

Original Research Article

A multicentric, prospective, observational study evaluating the practice pattern and use of fixed dose topical regimen for hyperpigmentation in intimate and high friction areas

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ABSTRACT

Background: Hyperpigmentation is the third most common dermatological disorder and has major psychosocial impairment. It comes in a variety of forms. The most well-known are age spots, freckles, melasma and post-inflammatory hyperpigmentation. Hyperpigmentation in friction-prone areas (armpits, inner thighs, elbows, knees, groin, etc.) has a significant impact on affected individuals. Unfortunately, there are currently no well-tolerated options available that are intended particularly for these sensitive areas.

Methods: Dermatologists across India were provided a questionnaire consisting of questions related to number of the patients seen with hyperpigmentation in intimate & high friction areas every week and their clinical experience regarding the use of Pigmentbio Sensitive areas containing active ingredients (Andrographolide+Glabridin+Lysine azelate+Laminaria ochroleuca extract). The results were analyzed using a visual analogue scale.

Results: The study included a total of 1402 patients, and 75 dermatologists provided complete responses. The majority (96%) of the dermatologists recommended Pigmentbio Sensitive areas for intimate & high friction areas. These dermatologists also rated tolerability and safety of Pigmentbio Sensitive areas as "excellent" to "good" based on various criteria. These included tolerability after waxing and shaving the bikini line, soothing effect after mechanical erythema from taking off tight clothing, hydrating power when compared to other products, cosmetic acceptability for frictional and intimate areas, and safety on intimate areas.

Conclusions: This study findings indicated that Pigmentbio Sensitive areas is a preferred formulation by dermatologists across India for the management of hyperpigmentation in intimate & high friction areas with proven tolerability and safety.

Keywords: Hyperpigmentation, Intimate areas, High-friction areas, Study, Pigmentbio sensitive areas

INTRODUCTION

Melanin is the primary component of skin colour. Darker skin types have a twice the amount of epidermal melanin in their melanosomes compared to lighter skin types.¹ Furthermore, melanosome breakdown inside the keratinocyte is slower in darkly pigmented skin than in lighter skin types.² Hyperpigmentation of the skin is one of the most distinctively varied human phenotypes, and making cutaneous pigmentation disorders one of the most common causes of a wide range of symptoms.³ Lentigines, melasma, post-inflammatory hyperpigmentation, and dark under-eye circles are the most prevalent among them.⁴ The diversity in skin tones across the world is well-documented, with some considered to be more prone than others to pigmentation disorders, particularly in India.^{5,6}

Frictional dermatoses is a poorly understood condition with no clear definition. It is a group of disorders "induced by repetitive stress to the skin as a result of friction of different aetiology and which can have a wide range of cutaneous symptoms depending on the type of insult."⁷ It is believed to be triggered by physical stress such as extended mechanical friction, pressure, heat, rubbing, and chronic inflammation.^{8,9} The actual prevalence of frictional dermatoses as a distinct entity is undetermined. Cosmeceuticals are frequently used to treat hyperpigmentation. These topical cosmetic-pharmaceutical mixtures improve the appearance of the skin via the use of ingredients that also have positive health benefits.¹⁰ They comprise ingredients that affect the biological function of the skin despite being administered topically as cosmetics.¹¹ Actually, they serve as a link between pharmaceuticals and products for personal care.

Pigmentbio Sensitive areas is such skincare product specifically designed to treat hyperpigmentation of sensitive and intimate areas. It is patented combination of active ingredients (Andrographolide+Glabridin+Lysine azelate+Laminaria ochroleuca extract) acting on melanogenesis as well as its induction.¹² It helps combat hyperpigmentation and prevent it from appearing. Glabridin, an antioxidant polyphenolic flavonoid component from liquorice (*Glycyrrhiza glabra*), has been proven to have anti-inflammatory properties and to protect against pigmentation caused by ultraviolet light.¹³ Furthermore, it works as a reversible inhibitor of tyrosinase (the rate limiting enzyme that controls melanin formation).¹⁴ Andrographolide, which is found in the medicinal plant *Andrographis paniculata*, has cytoprotective effects and can reduce melanin levels by preventing tyrosinase activity.¹⁵ The Laminaria ochroleuca extract in Pigmentbio Sensitive areas acts as a soothing agent for sensitive and intimate areas.¹⁶

Objectives

The objective of this study was to collect information regarding epidemiology of hyperpigmentation in intimate, high friction areas of skin in Indian population and the role

of Pigmentbio Sensitive areas containing active ingredients (Andrographolide+Glabridin+Lysine azelate+Laminaria ochroleuca extract) as a supportive care. The information collected would throw further light on proven safety and tolerability of Pigmentbio Sensitive areas for hyperpigmentation in intimate & high friction areas.

METHODS

In this multicentric, prospective, observational, questionnaire-based study, a total of 75 practicing dermatologists in private healthcare sector from major cities of India (Mumbai, Ahmedabad, Delhi, Pune, Bangalore, Chennai, Hyderabad, Nagpur) were contacted from June 2022 to November 2022 for their willingness to participate in the study. Those who were unwilling to participate were excluded from the study.

Convenience sampling was used for recruitment of participants. The sample size of the study included a total of 1402 patients. The questionnaire aimed at evaluating their clinical experience regarding epidemiology of hyperpigmentation in intimate, high friction areas of skin in Indian population and the role of Pigmentbio Sensitive areas containing active ingredients (Andrographolide+Glabridin+Lysine azelate+Laminaria ochroleuca extract) as a supportive care. It was validated and modified based on feedback by dermatologists.

The questions covered number of patients with hyperpigmentation in intimate, high friction areas seen every week; use of Pigmentbio Sensitive areas in these patients; its tolerability and safety for reducing different parameters of hyperpigmentation in intimate & high friction areas. The results of Pigmentbio Sensitive areas were analyzed using an ordinal scale which ranged from excellent, good, fair and poor. Descriptive statistics were used to present frequencies and percentages. The final statistical analysis of the parameters was carried out by pooling the data obtained. The graphs presented here were prepared using Microsoft Excel 2010.

RESULTS

Out of a total of 1402 patients, 1325 patients (95%) received Pigmentbio Sensitive areas. On an average, each of these dermatologists prescribed Pigmentbio Sensitive areas to 18 patients. It was observed that 43% of the dermatologists see 80-150 patients per week, 25% dermatologists see 151-300 patients each week, 25% dermatologists see less than 80 patients per week and 7% dermatologists see the highest number of more than 300 patients per week (Figure 1).

Among these, majority (46%) of the dermatologists opined that 10-20 patients presented with complaint of hyperpigmentation (Figure 2). Furthermore, majority (57%) of the dermatologists opined that 10-20 patients presented with hyperpigmentation of elbow and knees (Figure 3). In addition, 44% dermatologists opined that 10-

20 patients presented with complaint of hyperpigmentation of intimate sensitive areas such as armpits, groin, inframammary & natal cleft (Figure 4).

Table 1: Global assessment by dermatologists regarding efficacy and safety of Pigmentbio Sensitive areas.

Parameter	Excellent (%)	Good (%)	Fair (%)	Poor (%)
Tolerability after waxing and shaving the bikini line	59	34	5	1
Soothing effect after mechanical erythema from stripping of tight clothes	38	52	10	0
Hydrating power compared to other products	42	54	4	0
Cosmetic acceptability for frictional and intimate areas	57	39	3	1
Safety on intimate areas	54	45	1	0

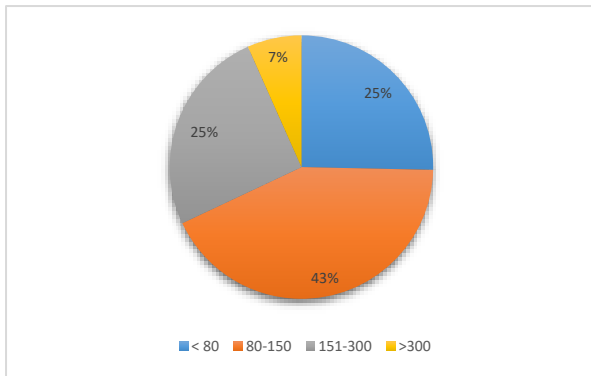


Figure 1: Percentage of overall patients seen by dermatologists per week.

The majority (96%) of the dermatologists recommended Pigmentbio Sensitive areas for intimate & high friction areas (Figure 5). Among these, 36% of the dermatologists opined that they would recommend Pigmentbio Sensitive areas to 10-20% of the patients with hyperpigmented skin in intimate & high friction areas. In terms of tolerability of Pigmentbio Sensitive areas after waxing and shaving the bikini line, 59% of the dermatologists opined it as “excellent”, 34% dermatologists opined as “good”, 5% dermatologists opined as “fair” whereas only 1% dermatologists opined as “poor” (Table 1). In terms of soothing effect of Pigmentbio Sensitive areas after mechanical erythema from stripping of tight clothes, 52%

of the dermatologists opined it as “good”, 38% dermatologists opined as “excellent”, 10% dermatologists opined as “fair” whereas none of them opined as “poor” (Table 1).

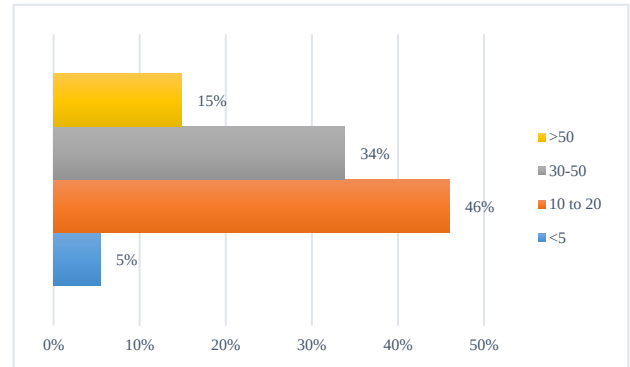


Figure 2: Percentage of patients presenting with complaint of hyperpigmentation.

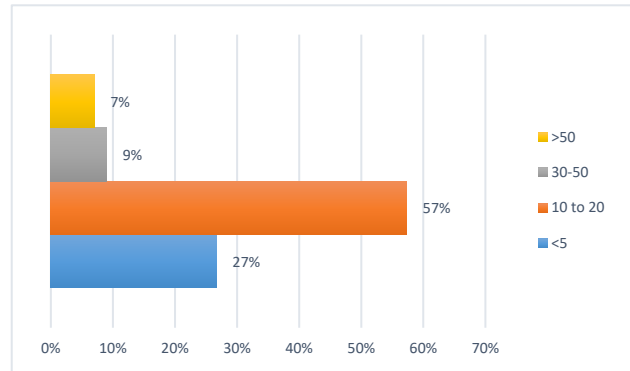


Figure 3: Percentage of patients presenting with complaint of hyperpigmentation of elbow and knees.

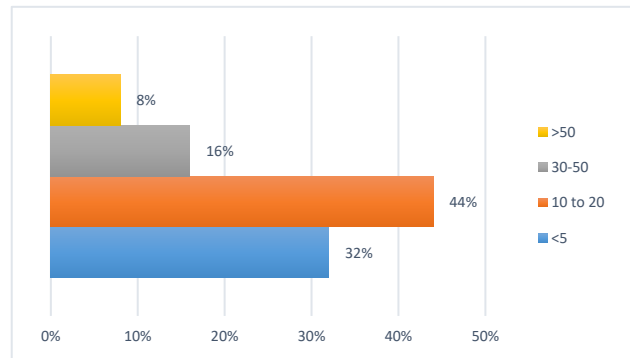


Figure 4: Percentage of patients presenting with hyperpigmentation of intimate sensitive areas such as armpits, groin, inframammary & natal cleft.

In terms of hydrating power of Pigmentbio Sensitive areas as compared to the products, 54% of the dermatologists opined as “good”, 42% dermatologists opined as “excellent”, 4% dermatologists opined as “fair” whereas none of them opined as “poor” (Table 1). For cosmetic acceptability of Pigmentbio Sensitive areas for frictional

and intimate areas, 57% of the dermatologists opined it as “excellent”, 39% dermatologists opined as “good”, 3% dermatologists opined as “fair” whereas only 1% dermatologists opined as “poor” (Table 1). 54% of the dermatologists found the safety of Pigmentbio Sensitive areas on intimate areas as “excellent”, 45% dermatologists found it as “good”, 1% dermatologists found it as “fair” & none of them found it as “poor” (Table 1). Also 96% of the dermatologists did not find any safety issue with Pigmentbio Sensitive areas.

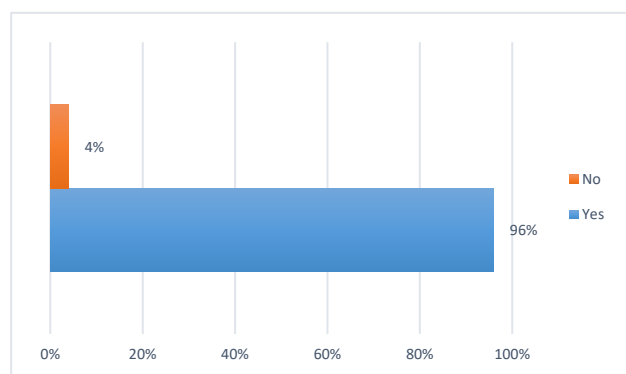


Figure 5: Percentage of dermatologists recommending Pigmentbio Sensitive areas for intimate & high friction areas.

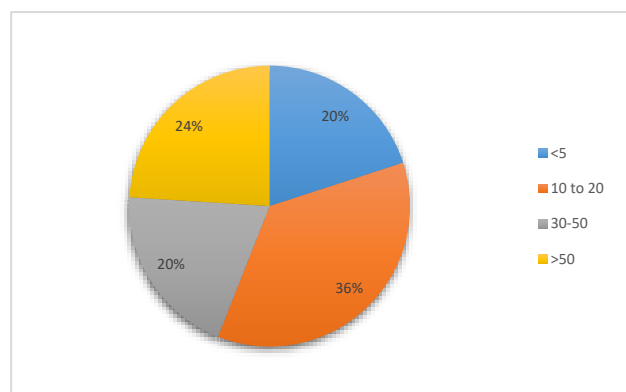


Figure 6: Percentage of patients with hyperpigmented skin in intimate & high friction areas recommended Pigmentbio Sensitive areas by dermatologists.

DISCUSSION

This questionnaire-based opinion study aimed to gather insightful data on the epidemiology of hyperpigmentation in intimate, high-friction areas of the skin among the Indian population. Additionally, the study explored the potential role of Pigmentbio Sensitive areas as a supportive care solution for this condition. The term "frictional dermatoses" is a broad category that encompasses a variety of conditions, including but not limited to frictional dermatitis, frictional melanosis, frictional pigmentary dermatoses, and various other named conditions. These conditions can often be difficult to diagnose and differentiate from one another, leading to confusion in the

medical community. Despite their differences, all of these conditions share a common link: they are caused or worsened by repetitive friction or pressure on the skin. Recognizing the signs and symptoms of each of these conditions is crucial for accurate diagnosis and appropriate treatment.¹⁷

When there is an abundance of moisture and continuous rubbing occurring between the skin surfaces found in flexures and intertriginous areas, it leads to increased moisture retention. This, in turn, further amplifies the coefficient of friction.¹⁸

The incorporation of *Laminaria ochroleuca* extracts into various cosmetic products such as makeup, cleansers, and moisturizers is becoming increasingly popular.¹⁹ This extract is widely known for its natural skin-soothing properties, making it a common ingredient in many skincare products today. *Laminaria ochroleuca* acts as both an anti-inflammatory agent that helps soothe skin irritations and boosts the immune response of the skin. Furthermore, it provides DNA protection by safeguarding the skin against damage caused by UV rays.²⁰ Glabridin, found predominantly in the hydrophobic fraction of licorice extract, is a key ingredient known for its impact on skin. Glabridin exhibits dual inhibitory effects, affecting both melanogenesis and inflammation.²¹

Andrographolide (AG), a naturally occurring bioactive compound derived from the medicinal plant *Andrographis paniculata*, has been observed to have significant effects in restoring skin barrier functions and reducing inflammation. In studies conducted on HaCaT cells stimulated with LPS or TNF- α /IFN- γ , AG demonstrated the ability to inhibit NF- κ B and c-Fos activation, while also modulating the expressions of filaggrin, involucrin, and loricrin. These findings suggest that AG holds potential as a therapeutic agent for the treatment of inflammatory skin diseases.²² The majority of dermatologists who participated in this study rated tolerability and safety of Pigmentbio Sensitive areas as "excellent" to "good". This was measured against a variety of criteria, including tolerability after waxing and shaving the bikini line, soothing effect after mechanical erythema from taking off tight clothing, hydrating power when compared to other products, cosmetic acceptability for frictional and intimate areas, and safety on intimate areas.

Limitations

Current study had some limitations. Firstly, although all efforts were made to gather the responses from dermatologists all over India, the selection of participants was performed by convenience method of sampling. Secondly, the sample size was small. In view of these limitations, care needs to be taken while inferring the results of this study. Future controlled trials will define the clinical potential and position of Pigmentbio Sensitive regions in a holistic management strategy for hyperpigmentation in intimate, high friction areas of skin.

CONCLUSION

In conclusion, the study demonstrated that according to dermatologists across India, hyperpigmentation in intimate, high friction areas of skin particularly armpits, inner thighs, elbows, knees, groin is a significant dermatological problem found in the population. It was demonstrated that Pigmentbio Sensitive areas was an excellent cosmeceutical product with good tolerance and safety, particularly in intimate, high friction areas.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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