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Original Research Article

Cosmetovigilance: knowledge, attitude and practice study

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ABSTRACT

Background: Adverse reactions due to cosmetics should be reported to avoid similar incidences and is highly required to evaluate the risks and benefits of ingredients used in cosmetics.

Methods: This study is to evaluate the knowledge, attitude, and practice of cosmetovigilance among PGs, interns, and consumers of cosmetics. This was a cross-sectional questionnaire- based study conducted among 180 participants of SSMC Tumkur, Karnataka, in India for a period of 1 month.

Results: The Results obtained were analysed using descriptive statistics.: About 46.1% of the participants were aware about the concept of cosmetovigilance. Only an average of about 5% of participants practiced this concept but the attitude towards this concept was satisfactory.

Conclusions: Overall the participants had a less satisfactory overview of this concept and hence educational interventions can aid in serving the purpose especially among medical students.

Keywords: Cosmetovigilance, Adverse cosmetic reactions, Reporting, PGs, Interns, Medical students

INTRODUCTION

Cosmetic use is universal and India is the 4th largest cosmetic market in Asia. The 'Drug and cosmetics act' defines cosmetics as any article intended to be poured, rubbed, sprinkled/sprayed on, or otherwise applied externally on the human body. Roughly an adult uses nine cosmetics per day and 25% of women use 15 or more cosmetics per day. Recently another important aspect of cosmetics has been considered and their use can be associated with adverse effects (ADR). But the knowledge of the fact that they do produce adverse effects is limited. Nearly 1-3% of the population is allergic to ingredients in cosmetics. The most common AR to cosmetics can be allergic/ irritant. Adverse Effects of cosmetics can range from a small rash to toxicity in the long term us.^{2,3} So far the number of known adverse effects to cosmetics is very low due to a lack of information. Moreover, the flaw of a system can reports, collect and analyse the ACRs (adverse cosmetic reactions), and this is fairly responsible for this information deficit. The concept of 'Cosmetovigilance' (CMV) is quite a recent and evolving one. The primary aim of CMV is to detect, monitor, assess the report of the ACRs associated with the use of cosmetics. The Cosmetovigilance branch is coming up and evolving as a strong regulatory science to protect beauty and health. Though there is more number of ACRs occurring at population level, reporting to the regulatory authority is minimal. The initiation of a formal CMV system in India could contribute to the increased safety of cosmetic use which is important for the safeguarding of public health.⁴ As this is a newly emerged concept in India there are only a few studies done regarding this. Hence this study is undertaken to assess the knowledge attitude and practice of CMV among PGs, Interns, and Consumers of cosmetics (MBBS students) of SSMC, Tumkur, Karnataka. This study

suggests the need for approaches such as awareness programs, workshops, and seminars among all the stakeholders of cosmetics on Cosmetovigilance that needs to be established, enforced, and evolved in all healthcare sectors.

Objectives

The main primary objective of current study was to evaluate the knowledge, attitude and practice of Cosmetovigilance, to create an awareness about this concept among the participants and the secondary objective was to motivate the participants to report the ACRs.

METHODS

This is a prospective cross- sectional study conducted in SSMC, Tumkur, Karnataka. The study was conducted among consumers of cosmetics (MBBS students), PGs and Interns. This study was done after getting approval from the institutional ethics committee of SSMC and the participants who were above the age of 18 and who have given informed consent to participate were included and those who were not willing to give consent was excluded.^{5,6} The study period was October 2022 to December 2022.

Procedure

Study approach was structured, validated questionnaires which contained 17 questions on knowledge, attitude and practice of Cosmetovigilance. The questionnaires were uploaded to Google forms and distributed among the study participants.⁷ All the participants were informed about the study objectives and study procedure before its initiation. The completed forms were taken for data analysis & the collected data was analysed for completeness.^{8,9} Analysis of Statistics were carried out in SPSS Software (Version 20). Categorical variables like age and sex were presented by frequency and percentages. Association of knowledge attitude and practise between three group of participants were tested using chi square test, p value <0.05 was set statistically significant.^{10,11}

RESULTS

Altogether 180 participants were enrolled in the study out of which 55 were Interns, 39 were PGs and 86 were the consumers. Age group of participants were represented in (Table 1) in which majority of them were among the age of 19-22 years. 32.8% of them were among the age group of 23-26 years and 12.8% were among the age group of 27-30 years. The sex differentiation among the group of participants of which 56.1% of them were females and 43.9% of them were males (Table 2).

Knowledge based questions were assessed with yes or no. About 83 participants (51.3% were post-graduates, 63.6% were Interns, 32.6% were the consumers) were aware

about the concept of Cosmetovigilance. 145 out of 180 (92.3% of post-graduates, 85.5% of Interns, 72.1% of Interns) knew that adverse effects due to cosmetics can be reported.

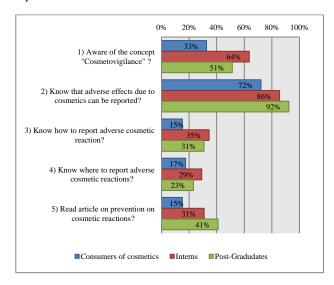


Figure 1: Knowledge levels between different groups of participants.

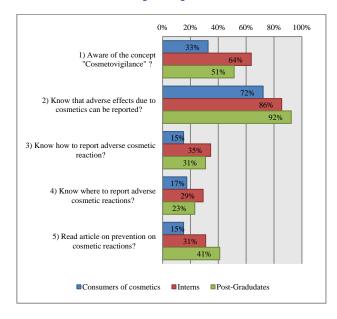


Figure 2: Practice levels shown among different group of participants.

An average of only about 24% of the participants had the knowledge of how and where to report ACR and have read articles about it. Association of knowledge levels among each group of participants were represented in (Table 3), thus it can be concluded that interns and PGs were more aware about this concept and had better knowledge compared to UG students. The descriptive data on the knowledge levels between the participants the data denotes the number of people who had knowledge on Cosmetovigilance (people who had answered yes) (Figure 1).

Table 1: Age distribution by type of participants.

Age (years)	Participants N (%)	Participants N (%)			
	Consumers of cosmetics	Interns	Post-graduates		
19-22	84 (97.7)	7 (12.7)	0 (0.0)	91 (50.6)	
23-26	2 (2.3)	48 (87.3)	9 (23.1)	59 (32.8)	
27-30	0 (0.0)	0 (0.0)	23 (59.0)	23 (12.8)	
>30	0 (0.0)	0 (0.0)	7 (17.9)	7 (3.9)	
Total	86 (100.0)	55 (100)	39 (100)	180 (100)	

Table 2: Sex distribution by type of participants.

Knowledge	Participants N (%)	Total	Chi canara n valua			
	Consumers of cosmetics	Interns	Post-graduates	10tai	Chi-square, p value	
Male	30 (34.9)	30 (54.5)	19 (48.7)	79 (43.9)		
Female	56 (65.1)	25 (45.5)	20 (51.3)	101 (56.1)	5.737, 0.057	
Total	86 (100.0)	55 (100.0)	39 (100.0)	180 (100)		

P value <0.005 is statistically significant

Table 3: Association of knowledge levels between different groups of participants.

	Participants N (%)					
Knowledge	Consumers of cosmetics	Interns	Post- graduates	Total	Chi-square, p value	
How many were aware of the concept "Cosmetovigilance"?	28 (32.6)	35 (63.6)	20 (51.3)	83 (46.1)	13.575, 0.001	
Know that adverse effects due to cosmetics can be reported?	62 (72.1)	47 (85.5)	36 (92.3)	145 (80.6)	8.213, 0.016	
Knowledge about how to report adverse cosmetic reaction?	13 (15.1)	19 (34.5)	12 (30.8)	44 (24.4)	7.935, 0.019	
knowledge about where to report adverse cosmetic reactions?	15 (17.4)	16 (29.1)	9 (23.1)	40 (22.2)	2.655, 0.265	
Read the article on prevention of adverse cosmetic reactions?	13 (15.1)	17 (30.9)	16 (41.0)	46 (25.6)	10.661, 0.005	

P value <0.005 is statistically significant

Majority of the participants (97.5% of post-graduates, 96.4% of Interns, 98.9% of the consumers) believed that reporting ACRs should be necessary. About 167 participants (97.4% of post-graduates, 92.7% of Interns, 90.7% of Consumers) disagreed that the cosmetics available in the market were safe. 96.9% of the participants agree that the concept of Cosmetovigilance should be up skilled to the health care professional. Average of 85.6% of the participants agreed that the concept should be included in the UG curriculum and every institute should enrol under it. But most of them unanimously agreed that reporting ACR benefits patients. Majority of the participants had a positive attitude towards this. The association of attitude levels among the group of participants was represented in (Table 4). The association of practice between participants groups where, more than 95% of participants were willing to report ACRs in the future is depicted in (Table 5). Only about 6.7% (12) of the participants have come across ACRs and very less conference participants have attended Cosmetovigilance. But the near future response of reporting ACR was 95% positive. The percentage of

different group of participants who had answered yes to the practice-based questions is depicted in (Figure 2).

DISCUSSION

Cosmetovigilance is considered one among the emerging branches in pharmacovigilance and every one should be aware of the knowledge regarding it, and reporting adverse drug reaction due to cosmetics and practising this on regular basis will help in improving the quality of the drugs and its prescription. ¹²

Our prospective, cross-sectional study on knowledge, attitude and practice towards Cosmetovigilance, among the postgraduates, interns and cosmetic consumers (medical students) was analysed. Study conducted by Rani et al shows that 80% were aware of adverse drug reaction, and it can be reported to pharmacovigilance centre which was similar to the results obtained in our study (86%). It could be due to awareness about the Cosmetovigilance and reporting adverse events due to cosmetics.

Table 4: Association of attitude levels between different groups of participants.

Attitude	Scale		Total	Chi- square, p value			
		Consumers of cosmetics	Interns	Post- graduates			
All the cosmetics	Strongly agree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
	Agree	0 (0.0)	1 (1.8)	1 (2.6)	2 (1.1)	19.277,	
products available in the market are	Neutral	8 (9.3)	3 (5.5)	0 (0.0)	11 (6.1)	= 0.004	
m the market are safe?	Disagree	56 (65.1)	30 (54.5)	14 (35.9)	100 (55.6)	0.004	
saic.	Strongly disagree	22 (25.6)	21 (38.2)	24 (61.5)	67 (37.2)		
	Strongly agree	38 (44.2)	27 (49.1)	20 (51.3)	85 (47.2)		
Reporting ACR,	Agree	47 (54.7)	26 (47.3)	18 (46.2)	91 (50.6)	1.047	
should be	Neutral	1 (1.2)	2 (3.6)	1 (2.6)	4 (2.2)	1.847,	
necessary?	Disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.764	
·	Strongly disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	_	
	Strongly agree	31 (36.0)	24 (43.6)	14 (35.9)	69 (38.3)		
Reporting ACR,	Agree	46 (53.5)	30 (54.5)	24 (61.5)	100 (55.6)	6.592, 0.360	
should be made	Neutral	6 (7.0)	1 (1.8)	1 (2.6)	8 (4.4)		
mandatory?	Disagree	3 (3.5)	0 (0.0)	0 (0.0)	3 (1.7)		
•	Strongly disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Cosmetovigilance,	Strongly agree	36 (41.9)	23 (41.8)	16 (41.0)	75 (41.7)		
should be taught	Agree	44 (51.2)	31 (56.4)	19 (48.7)	94 (52.2)	5.771, - 0.449	
in detail to the	Neutral	4 (4.7)	1 (1.8)	4 (10.3)	9 (5.0)		
health care	Disagree	2 (2.3)	0 (0.0)	0 (0.0)	2 (1.1)		
professionals?	Strongly disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
-	Strongly agree	22 (25.6)	20 (36.4)	15 (38.5)	57 (31.7)		
Cosmetovigilance	Agree	47 (54.7)	31 (56.4)	19 (48.7)	97 (53.9)		
should be included	Neutral	17 (19.8)	4 (7.3)	5 (12.8)	26 (14.4)	5.939, 0.204	
in UG	Disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
curriculum?	Strongly disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	_	
Every Institute should enroll under Cosmetovigilance?	Strongly agree	28 (32.6)	18 (32.7)	20 (51.3)	66 (36.7)		
	Agree	44 (51.2)	32 (58.2)	15 (38.5)	91 (50.6)	7.619,	
	Neutral	12 (14.0)	5 (9.1)	4 (10.3)	21 (11.7)		
	Disagree	2 (2.3)	0 (0.0)	0 (0.0)	2 (1.1)	0.267	
	Strongly disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	_	
Reporting of ACR benefits the patients?	Strongly agree	48 (55.8)	22 (40.0)	24 (61.5)	94 (52.2)		
	Agree	34 (39.5)	33 (60.0)	13 (33.3)	80 (44.4)	0.55.5	
	Neutral	4 (4.7)	0 (0.0)	2 (5.1)	6 (3.3)	9.636, 0.047	
	Disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
	Strongly disagree	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		

Table 5: Association of practice between participants groups.

	Participants I	N (%)		Chi-square,		
Practice	Consumers of cosmetics	Interns	Post- graduates	Total	p value	
Have you reported any ACRs?	0 (0.0)	2 (3.6)	0 (0.0)	2 (1.1)	4.597, 0.100	
Have you ever come across ACRs during your professional practice?	4 (4.7)	2 (3.6)	6 (15.4)	12 (6.7)	6.139, 0.046	
Have you attended any CMEs/Workshops/Seminars on Cosmetovigilance?	1 (1.2)	2 (3.6)	0 (0.0)	3 (1.7)	2.096, 0.352	
Have you documented any ACR?	2 (2.3)	1 (1.8)	2 (5.1)	5 (2.8)	1.050, 0.591	
Are you willing to report any ACRs in the future?	80 (93.0)	52 (94.5)	39 (100)	171 (95)	2.784, 0.249	

A study conducted by Dehvari et al in Iran shows that 50% of the women were aware of the adverse drug reactions due to cosmetics which was similar to our study where 50.6% women were aware about the adverse cosmetic reactions.³ In our study, majority of the participants opined that reporting Adverse reactions due to cosmetics, to the Cosmetovigilance unit will enhance the safety of patients in the future and having awareness of Cosmetovigilance reduces the usage of cosmetics which are not approved under drugs and cosmetics act. Conducting or attending the CME. Conferences will update the knowledge about the ACRs.

Limitations

Though there were higher response rate, our study was limited only to the medical profession. Limitations of the study are that the study was conducted only in one institute with small population and henceforth this study alone cannot represent the awareness and understanding of the concept of Cosmetovigilance among the other population and the results cannot be generalised.

CONCLUSION

Current study has shown that majority of the participants had inadequate knowledge and practice on Cosmetovigilance. The less satisfactory response was from the UG students, as it is a recent concept. Even then the participants believed that reporting ACRs is necessary and were willing to do it in the near future which is reassuring. Hence educational interventions can help in serving the purpose. Awareness regarding adverse reaction reporting and causality assessment at UG level may help promote public health, beauty and their safety.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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