

Original Research Article

A real-world data analysis on the usage of paraphenylenediamine and ammonia free hair dye

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ABSTRACT

Background: Dyeing of hair for various reasons is a common practice across a broad age group. Most hair dyes available in the market contain para-phenylenediamine (PPD) and/or ammonia, which are proven skin and scalp irritants. A quest for better tolerable hair dyes has led to emergence of toluene-2, 5-diamine sulfate (TDS) and monoethanolamine (MEA), as a substitute to PPD and ammonia, respectively.

Methods: This retrospective study was conducted on 35 participants from four centers across India to evaluate the efficacy, and tolerance of ammonia-free and PPD-free permanent hair dye.

Results: A PPD-free and ammonia-free cream-based hair dye showed promising results. The color uptake following 35 minutes of application was 100% in 54.2% of the participants. The color retention was more than 95% in 74.3% participants after 8-10 shampoo washes. The adverse effects were noted to be markedly less with only a few cases experiencing itching. The participants' feedback obtained showed a conclusively high satisfaction rate. The Physicians' assessment of efficacy and safety recorded favorable scores.

Conclusions: A TDS and MEA based cream hair color can be an effective and safe alternative to PPD and ammonia-based hair dye.

Keywords: Hair dye, PPD, Ammonia, TDS

INTRODUCTION

Permanent hair dyeing is the most common anti-aging procedure practiced by men and women to cover gray hair. In the present era, hair color reflects youthfulness and attractiveness as evident from the rising number of hair-dyed people. However, this is also associated with a steep increase in the number of cases of hair dye allergy. It is a known fact that hair care products are a milieu of potentially hazardous chemicals that may elicit

immediate-type hypersensitivity, like anaphylaxis or respiratory symptoms.^{1,2}

Many traditional permanent hair dyes contain PPD, a dye precursor that is often responsible for causing allergic contact dermatitis. Commonly seen side effects with PPD are flushing, dryness, rash, pruritus, epiphora etc.^{1,3} Thus; alternatives to PPD in hair dyes are highly required. TDS has recently taken the place of PPD in permanent and semi-permanent hair coloring products.^{4,5}

Another important chemical that is also an irritant is ammonia. The chemical reactions taking place in products like permanent hair dyes lead to release of ammonia, exposure to which may cause airway inflammation or severe irritation of the nose and throat, if inhaled.⁶ Thus, instead of ammonia, alternative bases should be used in hair coloring formulations. MEA is one of the more promising bases that can be used in hair coloring formulations as a substitute to ammonia, which contains less odor and may be less irritating.^{1,7}

Limited literature is available on PPD-free and ammonia-free hair dyes. The objective of our study is to evaluate the safety and effectiveness of cream-based hair dye, which is free from PPD and ammonia and instead contains TDS and MEA, as an alternative.

METHODS

This is a retrospective real-world analysis of data from 35 patients who have used PPD-free and ammonia-free cream-based hair dye. This hair dye contains TDS and MEA as a substitute of PPD and ammonia, respectively. The total duration of study was from May-22 to March-23. Total four centers of dermatology outpatient departments across India (Command hospital, Kolkata; Omni hospital, Hyderabad; BSD hospital, Karnal and Sagar hospital, Bangalore.) were selected and a data collection form was provided to them to collect the data. Data of patients above 18 years of age who were prescribed TDS and MEA based hair dye for grey hair were included in the analysis. Pregnant or lactating women were excluded from analysis. Data of demographic profile, past medical history, history of previous hair color and hair color allergies from different hair dyes, were acquired from their medical database. The patients were treated with a hair dye containing TDS and MEA after performing an open patch test. The data of post color evaluation i.e., color uptake and color retention were collected. Color uptake after washing the hair dye was assessed on the next day of 1st visit, telephonically. Additionally, color retention was assessed after one month, on the next visit. The doctors recommended the patients to use the shampoo twice or thrice a week, i.e., total 8-12 shampoo washes without repeating the hair color in the one-month period. The treatment response was also evaluated at the end of one month based on 'physician global assessment' of safety and efficacy on a scale of 0-10. Patient's level of satisfaction was also recorded. Quantitative data was expressed as mean and standard deviation, whereas categorical data was expressed as numbers and percentages.

RESULTS

Thirty-five patients were enrolled in the study, of the age range 25 to 60 years. The cohort composed of 60% females and 40% males, with the average age of 42.4±8.31 years. The age of first self-detection of graying hair ranged from 20 to 44 years. Out of 35, 85% of the

participants exhibited worry and low confidence due to their gray hair. The demographic details of the patients are mentioned below in Table 1.

Table 1: Demographic details of the patients involved in the study, (n=35).

Parameters	N	Percentages (%)
Age (years)		
18-30	3	8.57
31-40	13	37.14
41-50	12	34.28
>50	7	20
Gender		
Male	14	40
Female	21	60
Habitation		
Urban	26	74.28
Rural	9	25.71
Presence of co-morbidity		
Absent	22	62.85
Present	13	37.14
Diabetes	4	30.76
Hypertension	2	15.38
Hypothyroidism	4	30.76
Diabetes + hypertension	2	15.38
Asthma	1	7.69
Past skin allergies		
No	29	82.85
Yes	6	17.14

Past history of usage of different hair dyes

The mean age at which the participants started using hair dyes was around 29±6.25 years. The 68.5% of the patients had used different hair dyes in the past. The most common reason admitted behind the usage of hair dye was to cover gray hair (38.5%) (Figure 1). Of the total participants, 84.8% of the participants dyed their hair once a month, whereas the 15.2% dyed their hair twice a month. Thirty percent of the participants experienced adverse events after using different hair colors previously. These adverse reactions included contact dermatitis, non-specific itching and skin rash not classifiable as contact dermatitis (Figure 2). Only 48.5% of the participants mentioned that they always read the instruction manual/product pack before using and were aware of the type and contents of the dye. While 28.5% of the participants admitted reading, the product instruction manual/ product pack sometimes only and rest of the participants never referred to the product information.

Evaluation for tolerability and efficacy of a hair dye containing TDS and MEA instead of PPD and ammonia

The color uptake following 35 minutes of application of PPD and ammonia free hair dye was 100% in 54.2% of

the participants (Figure 3). The color retention after 8-10 shampoo washes, as observed after one month, was 96-100% in 74.3% of the participants and 75-95% in rest of the participants (Figure 4). Feedback was requested from all the participants, post hair color, regarding the level of satisfaction on a scale of '1-10'. Of the total participants, 22% rated the satisfaction level as '7', 46.7% participants rated as '8', 28.5% rated as '9' and 2.8% rated as '10'. Total seven out of the 35 participants experienced a mild adverse reaction, in the form of itching. The tolerability and efficacy of this hair dye was rated by physicians on a scale of '1-10'. It has shown good tolerability and efficacy as per physicians' global assessment scale (Figure 5).

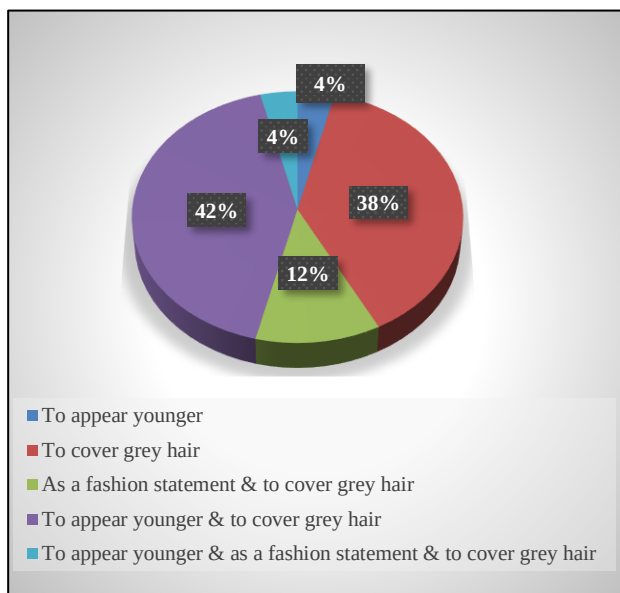


Figure 1: Past history of hair dye usage-reasons to use hair dye by the patients.

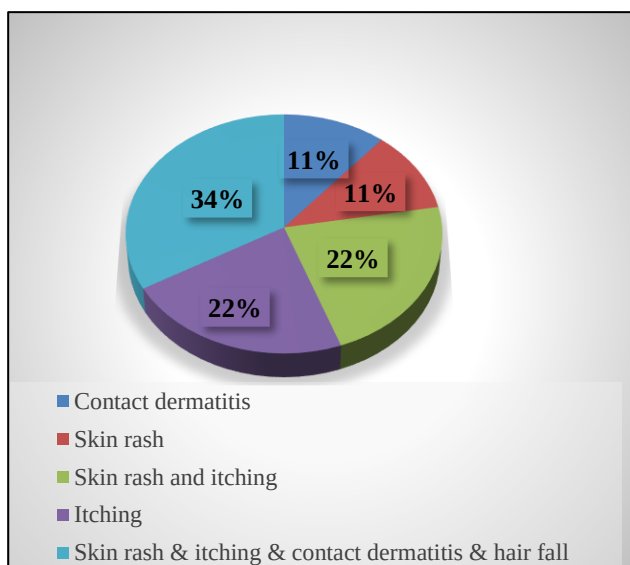


Figure 2: Past history of adverse reactions to the usage of hair dye.

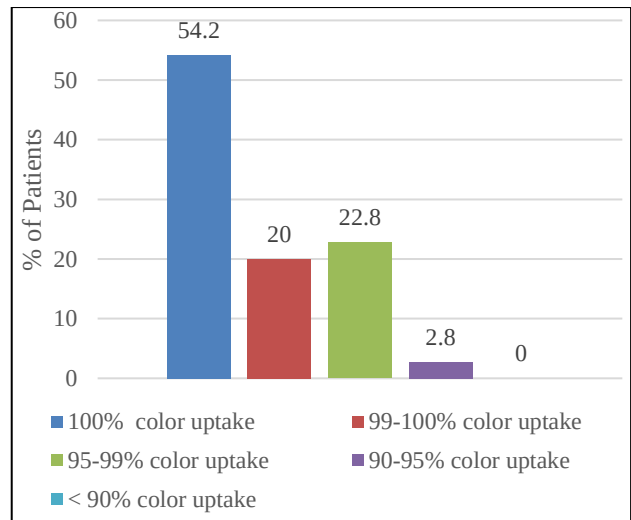


Figure 3: Proportion of the patients with percentage color uptake following 35 minutes of application of PPD and ammonia free hair dye.

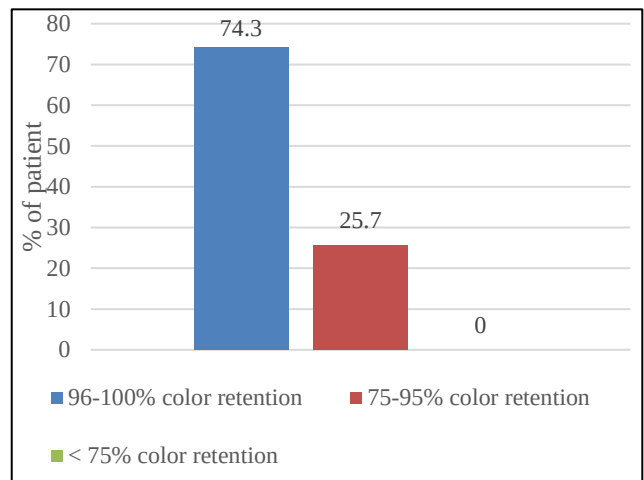


Figure 4: Proportion of the patients with percentage color retention following 8-10 shampoo washes.

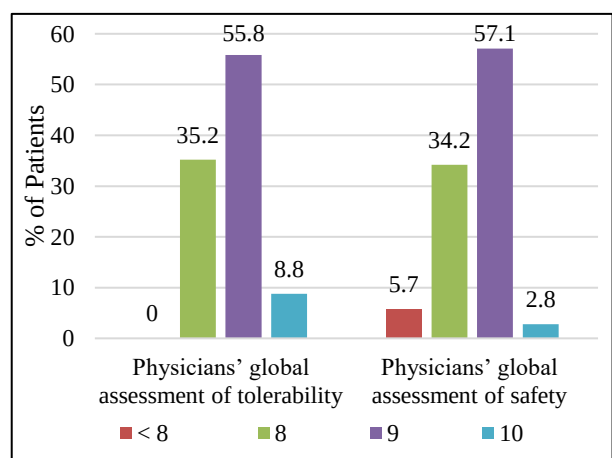


Figure 5: Physicians' global assessment scale for tolerability and efficacy on scale of 0 (least) to 10 (max).

DISCUSSION

Graying of the hair is a physiological change and forms a vital part of the aging process in humans. Although the primary aim of the hair dye is to conceal the grays, its usage has significantly risen owing to society and fashion norms. It is a usual practice for women to color their hair; with estimates ranging from 50 to 80% of women having done it at some point of their lives.⁸ A plethora of commercially available and marketed products exist with easy accessibility. Permanent hair dye is most commonly used nowadays. However, what is lacking is the awareness regarding the wide range of constituents of hair colorants and adverse reactions that accompany them. Most hair dying products contain PPD, a well-known skin sensitizer. PPD may result in allergic contact dermatitis, which is a concerning issue for both consumers and the cosmetic industry.⁴ The adverse reactions reported with PPD-based dyes are contact dermatitis, itching of scalp, hair loss and breakage, which were also reported by the participants in our study as a part of past history.⁹ Thus, alternatives to PPD in hair dyes are practically essential.

The mean age of our cohort is approximately 10 years older than a study by Patel et al but nearly equal to a study by Gupta et al.^{10,11} In our study, 48.6% of the participants had read the instructions on the package which is concordant with few previous studies.¹¹ An assessment of consumer's knowledge, attitude and practices regarding hair dyes revealed an urgent need for increase in awareness of the adverse effects.¹⁰ It is considered desirable to print directions of usage and safety instructions on the packaging.

TDS has recently taken the place of PPD in permanent and demi-permanent hair coloring products.^{6,7} Scheman et al evaluated, by patch test, the frequency of allergy to PPD-based dyes and concluded that 57% of the patients, who tested positive for PPD, will likely tolerate paratoluenediamine sulfate (PTDS)-based dyes better. The study also states that all patients who tested positive for PPD and negative for PTDS, tolerated PTDS-based dyes well and are likely to be non-allergic to other components of the dye.⁵ Draelos et al conducted a study on an ammonia-free and PPD-free permanent hair dye and observed no tolerability or safety issues during the study.¹ Similarly, in our study only seven of the 35 participants experienced itching after application of hair dye and no other serious adverse effects were observed.

The permanent hair dyes can cause irritant contact dermatitis as they commonly contain ammonia.¹ MEA is one of the more promising bases that can be used in hair coloring formulations as an alternative to ammonia.⁷ MEA is required to maintain optimum alkaline pH for the reaction. Thus, products containing MEA can be used ahead of ammonium hydroxide, as they are suitable for maintenance of similar shades or to darken hair. It also does not oxidize the natural hair pigment, melanin.¹² In

our study, color uptake after 35 mins of application and color retention after one month of hair dye was found to be satisfactory. The patients' satisfaction and physicians' assessment scores obtained in the current study reinforced the feasibility, tolerability and effectiveness of PPD and ammonia free hair dye.

Limitation

As this study is a real world study, randomization was not done. Sample size of the study was less. Therefore, to strengthen the evidence larger randomized studies are required.

CONCLUSION

PPD is the most common ingredient of permanent and demi-permanent hair dyes associated with contact dermatitis. Potent substitutes of PPD like TDS in the composition of hair dyes have shown promising outcomes. The current TDS- and MEA-based hair dye, evaluated in this study, can be an effective alternative to PPD and ammonia-based hair dye, with lesser side effects.

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Ethical approval: Not required

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