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Original Research Article

## Cosmetovigilance studies to assess the safety of cosmetic therapy in hair segments and skin non-laser

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### ABSTRACT

**Background:** Cosmetic procedures, especially non-laser skin treatments and hair rejuvenation therapies, are increasingly popular, yet ADRs remain a significant safety concern, particularly in patients with comorbidities. This study employed a cosmetovigilance-based approach to evaluate the safety, efficacy, and long-term outcomes of commonly used cosmetic therapies.

**Methods:** A retrospective interventional cohort study was conducted at Kosmoderma Ltd. involving 410 patients aged 18–60 years who received cosmetic treatments between April and July 2024. Hair rejuvenation therapies included QR678, platelet-rich plasma (PRP), and growth factor concentrate (GFC), while non-laser skin procedures comprised chemical peels and facials. A minimum sample size of 199 was calculated to ensure statistical reliability. ADRs were identified, monitored, and categorized using structured data collection forms. Statistical analyses were performed using Chi-square tests and Spearman correlation to assess associations and risk factors.

**Results:** Of the 410 patients evaluated, females constituted 78% of the study population, with equal representation of hair and non-laser skin treatments. A statistically significant association was observed between the type of hair therapy and ADR occurrence ( $\chi^2=6.89$ ,  $p=0.032$ ). No significant association was found between non-laser skin treatments and ADRs. Comorbidities, particularly diabetes mellitus, showed a strong association with both the incidence ( $p<0.001$ ) and severity ( $p=0.021$ ) of ADRs.

**Conclusions:** Hair rejuvenation therapies and patient comorbidities significantly influence ADR occurrence. Integration of cosmetovigilance practices and active involvement of clinical pharmacists can enhance patient safety, support informed decision-making, and optimize cosmetic treatment protocols.

**Keywords:** Cosmetovigilance, Platelet-rich plasma, Growth factors, Chemical peels

### INTRODUCTION

#### *Cosmetovigilance as a public health safety framework*

Cosmetovigilance is a systematic post-marketing surveillance mechanism aimed at identifying, assessing, and preventing adverse reactions related to cosmetic products and aesthetic procedures.<sup>1</sup> Unlike pharmaceuticals, cosmetic products and procedures often

enter routine clinical use with limited long-term safety data, making post-marketing monitoring crucial for early detection of rare, delayed, or cumulative adverse effects.<sup>2</sup> The rapid expansion of cosmetic dermatology and minimally invasive aesthetic procedures has further emphasized the importance of cosmetovigilance as a public health safety framework.

Regulatory initiatives such as the European Union Cosmetics Regulation (EC No. 1223/2009) mandate reporting of serious undesirable effects, thereby promoting regulatory accountability, transparency, and consumer protection.<sup>3</sup> In recent years, the scope of cosmetovigilance has expanded to include cosmeceuticals, injectable aesthetic agents, and non-surgical cosmetic medical devices, reflecting the evolving complexity of cosmetic therapy and the need for structured real-world safety evaluation.<sup>4</sup>

### ***Cosmetovigilance challenges in the Indian setting***

India has witnessed a substantial rise in the use of cosmetic products and aesthetic procedures due to increased awareness, affordability, and accessibility of dermatological services. However, this growth has been accompanied by significant safety challenges. Variability in manufacturing standards, coexistence of traditional and modern cosmetic formulations, inappropriate product labelling, and reports of microbial contamination and heavy metal adulteration raise serious consumer safety concerns.<sup>5,6</sup>

Despite these challenges, cosmetic-related adverse reactions remain underreported in India. Limited awareness among consumers and healthcare professionals, lack of standardized reporting systems, and insufficient integration of cosmetovigilance into routine clinical practice contribute to this gap.<sup>7</sup> Strengthening cosmetovigilance in the Indian context is therefore essential to improve patient safety and generate reliable real-world safety data.

### ***Importance of post-marketing surveillance in cosmetic practice***

Post-marketing surveillance constitutes the cornerstone of cosmetovigilance by capturing adverse reactions that may not be evident during pre-marketing evaluation. Continuous monitoring enables early identification of safety signals and supports timely regulatory actions such as modification of usage guidelines, restriction of indications, or product withdrawal.<sup>8</sup>

In cosmetic dermatology, where procedures are frequently repeated, combined, or used off-label, post-marketing surveillance assumes greater importance. Evidence suggests that structured adverse reaction reporting systems significantly enhance patient safety and clinical decision-making in aesthetic practice.<sup>9</sup>

### ***Safety considerations in hair rejuvenation therapies***

Hair rejuvenation therapies involve repeated intradermal administration and prolonged treatment duration, increasing the risk of local adverse reactions. Commonly reported events include injection-site pain, erythema, edema, hypersensitivity reactions, and transient treatment-induced hair shedding.<sup>10</sup> Cosmetovigilance plays a critical

role in distinguishing therapy-related adverse reactions from disease progression or procedural variability.

International regulatory authorities and professional dermatology associations emphasize standardized treatment protocols, practitioner training, and risk-based safety monitoring to minimize adverse outcomes associated with hair restoration therapies.<sup>11</sup>

### ***Non-surgical hair regeneration modalities***

#### ***Qr678 therapy***

QR678 is an indigenously developed injectable hair rejuvenation therapy containing a proprietary combination of growth factors and peptides intended to stimulate dormant hair follicles and enhance follicular microcirculation. While clinical studies report improvements in hair density, the multi-component formulation may increase the likelihood of localized inflammatory responses, highlighting the importance of structured post-marketing safety monitoring.<sup>12</sup>

#### ***Platelet-rich plasma (PRP) therapy***

Platelet-rich plasma therapy is an autologous regenerative approach involving intradermal injection of platelet-concentrated plasma derived from the patient's own blood. Due to its autologous origin and minimal immunogenic potential, PRP demonstrates a favourable safety profile, with reported adverse reactions being mild, transient, and self-limiting.<sup>13</sup>

#### ***Growth factor concentrate (GFC) therapy***

Growth factor concentrate therapy represents an advanced refinement of autologous regenerative techniques, involving selective isolation of growth factors from platelets. This targeted approach enhances follicular regeneration while maintaining a strong safety profile, making GFC therapy an increasingly preferred modality in hair restoration practice.<sup>14</sup>

### ***Non-laser dermo cosmetic procedures***

The growing demand for minimally invasive aesthetic interventions has led to widespread use of non-laser dermo cosmetic procedures such as facials and chemical peels. These interventions are commonly employed for acne management, pigmentation disorders, and skin rejuvenation.<sup>15</sup> Although generally safe, adverse reactions including erythema, irritation, post-inflammatory hyperpigmentation, and secondary infection have been reported, emphasizing the need for standardized protocols and patient education.<sup>16</sup>

#### ***Cosmetic facials***

Cosmetic facials aim to improve skin health through cleansing, exfoliation, hydration, and targeted treatment.

Advances in personalized dermatology allow customization based on skin type and sensitivity. While adverse effects are typically mild and transient, inappropriate product selection or underlying dermatological conditions may increase the risk of irritation or allergic reactions.<sup>17</sup>

### *Chemical peels*

Chemical peels involve controlled chemical exfoliation to improve skin texture, tone, and pigmentation. Depending on the agent and depth of penetration, predictable adverse reactions may occur, necessitating careful patient selection, procedural expertise, and post-procedure monitoring to ensure safety.<sup>18</sup>

## **METHODS**

### *Study setting and design*

This retrospective interventional cohort study was conducted at Kosmoderma Pvt. Ltd., Bengaluru, a multispecialty aesthetic centre. Medical records of 410 patients treated between April and July 2024 were reviewed to assess adverse drug reactions (ADRs), identify treatment-related patterns, and evaluate potential risk factors across diverse demographic groups undergoing hair and non-laser skin procedures.

### *Study criteria*

#### *Inclusion criteria*

Adults aged  $\geq 18$  years with conditions such as alopecia, pigmentation, melasma, acne scars, and eligible for hair or non-laser skin treatments. Participants included Indian men and women aged 20–60 who consented to share medical history and comply with follow-up.

#### *Exclusion criteria*

Patients  $< 18$  years, pregnant individuals, those unable to consent, and those with pre-existing dermatological diseases, severe allergies, recent cosmetic procedures, interacting medications, recent finasteride discontinuation, hair transplant within six months, or suspected malignancy were excluded.

### *Sample size*

The estimated sample size was calculated as 199 using a 95% confidence level, 5% margin of error, 50% population proportion, and a population size of 410. This indicates that a minimum of 199 participants is required, with additional cases included when available to improve study reliability.

### *Sampling technique*

The study used a structured patient documentation form to systematically record ADRs associated with cosmetic therapies. Categorical variables were analysed using frequencies, percentages, and Chi-square tests to assess associations. Spearman correlation was applied to evaluate relationships between ADR severity and continuous risk factors.

### *Ethical considerations and informed consent*

This retrospective study was approved by the IRB of Aditya Bangalore Institute of Pharmacy Education and Research and complied with ethical guidelines. Only anonymized patient data were used, so individual informed consent was not required. All procedures followed the Declaration of Helsinki and ensured participant confidentiality.

### *Data collection and management*

The patient data collection forms (form 1: hair segments; form 2: skin non-laser) were designed as structured tools to systematically capture comprehensive patient information for cosmetovigilance analysis. Each form documented demographic details, medical history, relevant pre-treatment factors, and prior cosmetic procedures to assess baseline risk. Treatment-specific sections recorded the use of hair therapies (QR678, GFC, PRP), chemical peels such as Glycolic acid peels (25%,50%,75%) retinol peels (mild, intense), salicylic acid peels (10%,30%) trichloroacetic acid peels (15%,25%,30%), arginine and lactic acid peels, and various facials named such as Dermalogica, Hydrafacial, Oxygeneo, Oxybrite, and Kosmo glow focus on deep cleansing, exfoliation, hydration, and overall skin rejuvenation using professional products and advanced infusion technologies. Treatments like laser toning, celebrity photo facial (IPL), and the Red-Carpet Facial (laser toning + mild peel) specifically target pigmentation, uneven skin tone, dullness, and tanning, offering instant brightness and improved clarity, along with detailed documentation of associated adverse drug reactions (ADRs), including scalp reactions, injection-site effects, irritation, redness, pigmentary changes, infection, and rare complications. These standardized forms ensured consistent, thorough, and accurate monitoring of treatment safety across all cosmetic procedures included in the study.

### *Data entry and processing*

The completed formats were coded individually and entered in a computer using Microsoft Excel version 2407 mean median and standard deviation was calculated using MS excel. And the data is exported to Jamovi version 2.3.26 for Statistical Analysis, Patients who received various hair and skin non laser therapies.

## RESULTS

Represents the demographics and clinical profile of 410 patients, showing a predominance of females (78%) and higher representation of younger adults aged 18–30. Most patients were from the South region (48%), and common

comorbidities included vitamin D deficiency (56%) and acne (40%). Previous cosmetic procedures such as fillers (20%) and RF therapy (28%) were frequently reported, with an equal distribution of hair and non-laser skin treatments (50% each).

**Table 1: Detailed breakdown of the demographic characteristics, geographic distribution, clinical history, and types of cosmetic procedures.**

Variables	Frequency	Percentage (%)
<b>Gender</b>	Male	22
	Female	78
<b>Age group (in years)</b>	18-24	30
	25-30	23
	31-35	20
	36-40	14
	41-45	13
	<b>Place</b>	North
South		48
East		10
West		15
<b>Comorbidity</b>	Thyroid	33
	PCOD	43
	Diabetics	7
	Rosacea	14
	Acne	40
	B12 deficiency	56
	Vit D deficiency	33
	COPD	5
	Obesity	22
	Autoimmune disorder	2
	Porphyria	3
	Chronic urticaria	3
	SLE	2
	Prehistory of LOAE	5
	PIH history	12
<b>Prehistory</b>	Prehistory of covid	80
	Dermatitis	15
	Vaccination	97
	Immunosuppressive	2
	Antibiotics taken last 3 months	20
	Previous fillers history	18
	Previous botox history	22
	Previous history of rf	28
	Previous history of skin	8
	Ultrasound severe allergy	11
<b>Type of Procedure</b>	Hair segments	50
	Skin non laser	50

### Subjects undergone various hair treatments

Highlights that QR678, PRP, and GFC were predominantly used for telogen effluvium and alopecia areata, with QR678 having the highest overall usage. Less common conditions like traction alopecia, trichotillomania, and minoxidil resistance showed minimal cases across all treatment types.

### Application of various chemical peels and treatments for specific skin conditions.

Represents a tailored approach to skincare, with GA, retinol, salicylic acid, and TCA peels used according to specific concerns like rejuvenation, pigmentation, and texture improvement. Additional treatments such as arginine and lactic acid peels supported hydration and gentle exfoliation.

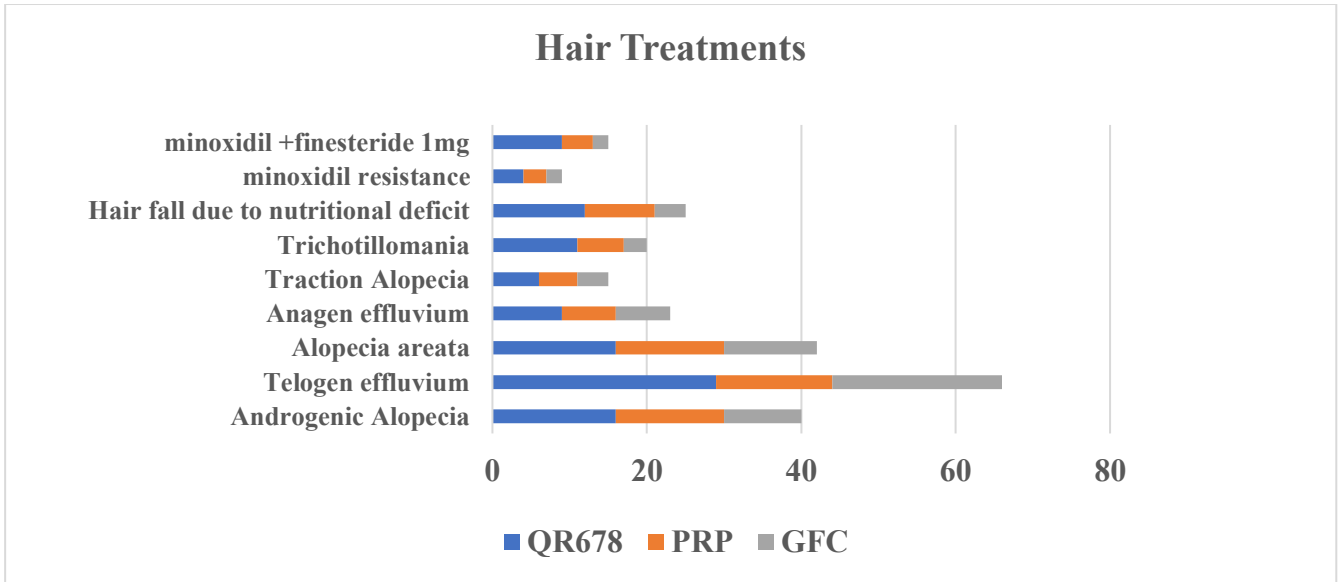


Figure 1: Subjects undergone various hair treatments

Table 2: Application of various chemical peels and treatments for specific skin conditions.

Indication	GA25 %	GA50 %	GA70 %	Retinol (mild)	Retinol (intense)	Salicylic (10%)	Salicylic (30%)	TCA 15%	TCA 25%	TCA 30%	Arginine	Lactic
Skin rejuvenation	13											
Increase collagen production		12										
Fine line			13									
Texture improvement				22								
Exfoliation					10							
Skin lightening						20						
Brightening							17					
Sun damage								12				
Hyperpigmentation									19			
Wrinkle reduction										24		
Dark circle reduction											29	
Anti-aging												14

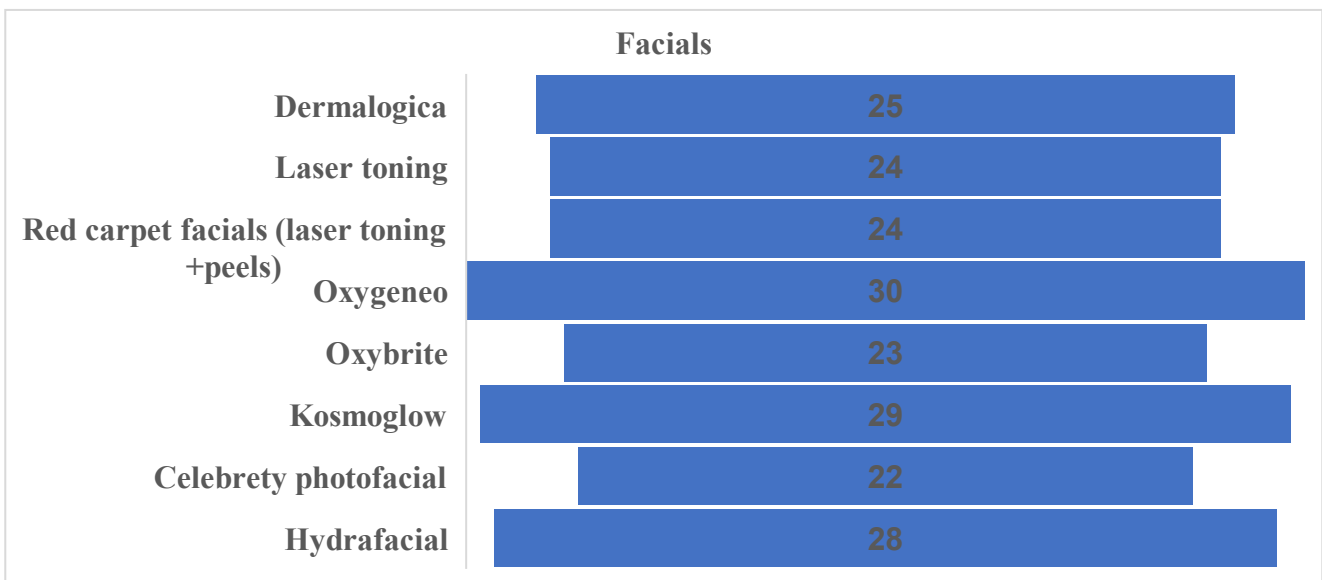


Figure 2: Subjects undergone various facial treatments.

**Table 3: Significant association between the type of therapy and the occurrence of ADRs for hair.**

ADRs (yes/no)			
Therapy type	Yes	No	Total
QR678	137	28	165
PRP	19	9	28
GFC	7	5	12
<b>Total</b>	<b>163</b>	<b>42</b>	<b>205</b>
X <sup>2</sup> tests			
	Value	DF	P
X <sup>2</sup>	6.89	2	0.032
N	205		

**Table 4: Significant association between the type of therapy and the occurrence of ADRs for skin non laser.**

ADRs (yes/no)			
Treatment	Yes	No	Total
Chemical peels	76	27	103
Facials	65	37	102
<b>Total</b>	<b>141</b>	<b>64</b>	<b>205</b>
X <sup>2</sup> tests			
	Value	DF	P
X <sup>2</sup>	2.42	1	0.120
N	205		

**Table 5: Correlation between the severity of ADRs and other continuous variables, such as the number of age of patients.**

		Age	Severity
Age	Spearman's RHO	-	-
	DF	-	-
	P-value	-	-
Severity	Spearman's RHO	0.042	-
	DF	408	-
	P-value	0.396	-

**Table 6: Assess the association between categorical variables, such as the presence of comorbidities and the occurrence of ADRs.**

Comorbidities	ADRs(yes/no)		Total
	Yes	No	
Yes	275	105	380
No	30	0	30
<b>Total</b>	<b>305</b>	<b>105</b>	<b>410</b>
X <sup>2</sup> tests			
	Value	DF	P
X <sup>2</sup>	11.1	1	
N	410		

**Subjects undergone various facial treatments**

The bar graph illustrates the distribution of patients undergoing various facial treatments, indicating notable variation in procedure preference across the study population. Among the eight facial types assessed, Oxygeneo and Kosmo glow treatments demonstrated the highest utilization, while Celebrity Photo facial showed the lowest frequency.

**Statistical analysis**

The Chi-square test ( $\chi^2=6.89$ ,  $p=0.032$ ) showed a significant association between hair therapy type and ADR occurrence, indicating that ADR likelihood varies with the treatment used.

Chi-square Test: ( $\chi^2=2.42$ ,  $p=0.120$ ) showed no significant association between skin treatment type and ADR

occurrence, indicating similar ADR likelihood for Chemical Peels and Facials.

**Spearman correlation**

A very weak, non-significant inverse correlation was observed between patient age and ADR severity (Spearman’s rho=−0.042, p=0.396). This indicates that age has no meaningful relationship with ADR severity in this dataset.

Chi Square Test The analysis revealed a statistically significant association between comorbidities and ADR occurrence, with patients having comorbidities showing a higher incidence of ADRs ( $\chi^2=11.1$ ,  $p<0.001$ ).

Assess the association between categorical variables, such as the presence of comorbidities and the occurrence of ADRs. Among the assessed comorbidities, only diabetes exhibited a statistically significant association with ADR severity (p=0.021), whereas all other conditions showed no meaningful correlation.

**Table 7: Assess the association between categorical variables, such as the presence of comorbidities and the occurrence of ADRs.**

Comorbidity	Status	Low (%)	Medium (%)	High (%)	Total	Chi	P value
<b>Thyroid</b>	No	35 (24.5)	96 (67.1)	12 (8.4)	143	3.86	0.145
	Yes	22 (37.9)	31 (53.4)	5 (8.6)	58		
<b>PCOD</b>	No	33 (30.3)	66 (60.6)	10 (9.2)	109	0.715	0.700
	Yes	24 (26.1)	61 (66.3)	7 (7.6)	92		
<b>Diabetes</b>	No	56 (30.4)	111 (60.3)	17 (9.2)	184	7.691	0.021
	Yes	1 (5.9)	16 (94.1)	0 (0)	17		
<b>Rosacea</b>	No	48 (29.4)	102 (62.6)	13 (8)	163	0.648	0.723
	Yes	9 (23.7)	25 (65.8)	4 (10.5)	38		
<b>Acne</b>	No	30 (26.1)	72 (62.6)	13 (11.3)	115	3.078	0.215
	Yes	27 (31.4)	55 (64)	4 (4.7)	86		
<b>B12 deficiency</b>	No	46 (27.4)	110 (65.5)	12 (7.1)	168	3.287	0.193
	Yes	11 (33.3)	17 (51.5)	5 (15.2)	33		
<b>Vitamin D deficiency</b>	No	38 (27.1)	90 (64.3)	12 (8.6)	140	0.336	0.845
	Yes	19 (31.1)	37 (60.7)	5 (8.2)	61		
<b>COPD</b>	No	54 (28.9)	119 (63.6)	14 (7.5)	187	3.335	0.189
	Yes	3 (21.4)	8 (57.1)	3 (21.4)	14		
<b>Obesity</b>	No	48 (28.4)	108 (63.9)	13 (7.7)	169	0.823	0.663
	Yes	9 (28.1)	19 (59.4)	4 (12.5)	32		
<b>Autoimmune disorder</b>	No	55 (28.2)	124 (63.6)	16 (8.2)	195	0.717	0.699
	Yes	2 (33.3)	3 (50)	1 (16.7)	6		
<b>Porphyria</b>	No	53 (28.2)	121 (64.4)	14 (7.4)	188	4.179	0.124
	Yes	4 (30.8)	6 (46.2)	3 (23.1)	13		
<b>Chronic urticaria</b>	No	53 (27.6)	124 (64.6)	15 (7.8)	192	4.299	0.117
	Yes	4 (44.4)	3 (33.3)	2 (22.2)	9		
<b>Systemic lupus erythematosus</b>	No	55 (28.8)	119 (62.3)	17 (8.9)	191	1.62	0.445
	Yes	2 (20)	8 (80)	0 (0)	10		

**DISCUSSION**

This cosmetovigilance study provides real-world safety data from 410 patients undergoing hair rejuvenation therapies and non-laser skin procedures, contributing valuable evidence to the limited Indian literature on cosmetic-related adverse drug reactions. The predominance of young female participants observed in this study mirrors global trends, reflecting greater aesthetic awareness, sociocultural acceptance, and health-seeking behaviour among women.<sup>19,20</sup>

A notable proportion of participants presented with comorbid conditions, particularly vitamin D deficiency, acne, and diabetes mellitus. Emerging evidence suggests

that nutritional deficiencies and chronic metabolic disorders may exacerbate inflammatory responses and impair tissue recovery following cosmetic procedures.<sup>21,22</sup> These findings highlight the importance of comprehensive pre-procedure assessment and optimization of underlying conditions to minimize adverse outcomes.

A statistically significant association between hair therapy type and adverse reaction occurrence was observed. QR678 therapy demonstrated a higher incidence of adverse reactions compared to PRP and GFC therapies. This may be attributed to its multi-component peptide and growth factor composition, which could increase the likelihood of localized inflammatory or hypersensitivity responses. Similar observations have been reported in post-marketing surveillance studies of injectable peptide-based cosmetic

therapies.<sup>23,24</sup> In contrast, PRP and GFC therapies exhibited favorable safety profiles, consistent with literature emphasizing the reduced immunogenicity of autologous preparations.<sup>25,26</sup>

For non-laser skin procedures, chemical peels and facials demonstrated comparable adverse reaction frequencies. Most reported reactions were mild and self-limiting, supporting previous studies that highlight the overall safety of these interventions when performed under standardized clinical protocols.<sup>27,28</sup> The absence of significant differences between these modalities reinforces their suitability for routine dermatological practice.

A strong association was identified between diabetes mellitus and adverse reaction occurrence. Impaired wound healing, altered immune responses, and microvascular dysfunction in diabetic patients are well-documented contributors to increased post-procedural complications.<sup>29,30</sup> These findings underscore the need for individualized risk stratification, strict metabolic control, and enhanced post-procedure monitoring in this population.

Importantly, patient age did not significantly influence adverse reaction severity, suggesting that clinical factors such as therapy type and comorbidities play a more decisive role in determining safety outcomes than demographic variables alone. This observation aligns with contemporary cosmetovigilance research emphasizing personalized risk assessment over age-based predictors.<sup>31</sup>

Overall, this study reinforces the critical role of cosmetovigilance in identifying therapy-specific safety profiles and patient-related risk factors. Integrating clinical pharmacists into cosmetovigilance frameworks can further strengthen adverse reaction reporting, improve patient counselling, and promote safer, evidence-based cosmetic practice.

### Limitations of the study

This study is limited by its small, retrospective design and reliance on medical records may underreport ADRs, and the lack of a control group prevents causal conclusions. Short follow-up, self-reported data, and exclusion of major treatments like injectables and lasers further restrict findings, while regional reporting variations may affect data accuracy.

### CONCLUSION

This study emphasizes the critical role of cosmetovigilance in ensuring the safe delivery of hair and non-laser skin therapies. Hair treatments demonstrated significant variability in ADR occurrence, while skin procedures showed comparable safety outcomes. Comorbidities—especially diabetes—were strongly associated with increased ADR risk, reinforcing the need for comprehensive pre-procedure screening. Strengthening

awareness, monitoring systems, and clinical pharmacist involvement can improve safety, optimize treatment outcomes, and enhance patient confidence in cosmetic therapies.

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