Severe Cutaneous adverse reactions Caused by Black Henna in Morocco - Series cases report

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ABSTRACT: Traditional henna rarely causes adverse events. However, to obtain a black color, many ingredients are mixed with this plant such as paraphenylene diamine and solvents. The aim of our study is to describe severe cutaneous adverse events caused by black henna collected at the Moroccan Pharmacovigilance Centre. **Materials and Methods:** We analyzed the coetaneous adverse reactions associated with the use of black henna, collected during 2012 in Morocco. The severity ofreactions wasan inclusion criteria. We analyzed the characteristics of patients, adverse reactions and type of exposure. **Results:** Nine serious cutaneous cases were collected, which represent 6.42% of all adverse reactions related to cosmetics products. Hospitalization and sequelae were the reason of seriousness. Outcomes were favorable for-all cases. **Conclusion:** the severity of those cases showed the importance of the pharmacovigilance of cosmetics products.

KEYWORDS: black henna, pharmacovigilance, cutaneous adverse reaction.

1 INTRODUCTION

Natural traditional products are frequently used as cosmetics since the time of *pharaouns*, continues over the years, particularly in Mediterranean region regarding cultural, traditional, religious and the availability of natural products. Currently, standards of beauty have changed and the utilization of these products has undergone remarkable changes by mixing them with many hazardous ingredients. Moroccan women use a lot of traditional cosmetics to embellish themselves. *Henna* is one in palette of various natural products which refers in cosmetic to the dye prepared from the plant "lawsoniainermis". It is used to dye skin like tattoo, to dye hair and nails. Traditional henna, which colors range between orange, red or brown, rarely causes adverse reactions [1]. However, to obtain black color, many ingredients are mixed with this plant mainly the *Para-phenylenediamine PPD* and solvents. The aim of this study is to describe and discuss severe cutaneous adverse reactions (ARs) caused by black henna collected at the Moroccan Pharmacovigilance Centre.

2 PATIENTS AND METHODS

Study design: It is a retrospective case study of the Cosmetic adverse reactions database regarding to ARs related to black henna tattoo received during 2013 in Moroccan pharmacovigilance centre.

Inclusion criteria: Were included all serious cutaneous adverse reactions related to the use of black henna. We used the OMS classification of seriousness [2], the Who art terminology [3] was used to extract the skin ARs from a database.

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Two patients consent to use the photographs for publication. We analyzed the characteristics of patients, adverse reactions and evolution.

3 RESULTS

Nine serious cutaneous ARs related to the use of black henna tattoo were collected at the CAPM during 2013. It represents 26.4% of all cases related to black henna, and 6.42% of Moroccan database adverse cosmetic reactions. All patients were female. Seven of them are adults and two children under 10 years. Six patients have used the black traditional henna and three of them have used the industrial preparation. Clinical signs developed few days [2-7 days] after the use of black henna were maculapapular dermatitis in five cases [Figure 1], bullous dermatitis in four cases [Figure 2] among them one case has presented necrosis, two patients has presented angioneurotic oedema and one patient has presented erysipelas secondary to feet dermatitis. Three patients were hospitalized and the patch test to PPD positive appeared. All patients required medical treatment according to their symptoms and fortunately, they recovered. However, six of them have kept sequelae, keloid scars in two cases, hypo and hyper pigmentation in four cases.

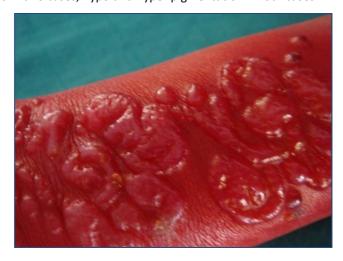


Figure 1: Patient's forearm maculopapular dermatitis



Figure 2: Patient's forearm bullous dermatitis

4 DISCUSSION

Despite the wide spread use of natural henna, specially, in countries where henna art is traditionally practiced, reports of allergic contact dermatitis to natural henna are very rare in the literature. Recently Para Phenylene diamine (PPD) has been mixed with natural henna to give an ebony color (black henna) and to have persistent tattoo. The adverse reaction reported

cannot be attributed to henna which used for cosmetic purposes and also used in Traditional medicine for the treatment of some skin diseases, as an anti-inflammatory, antipyretic and analgesic agent **[4,5].** In Morocco, woman use two type of product named TAKAOUT: Takaout beldia indicates a non-toxic vegetable product extracted from the gallnut of Tamaris Orientalis. This non-toxic substance is highly appreciated by women for its hair dyeing properties. Its rarefaction resulted in the use of paraphenylene diamine as substitute under the name of *Takaout Erroumia* **[Figure 3].**

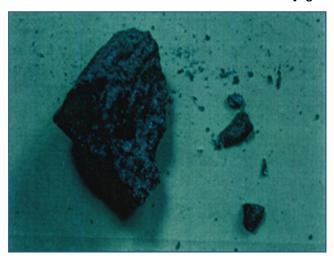


Figure 3: Takaout Erroumia (PPD)

Black henna is not, and never was, intended for use as tattoo dye. Actually, PPD is a component of some hair dyes. It is well known that PPD cannot be in contact with skin, its dermal absorption can lead to cutaneous and systemic effects. Acute allergic contact dermatitis, eczema, chemical burn, acute renal failure, severe oedema, abdominal pain and vomiting as adverse reactions associated with the use of henna containing PPD (black henna) are well documented in the literature [6].

The reported adverse reactions in our series are Known and well described related to the PPD. One of our patients presented an erysipelas, that defined as bacterial skin infection involving the upper dermis that characteristically extends into the superficial cutaneous lymphatics, it was not directly attributable to PPD but secondary of no treated feet rash that constitute the gateway to the streptococcus bacteria usually responsible of erysipelas.

The causality assessment performed to OMS method [7] was certain for three patients and probable for six patients; the diagnostic of PPD hyper sensibility requires the confirmation by the patch test. Unfortunately the patch test has not been performed for seven patients. Furthermore, The Adverse reactions were more severe with the traditional henna mixed with PPD compared to that related to the industrial preparation. This may be related to the content of PPD which is fixed and lowest in the industrial preparations. Researchers found the level of PPD in Traditional Black henna tattoos was much higher than that found in hair color. However, the concentration of PPD in industrial preparation was higher than the permitted concentration in hair dye products established by the European Union, which is 6%. PPD is still used with henna even if importation and sale in Morocco are regulatory for other uses. PPD is not the only ingredient used to make black henna. There are also other chemical dyes in use, but none of them stains as fast or as black, or lasts as long as PPD. Three of our patients have used traditional henna mixed with PPD and solvent, which increased the PPD cutaneous absorption leading to enhance its toxicity.

In order to ensure the safety of Moroccan consumers, the Moroccan pharmacovigilance center has organized during 2013 and 2014 the awareness campaigns through the media to warn the public against the risks of using black henna [Figure 4]. During 2015, the number of reported cases related to the black henna use has dropped significantly and we have no serious cases reported.



Figure 4: Awareness articles in Moroccan press

5 CONCLUSION

The severity and the management of these cases showed the importance of the pharmacovigilance of cosmetics products in Morocco. The lack of surveillance of the cosmetic market and the large use of natural product by the population requires to set up an adverse event cosmetic surveillance among patients in the national health system following other vigilances systems.

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