous during fetal development and is readily absorbed by the skin. The presence of mercury in any cosmetic is a concern and should not be treated lightly. (9)

Microbial Contamination – Bacteria:

Different kinds of bacteria have been found in Counterfeit cosmetics and they are causing infections, skin rashes, and allergic reactions. One more common type of bacteria that has been found in counterfeit cosmetics is E. Coli (Escherichia coli) which can cause severe diarrhoea, kidney failure, and anaemia.

Guidelines to safeguard yourself from harmful chemicals:

Review product labels:

Before purchasing skincare products, always take the time to read and examine the labels. Payattention to the listed ingredients and remain cautious of any potentially harmful chemicals.

Avoid Sulfates:

Be on the lookout for sulfates such as SLS (sodium lauryl sulfate) and SLES (sodium laureth sulfate) in shampoos and other personal care items. These substances can be harsh on the skinand strip away natural oils. (9)

Exercise caution with parabens:

Chemicals like methyl, butyl, and propyl parabens are commonly used as preservatives in cosmetics. Due to potential health concerns, it's advisable to avoid products containing these ingredients.(7)

Be wary of Toluene:

Toluene is often listed under alternative names such as benzene, phenylmethane, toluol, or methyl benzene. As a solvent, it can be harmful, so it's best to steer clear of products that include it. (9)

Stay alert to PEGs:

Polyethylene glycols (PEGs) are often identified by numerical values like 100, 120, 14M, 30, 32, 40, 75, and so on. These ingredients can potentially cause irritation, so it's wise to avoid them.

Conclusion:

Because of worries about the safety of different components and the rise in fake goods, the cosmetics and personal product industry has received a lot of attention lately. To safeguard the security and welfare of customers, the practice of "cosmetovigilance," or the surveillance and monitoring of cosmetic items, has grown in importance. In order to identify ADRs brought on by cosmetic goods, family medicine doctors and primary care providers play a crucial role. This article has emphasized the harmful effects of certain chemicals that are frequently included in cosmetics, including lead, talc, triclosan, parabens, phthalates, synthetic colors, and perfumes. These substances have been connected to a number of health problems, such as hormone imbalance, toxicity to the reproductive and developmental systems, skin irritation, cancer, and the existence of these dangerous chemicals. The piece also highlighted how concerningly common it is to find fake beauty products on the market. With the increasing globalization of postmarketing surveillance of cosmetics, issues associated with these items can be found and fixed, resulting in increased safety. Encourage patients to report adverse drug reactions and raise awareness of this novel idea. will be a valuable remark on global public health.

Author contributions

All authors are contributed equally.

Financial support

None

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

Acknowledgements

None

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