

Original Article

Clinical audit on monitoring of clinical and laboratory parameters in patient of acne taking oral isotretinoin

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Abstract

Objective The aims of this study were to evaluate whether oral retinoids (isotretinoin) prescription in female patients of acne is following standard guidelines/ set protocol or not.

Methods This clinical audit involved 50 female patients of child bearing age, with acne taking oral isotretinoin, who presented in the outpatient department of Mayo hospital Lahore. Patients were diagnosed clinically by the presence of open and closed comedones, papules, pustules, nodules involving the seborrhoeic sites. An informed consent was taken after which they were asked the relevant questions from the questionnaire. The standard was that 100% of patients should be counseled about the key three components (1) Liver function tests and fasting lipid profile monitoring at baseline, (2) Counseling for contraception and (3) Counseling for depressive symptoms.

Results Out of 50 patients enrolled in our study, all (100%) were females, mean age being 23.32. 49 (98%) of our patients were being counseled for contraception, while in 37 (70%) of the patients, routine monitoring for liver function tests and fasting lipid profile was being carried out. 15 (37%) of our patients were being counseled for depressive symptoms.

Conclusion Prescribing oral isotretinoin requires certain prerequisites that are being fulfilled. However, more focused perspective should be followed in this regard.

Key words

Clinical audit; Acne; Isotretinoin.

Introduction

Acne is a chronic skin condition involving the inflammation of pilosebaceous unit and having a significant psychosocial impact on quality of life. The commonly affected age group is the adolescents, but adults and children can also get

affected. A number of factors like polycystic ovarian disease, obesity, smoking and dairy products have been found to aggravate the condition.¹ The severity of acne varies among races. Asians and Africans tend to develop severe acne but mild acne is more common in the white population.²

Acne can present with papules, pustules, nodules, open and closed comedones and the disease severity can range from mild to moderate and severe. The treatment varies

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according to the type of acne, ranging from topical to systemic therapy. For severe nodular acne treatment, oral isotretinoin is recommended.³ However, there are certain important prerequisites that must be carried out before prescribing oral retinoids as there are a number of side effects that this drug can produce, thus having a significant impact on quality of life of the patient.

Retinoids are vitamin A derivatives that are available in both topical and systemic forms and are being used for the treatment of a wide range of dermatological disorders. They are classified into four generations Non-aromatic retinoids, Mono-aromatic retinoids, Poly-aromatic retinoids and Trifarotene.

Oral retinoids include: Acitretin, Alitretinoin, Bexarotene, Isotretinoin, Vitamin A (retinol). Amongst these, isotretinoin is indicated in the treatment of rosacea, hidradenitis suppurative and scalp folliculitis.⁴ It is also indicated in acne conglobata, early mycosis fungoides, Sezary syndrome, along with other dermatological conditions. The indication of isotretinoin in acne vulgaris is severe recalcitrant nodular acne not responding to other treatments. Retinoids exert their effect by binding to, and activating the specific receptors. There are two types of receptors. 1) retinoid acid receptor (RAR). 2) retinoid X receptor (RXR). These are involved in the regulation of cellular proliferation, differentiation and apoptosis as well as in immunomodulation and activation of tumor suppressor genes.

Isotretinoin can exert a number of side effects ranging from dryness of skin to severe birth defects. There can be dryness of eyes, lips, mouth and nasal mucosa. There are increased chances of sunburns because of increased sensitivity to sun. There can be worsening of acne in the beginning of treatment that is usually temporary. In addition, there may be liver

damage and disturbance of lipid profile. Thinning of hair, night blindness and muscle aches may occur. There have been reports of depression and inflammatory bowel disease with the use of isotretinoin.

Other very important and major side effects of oral retinoids are still-birth, miscarriage and severe birth defects that may occur if a patient takes isotretinoin during her pregnancy.

This wide range of adverse effects of oral retinoids suggest that prescribing oral retinoids needs careful patient monitoring for certain clinical and laboratory parameters.

One of the methods to monitor and improve patient care in this aspect is the clinical audit. Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Here we select the particular aspect of management that we want to evaluate and compare it to the standard protocol. This helps in stratification of the management protocols, helping a better outcome ahead. There are three main types of clinical audit: Structure, Process, Outcome.⁵

This clinical audit was carried out to see whether the prescription of oral retinoids meets the standard protocols or not as systemic retinoids have a range of adverse effects and caution is required when taken systemically.

Material and Methods

This study was carried out in the department of dermatology, Mayo hospital Lahore. The collection of data was made in a prospective way. Female patients of child bearing age, presenting with acne and taking oral isotretinoin were included in the study. Males were excluded. Informed consent was taken and

patient was asked the questions included in the questionnaire. The questions were about: Counseling for contraception, counseling for depressive symptoms, Routine monitoring of LFTs, serum cholesterol and triglycerides at baseline and again until response to treatment is established.

The data was entered and analyzed in SPSS version 17. Qualitative variables like counselling were described in terms of frequencies and percentages while quantitative variables like age and marital status were described in terms of mean and standard deviation.

Results

This study included 50 female patients of child bearing age. Minimum and maximum ages were 17 and 39 years respectively. Mean age of the sample was 23.32. Males were excluded. All of the patients were having moderate to severe acne with scarring, and were on oral isotretinoin for treatment of their skin condition. Out of these, 7 (14%) patients were married while 43(86%) patients were unmarried (**Figure 1**).

The assessment for clinical and laboratory parameters in these patients was as follows: In 49 out of 50 (98%) patients, appropriate counselling for contraception while taking systemic retinoids was done, while 1 (2%) patient was not counselled in this regard (**Figure 2**). In 35 (70%) out of 50 patients, counselling for depressive symptoms was done, while the remaining 15 (30%) were not aware of this (**Figure 3**).

37 (74%) patients were advised to have their LFTs and fasting lipid profile done, before starting treatment, while 13 (26%) were not advised. Similarly 27 (54%) patients were advised the same investigations at follow up (including some patients in whom baseline testing was not done), while 23 (46%) were not.

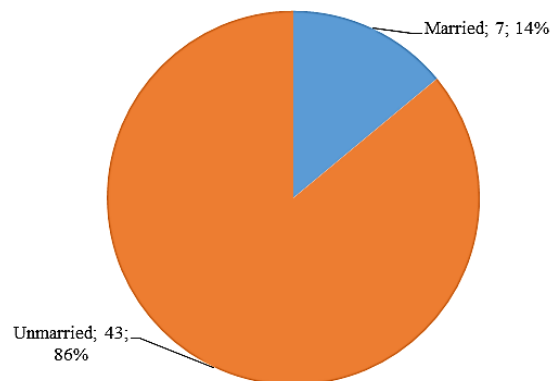


Figure 1 Marital status.

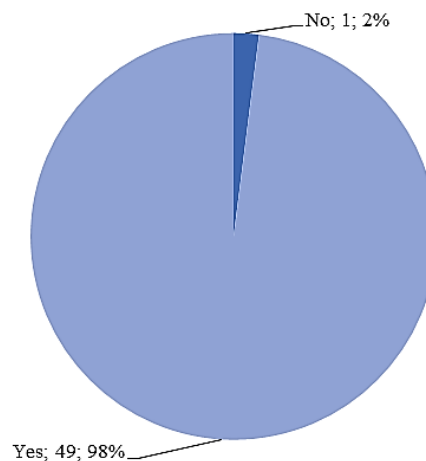


Figure 2 Contraception counseling.

Discussion

Acne is a chronic inflammatory skin disease of pilosebaceous unit and if not treated promptly, causes not only physical effects like scarring and post inflammatory hyperpigmentation but can produce significant psychiatric impacts on the patient⁶.

Amongst the various treatment options, systemic retinoids are also included, that are usually prescribed for moderate to severe acne, especially where scarring is also seen as a sequelae. However, systemic retinoids intake has certain prerequisites that must be fulfilled to prevent adverse outcome. The purpose of this clinical audit was to check whether these prerequisites were fulfilled or not.

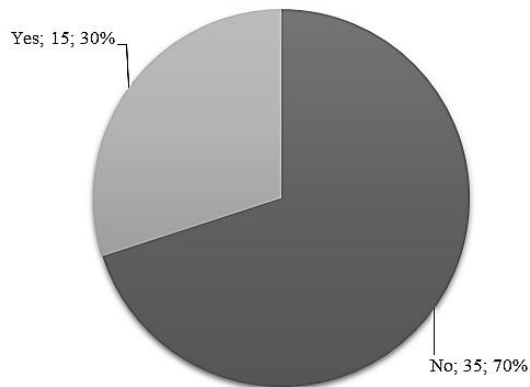


Figure 3 Depression counseling.

Our study included 50 female patients with age ranging from 17 to 39 years. Our study results were comparable with a study conducted by Alshehri *et al.* in 2023 which showed that acne is not restricted to adolescents but can occur at various ages.⁶ In the current study, 35 patients had moderate acne with scarring and 15 had severe acne with scarring. These patients were already taking oral isotretinoin according to their weight. Seven out of them were married while 43 were unmarried.

In a cross-sectional study on awareness of isotretinoin use and pregnancy prevention program, in Saudia Arabia, conducted by Ibrahim *et al.* it was seen that although a vast majority of participants were aware of isotretinoin's teratogenic effect, many of them had no information about the PPP (pregnancy prevention program).⁷ However, in our study 49.98% of our patients were counseled for contraception regarding oral retinoids.

In another study in Netherland, isotretinoin exposure during pregnancy was studied by Zomerdijk I M and others, and it was seen that despite the implementation of PPP, there was still an exposure of pregnant ladies to isotretinoin and consequently there were adverse neonatal and fetal outcomes.⁸ So compliance to this aspect is particularly important, as was seen in 98 percent of our patients.

According to the American Academy of Dermatology Association guidelines, routine monitoring of liver function tests, serum cholesterol and triglycerides at baseline and again until response to treatment is established, is recommended.³ There is no need for monthly monitoring, however patients with higher body weight are more prone to have deranged labs and should be monitored frequently. Out of our 50 patients, 37 patients were advised for LFTs and fasting lipid profile at baseline. There was no history of jaundice and these patients were not obese, so monthly monitoring was not carried out.

Isotretinoin potential to affect the patient's mental health is one of the most serious adverse effects.⁶

In a retrospective data collection study by Ludwig R J and Kridin K, psychiatric outcomes in two groups were compared. It was seen that the risk of depression was low in the isotretinoin group, compared with the antibiotic group. However the risk of suicidal ideation was high in the isotretinoin group, compared to the other group.⁹ 30 percent of our patients were being counselled for appearance of psychiatric symptoms. This factor should be added in the list of frequently asked side effects of oral isotretinoin. Even wider screening using a validated questionnaire may be useful. The Beck questionnaire, the Baer HANDS questionnaire, or the six-question screening tool promoted in a recent British Medical Journal review may be helpful.¹⁰

Conclusion

Prescribing oral isotretinoin requires certain prerequisites that are being fulfilled. Although this clinical audit revealed that the vast majority of patients were aware of isotretinoin effects more focused perspective should be pursued in

this regard. Overall this study highlights the importance of effective counselling in warranting safe and effective use of isotretinoin.

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