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## COSMETIC USE RELATED ADVERSE EVENTS AND NEED FOR COSMETOVIGILANCE

Merrin Joseph, Ms Karishma Shaji, Mr Mahin T M, Ms Nandana P B, Ms krishna Das\*

Nirmala College of Pharmacy Muvattupuzha P O, Ernakulam, Kerala, Pin code : 68666

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### Abstract

Cosmetics are applied to human body for cleansing, beautifying, promoting attractiveness or altering appearance. Cosmetics are causing adverse events to users, yet evidence about its magnitude is limited among students due self-diagnosis and self-medication. To know about the cosmetic use related adverse events and to enhance awareness regarding cosmetovigilance among the students of Nirmala College of pharmacy, Muvattupuzha by an educational intervention. To assess the prevalence of cosmetics, use among the students of Nirmala college of pharmacy, Muvattupuzha. To identify the cosmetics related adverse events and knowledge, To improve the awareness regarding cosmetovigilance. By online survey using google form. The questionnaire consisted of three parts, demographic profile, utilization pattern, participant's experience of cosmetics-related adverse reactions for the last two years. An awareness program about cosmetovigilance system. Access the knowledge of students one month after awareness. 502 participants, 55.2% with pimple, 55.2% with hair loss, 41.4% with allergic reaction, dryness of skin, etc




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### \*Corresponding Author

Ms krishna Das

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### Introduction

The word 'cosmetic' comes from the Greek word 'kosmetikos,' which implies adorn. Cosmetics are an important part of people's daily lives across generations, and they are used for a variety of functions. Cosmetics are defined as "articles for beautification cleansing or altering physical appearance or the cosmetics in general are external preparation and are meant to be applied to external parts of body for the purpose of beautifying, cleansing or improving appearance and enhancing attractive features. Although the word "cosmeceuticals" is occasionally applied to cosmetics containing bioactive substances that are claimed to have medicinal advantages, the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not recognize any such category. A product can be a medication, a cosmetic, or a mixture of the two, but the phrase "cosmeceutical" has no legal definition. Some cosmetics and drugs may fit both cosmetic and drug classifications, depending on their intended use and components. The term "pharmacovigilance" defines the activities related to the collection, detection, assessment, monitoring, and prevention

of adverse reactions (ADRs) due to pharmaceuticals. An ADR is any response to a drug which is noxious and unintended, including lack of efficacy. Recently the spectrum of "-vigilance" broadened to include safety of herbal products and cosmetic products as well. The phrase "cosmetovigilance" refers to the actions of gathering, evaluating, and monitoring spontaneous reports of unfavorable occurrences that occur during or after normal or reasonably expected usage of a cosmetic product. Vigan (1997) was the first to use the term in the literature to refer to industry's post market surveillance. The French health products safety agency established cosmetovigilance as a component of the pharmacovigilance system for cosmetics. It is now widely acknowledged as a public health concept to address the safety of cosmetic products. Cosmetovigilance is a novel type of cosmetics product safety monitoring that refers to the post-marketing surveillance of any health-related adverse effects that may be caused by the use of cosmetics. The goal of cosmetovigilance is to collect, evaluate, and assess adverse reactions in consumers in order to identify any potential health risks, ensuring even greater consumer safety. Cosmetovigilance also enables for the management or elimination of potentially harmful substances included in cosmetic products. Cosmetovigilance is a new idea in cosmetic product safety monitoring. It could be regarded a significant part of public health efforts. As post marketing surveillance of cosmetics becomes more common around the world, problems associated with these items can be recognized and resolved, ensuring product safety. The problem of cosmetic-related injuries, and the necessity for a method to record, collect, and assess them,

cannot be overlooked, given the widespread use of these products and the relatively high prevalence of reported ACEs. A key responsibility for family medicine physicians and primary care practitioners is to spot ADRs caused by cosmetic items and encourage patients to report them. Raising awareness of this new notion will make a significant contribution to worldwide public health. India has a large population, and its cosmetics business is similarly large. In India, Contact dermatitis and other dermatoses are frequent, and cosmetics have been linked to them. Traditional agents, such as kajal and kumkum dermatitis, are also regularly reported to cause adverse responses. The Drugs and Cosmetics Act, Section 135 B, makes it illegal to import cosmetics that have been tested on animals in India. Cosmetic-related problems, like other diseases, result in pharmaco-economic losses. To protect the health of the Indian population, in addition to adequate regulation of these agents, a proper vigilance system is also essential. According to Vigan and Castelain (2014) [20], good cosmetovigilance can help to control or rule out dangerous substances in cosmetics, improving our confidence in their use.

**Materials and Methods**

The study will be done as an online survey using Google form. The developed questionnaire consisted of three parts: (1) demographic profile (2) utilization pattern (3) participant's experience of cosmetics-related adverse reactions for the last two years.

- Demographic section consists of socio demographic details of study participants.
- The second part includes the questions about the cosmetic usage pattern. Types of cosmetics, cosmetics utilization behavior, safety measures on cosmetic habit, sources of recommendation for the cosmetic products.
- For the adverse cosmetic reaction part, the respondents were allowed to choose more than one answer if they thought they were appropriate their condition. The type of consultation adopted, and the measures taken can be extracted and knowledge cosmetovigilance.

**Steps Involved In the Study**

1. NCP students who met inclusion criteria were enrolled in the study
2. Data collected using Google form questionnaires.
3. Access knowledge on cosmetovigilance before awareness.
4. Conducted a seminar on cosmetovigilance.
5. Access knowledge on cosmetovigilance after awareness.
6. Access knowledge on cosmetovigilance one month after awareness.
7. Google form questionnaires were scored.
8. The cosmetic use related adverse events and need of cosmetovigilance were identified
9. The data collected from the respondents were recorded and documented

**Result and Discussion**

Demographic feature

Age distribution (n=502)

Age	Number	Percentage
17	7	3.38
18	122	24.3
19	90	17.92
20	86	17.13
21	79	15.73
22	67	13.34
23	39	7.76
24 and above	39	7.76

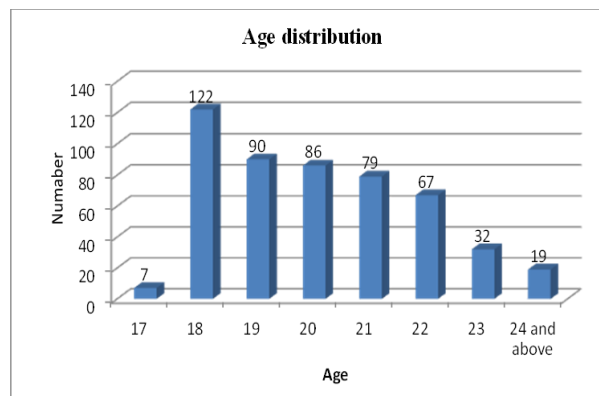
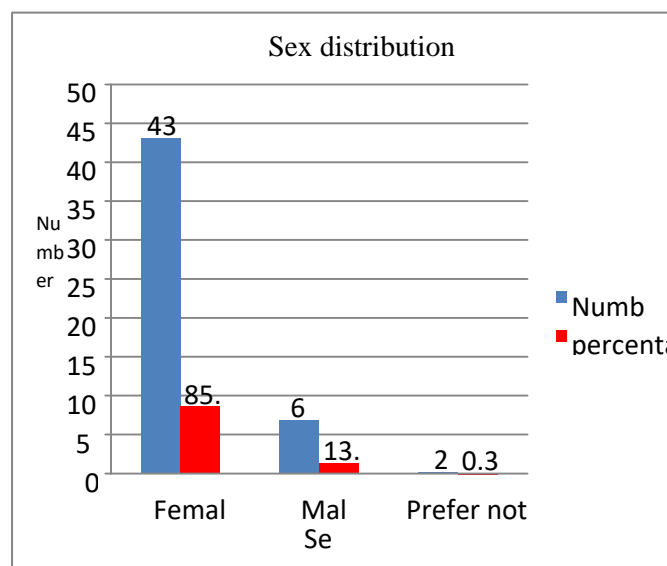


Figure: 5.1 Age distribution

**1.2 Sex determination**

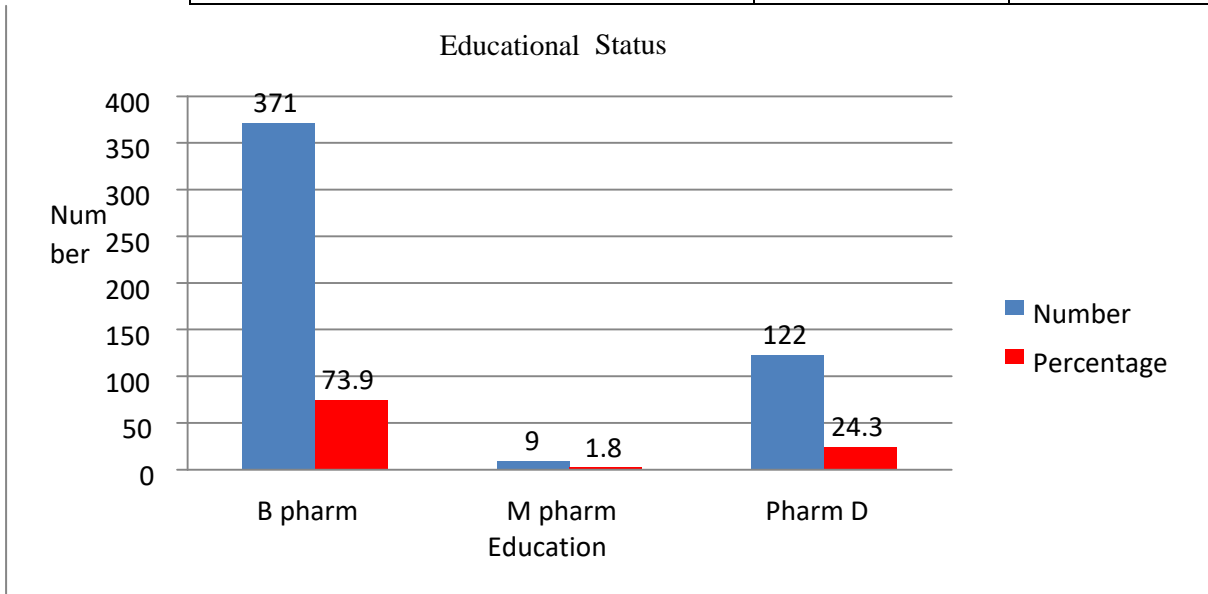
Sex	Number	percentage
Female	431	85.9
Male	69	13.7
Prefer not say	2	0.39



1.2 sex distributions

1.3 Educational Status (n = 502)

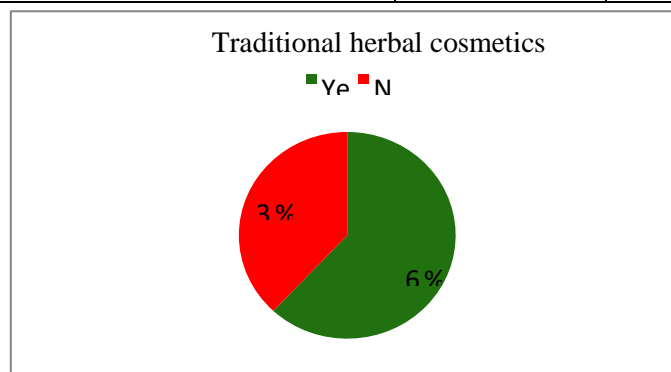
Education	Number	percentage
B pharm	371	73.9
M pharm	9	1.8
Pharm D	122	24.3



1.3 Educational Status

1.4 Traditional herbal cosmetics

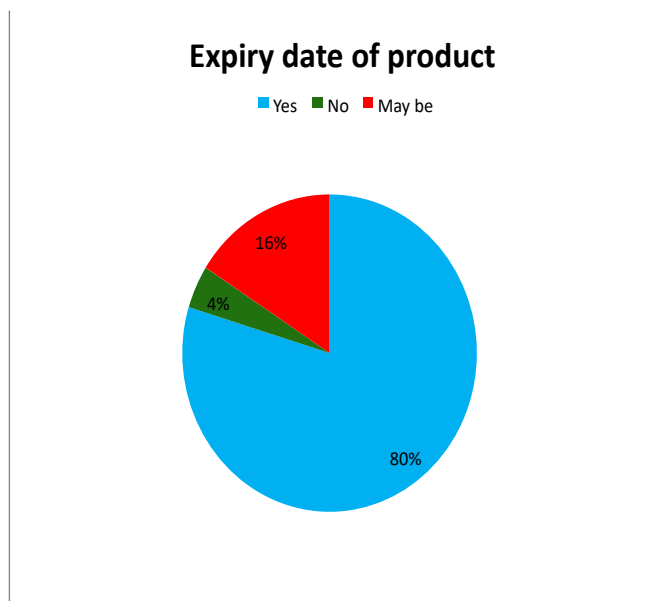
Traditional Cosmetics	Number	percentage
yes	311	62
No	191	38



1.4 Traditional herbal cosmetics

5 Expiry date of cosmetics

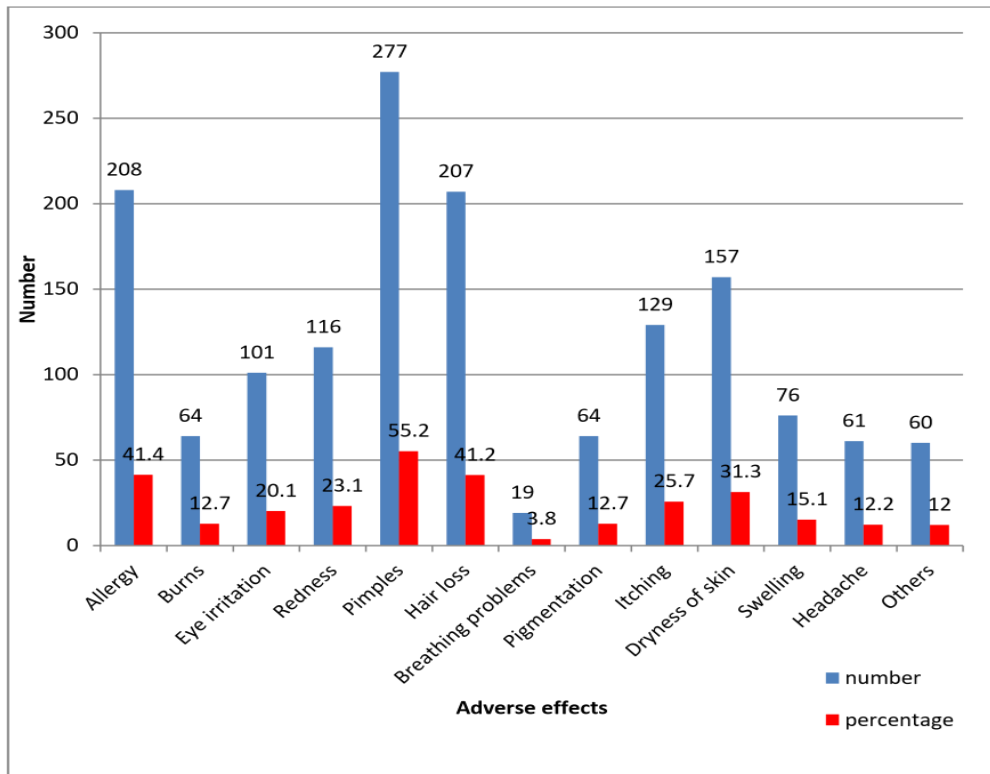
Expiry date	Number	percentage
Yes	400	79.7
No	80	15.9
May be	22	4.4



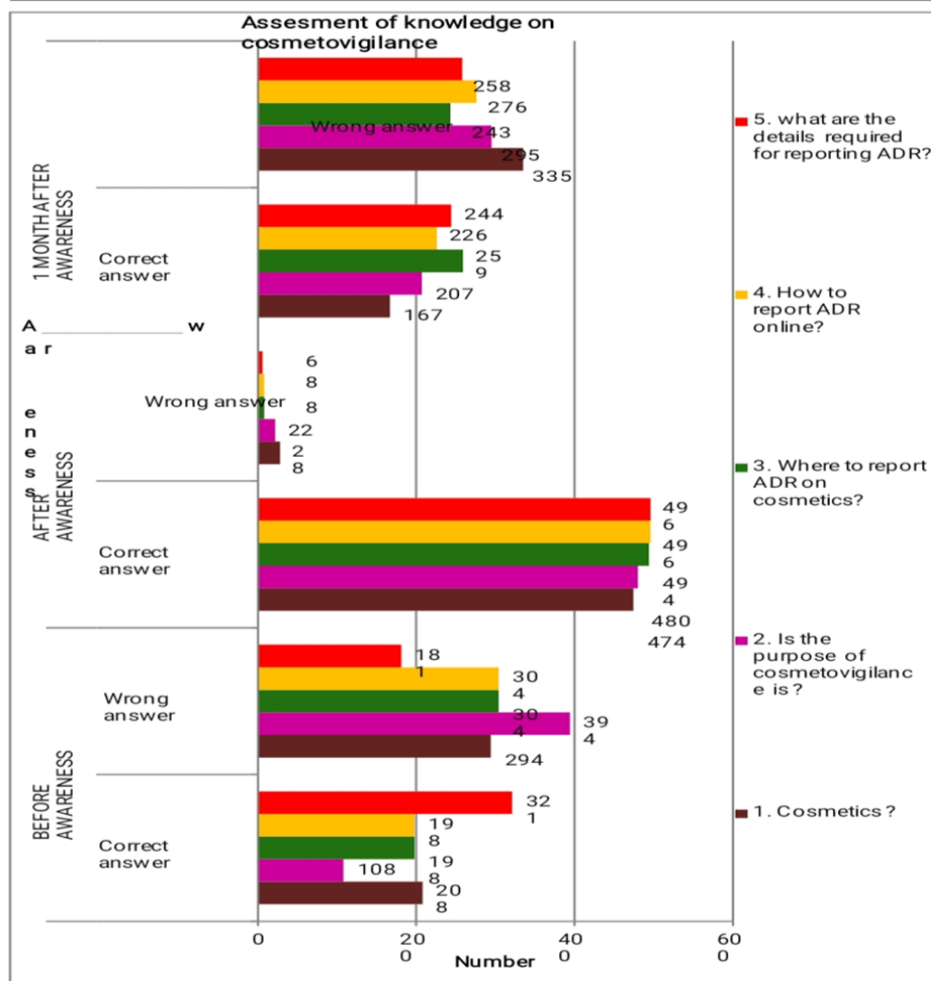
### 1.6 Adverse effects

Adverse effects	number	percentage
Allergy	208	41.4
Burns	64	12.7
Eye irritation	101	20.1
Redness	116	23.1
Pimples	277	55.2
Hair loss	207	41.2
Breathing problems	19	3.8
Pigmentation	64	12.7
Itching	129	25.7
Dryness of skin	157	31.3
Swelling	76	15.1
Headache	61	12.2
Others	60	12





1.7 Assesment of knowledge on cosmetovigilance



**1.7 Before awareness**

Observation	Before awareness			
	Correct answer		Wrong answer	
	Number	Percentage	Number	Percentage
1. Cosmetics?	208	41.4	294	58.56
2. Is the purpose of cosmetovigilance is?	108	21.5	394	78.5
3. Where to report ADR on cosmetics?	198	39.4	304	60.55
4. How to report ADR online?	198	39.4	304	60.55
5. What are the details required for reporting ADR?	321	63.9	181	36.1

**1.7 After awareness**

Observation	After awareness			
	Correct answer		Wrong answer	
	Number	Percentage	Number	Percentage
1. Cosmetics?	474	94.4	28	5.8
2. Is the purpose of cosmetovigilance is?	480	95.6	22	4.4
3. Where to report ADR on cosmetics?	494	98.4	8	1.6
4. How to report ADR online?	496	98.8	8	1.2
5. What are the details required for reporting ADR?	496	98.8	6	1.2

**1.7 One month after awareness**

observation	1 Month after awareness			
	Correct answer		Wrong answer	
	Number	Percentage	Number	Percentage
1. Cosmetics?	167	33.3	335	66.7
2. Is the purpose of cosmetovigilance is?	207	41.2	295	58.8
3. Where to report ADR on cosmetics?	259	51.6	243	48.4
4. How to report ADR online?	226	45	276	55

## Discussion

Cosmetovigilance is a rapidly expanding subset of pharmacovigilance. Using a self-reported survey, this study examines the cosmetic usage pattern and related ARs. Drug safety is monitored longitudinally in nations such as the Netherlands. The study concluded with the finding on the cosmetic use related adverse events and need for Cosmetovigilance.

The study concluded with the finding on the cosmetic use related adverse events and need for Cosmetovigilance. The study finding involved collection of data from 502 individuals from Nirmala College of pharmacy Muvattupuzha. The collected data, which involved 4 sections of questionnaire, which includes:

- Assessment of cosmetic use related adverse events
- Assessment of knowledge about Cosmetovigilance -before ,after and onemonth after awareness

Cosmetics are reported to cause a wide array of adverse reactions, including pigment disorders, irritant, contact urticarial, and photosensitization, damage of hair and nails, and acne form eruptions. (49) In our study, of the total 502 participants involved in the study, 55.2 %( no: 207) came across with pimple, about 207 students responded with hair loss, 41.4% of the population experienced allergic reaction by using the cosmetics. followed by this dryness of skin (no:157,31.3%), itching (no:129,25.7%), redness (no:116,23.1%), swelling(no:76,15.1%), headache(no:61,12.2%) were the common adverse events faced by the population. The adverse reactions may occur to one of the primary constituents of the cosmetic formulation or contamination or procedural misconduct. Preservatives are the second most common cause of skin reactions, besides fragrances. Most reactions being irritant rather than allergic in nature. Allergic to medication and family history of allergy were may be the reason associated with cosmetic related AR's and also, mixing cosmetics, and changing the brands of cosmetic products were recognized as important predictors for experiencing an adverse event. A major proportion of the ARs were related with skin care (no: 337, 67.1%) and hair care (no: 259, 51.6%) respectively. The students responded that they also encountered with adverse reaction from makeup products, personnel care products, traditional products and also from perfumes. Details are given in table and figure. Our last section of the of question are to assess the insight of students, about the Cosmetovigilance system, surprisingly 96.2% were not aware about it.. A same questionnaire containing 5 questions were circulated among the students before and after the seminar. The first question asked about the definition of cosmetics, 94.4 %of the study population gave correct answer, which is about 41.4% before the awareness. Only 21.1% were aware about the purpose of Cosmetovigilance system, yet so later 95.6% of students understand about it. by conducting the awareness program we were able to provide the information about the reporting of adverse reaction. Only regular awareness program and updation procedures can bring about proper reporting, management and need of cosmetovigilance system.

## Conclusion

Usage of cosmetic products has been increased significantly in last few decades. Their usage has increased beyond the purpose of beautification. The definition of cosmetic product varies widely amidst different countries. Increased concern of physical appearance in population throughout the globe has been taken as an advantage by the cosmetic industries. Heavy metals have been found in certain cosmetic products which not only lead to dermatological but systemic adverse effects too. Further to this, pharmacologically active agents have been found in anti-aging products. These cosmeceutical agents may possess chemical agents which are toxic to human body. Heavy metals have been found in certain cosmetic products which not only lead to dermatological but systemic adverse effects too. Further to this, pharmacologically active agents have been found in anti-aging products. These cosmeceutical agents may possess chemical agents which are toxic to human body. . In conclusion, our experience regarding the notification of adverse effects of cosmetics, suggests that for an efficient and reliable monitoring system to be in place, which includes all the necessary measures to protect public health, an education and training Programme for all stakeholders (health professionals, consumers and appropriate authorities) is required.

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No Conflict of interest

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