

Isotretinoin therapy: Any need for laboratory assessment?

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Summary

Background: Recently studies showed the no need for laboratory follow up of patients on isotretinoin therapy. The aim of this study is to assess this issue.

Patients and methods: A retrospective study on 400 patients was performed to analyze the laboratory data before and after isotretinoin therapy of acne vulgaris patients. All patients received isotretinoin at a dose of 1mg/kg for 20 weeks.

Results: AST was elevated in 25/400 (6.25%), ALT was elevated in 10/400 (2.5%). Cholesterol was elevated in 55/400 (13.75%). Triglycerides were elevated in 20/400 (5%).

Conclusion: This study supports the previous evidence for the no need for performing laboratory investigations for patients on isotretinoin therapy.

Keywords: Acne vulgaris, Isotretinoin

Résumé

Introduction: Récemment, des études avaient démontré le besoin d'un examen laboratoire de controles à longue terme des patients qui prennent la thérapie d'insotretinoin. Le but de cette étude est d'valuer cette question.

Patients et méthodes: Une étude retrospective chez 400 patients a été effectuée afin d'analyser les données laboratoires avant et après la thérapie d'insotretinoin des patients acné vulgarise. Tous les patients avaient pris la thérapie d'insotretinoin de la dose de 1mg/kg pendant 20 semaines.

Résultats: AST était élevé dans 25/400 soit 6,25% ALT était élevé dans 10/400 soit 2,5%. Cholestérol était élevé dans 55/400 soit 13,75%. Triglycerides étaient élevé dans 20/400 soit 5%.

Conclusion: Cette étude soutient des preuves précédentes que ce n'est pas nécessaire d'effectuer des inqêtes laboratoires pour des patients sur la thérapie d'isotrétinoin.

Introduction

Isotretinoin (a synthetic retinoid, roaccutane) had proved its efficacy and safety since its introduction in 1982.^(1,2) The drug works in many different mechanisms against Acne Vulgaris.⁽³⁾ Since its introduction, it had been suggested to follow the patients liver functions and lipid profile.⁽⁴⁾ Recent studies suggest the no need for such a follow-up.⁽⁵⁻⁷⁾ Our aim of this study is to assess the effect

of isotretinoin on some aspects of liver functions, and lipid profile for patients treated for acne vulgaris in our locality. Previous published works have used AST, ALT as indicators of liver functions.

Patients and methods

This is a retrospective study in which the laboratory data of 400 patients on isotretinoin therapy were analyzed. The data of 400 patients were analyzed at six weeks after initiation of therapy. There were 325 females (81.25%) and 75 males (18.75%). The male to female ratio was 1:4.3. The mean age for the study group 21.3 +/- 4.4 years (range: 14-

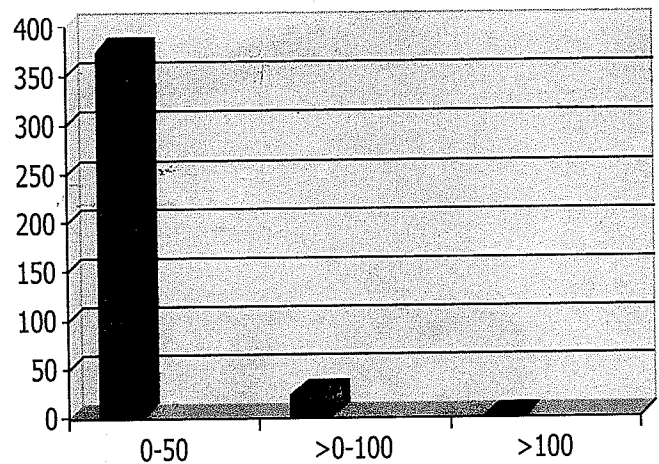


Fig. 1 AST level at 6 weeks

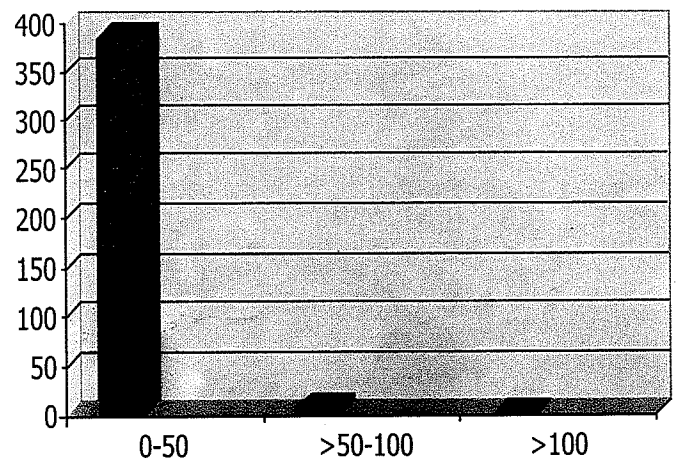


Fig. 2 ALT level at 6 weeks

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48 years). The data included AST, ALT, serum cholesterol, and serum triglycerides. The laboratory data at the start of the course of therapy were compared with the ones after six weeks from the initiation of therapy. The same laboratory data were performed four weeks after the termination of the isotretinoin therapy. The normal values were as follow: AST=0-38 U/L, ALT=0-41U/L, serum cholesterol = 0-200mg/dl (0-6.5mmol/L), serum triglycerides = 0-250 mg/dl (0-2.3 mmol/L). The study period was between June 1998 and June 2003. All patients received the same standard dose of isotretinoin (1 mg/kg) for 20 weeks.

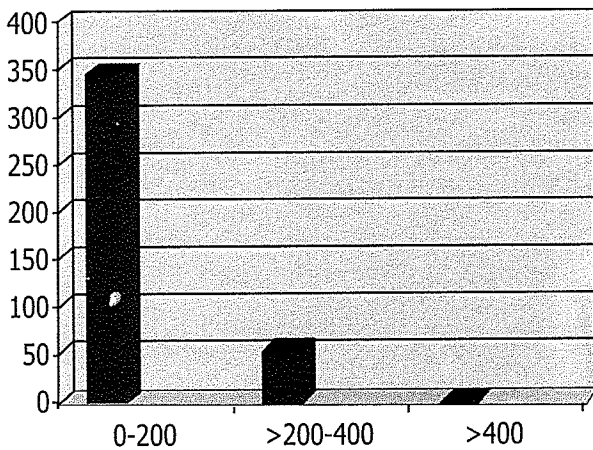


Fig. 3. Cholesterol level at 6 weeks

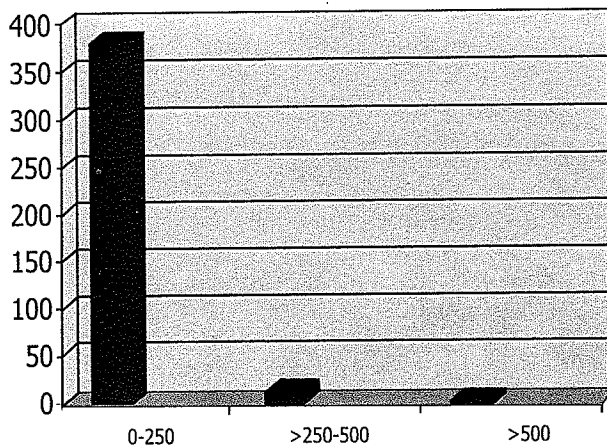


Fig. 4. Triglycerides level at 6 weeks

Results

AST was Normal in 375/400 (93.75%), elevated in 25/400 (6.25%) Figure 1. ALT was normal in 390/400 (97.5%), elevated in 10/400 (2.5%) Figure 2. Cholesterol was normal in 345/400 (86.25%), elevated in 55/400(13.75%). Figure 3. Triglycerides were normal in 380/400 (95%), elevated in 20/400 (5%). Figure 4.

Table 1. Cholesterol and Triglycerides in different studies.

Study	(Patients' no.)	Cholesterol elevation %	Triglycerides elevation %
Barth JH et al	(n=209)	8%	19%
Alcalay J et al	(n=907)	5%	6%
Sadick et al	(n=473)	16%	8.7%
Current study	(n=400)	13.75%	5%

Discussion

Recent studies had been found in the literature to address the issue of the no need for the no need of laboratory follow-up of patients on isotretinoin therapy.⁽⁵⁻⁷⁾ The first study was performed in 1993 by Barth JH et al.⁽⁵⁾ The study was performed on 209 patients only. Minority of patients showed elevation of AST and ALT, while cholesterol and triglycerides were elevated in 8%, 19% respectively. (Table-1) His conclusion was that there appears to be little evidence to support the previously recommended regular biochemical monitoring of liver function and lipid profiles in patients who are treated with isotretinoin for 16 weeks. It would appear prudent to ensure that there is neither liver disease nor hyperlipidaemia prior to the onset of therapy, and to determine the triglyceride response to therapy on one occasion after 4 weeks' treatment. This change in patient management should result in considerable savings both in patient time and in blood collection and analysis. The second study was done 2001 by Alcalay J et al.⁽⁶⁾ The study was done on 907 patients. Liver enzymes were moderately elevated in minority of cases, which returned to normal after discontinuation of isotretinoin. Cholesterol was elevated in 54/903 patients (6%). Triglycerides were elevated in 45/907 patients (5%). (Table-1) The third study by Sadick N. showed that the elevations of AST, ALT, cholesterol, triglycerides were as follows: 0.6%, 16%, and 8.7% respectively.⁽⁷⁾ (Table-1) Our study showed that there was no serious elevations of the laboratory data and that these elevations returned to normal after discontinuation of treatment. Dominguez-Munoz et al showed that even marked elevation of serum lipid levels should not be invariably considered as an aetiological factor for pancreatic disease.⁽⁸⁾ Lestringant et al have stated that significant variations in lipid levels in young and healthy acne patients treated with isotretinoin do not influence the overall risk for cardiovascular disease.⁽⁹⁾ In conclusion our results support the conclusions of the previous studies for the no need of laboratory follow-up for patients on isotretinoin therapy.

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