Effectiveness of Conventional Drug Therapy of Plaque Psoriasis in the Context of Consensus Guidelines: A Prospective Observational Study in 150 Patients

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Background: Evidence for superior outcome by adhering to therapy guidelines is imperative to their acceptance and adaptation for the optimal management of disease variants.

Objective: Comparative study of prospective outcomes in simultaneous consideration of independent variables in groups of 150 patients of plaque psoriasis either treated adhering to or in digression of standard guidelines.

Methods: The psoriasis area severity index (PASI) and the dermatology life quality index (DLQI), prior to and after three months of uninterrupted therapy were examined in treatment groups among 150 patients. Recovery rates of 75% or more in PASI were compared. Independent variables were also examined for their bearing on the outcome.

Results: The vast majority was early onset disease phenotype. All three treatment regimens when administered in adherence to the guidelines yielded significantly superior rates of defined recovery both in PASI and DLQI. Compromise of the therapeutic outcome appeared in high stress profiles, obesity, female sex and alcohol, tobacco or smoking habit.

Conclusion: Conventional drug therapy of plaque psoriasis yields superior outcome by adhering to the consensus guidelines. Psychiatric address to stress must be integral and special considerations for phenotypic/syndromic variants is emphasized for effective therapy of psoriasis.

Keywords: Comparative effectiveness study, DLQI, PASI, Psoriasis, Therapeutic guidelines

INTRODUCTION

Pharmacoepidemiologic investigation of therapy effectiveness can provide pharmacogenomic clues. Potential predictors of response to therapy may be indicated from such studies, which is vital to conceiving individualized approaches to treatment. Prospective recording of the objective response to treatment in suitably defined patient subsets administered similar treatment and assessment is a prudent approach to advancing the pharmacogenomic understanding of psoriasis. Factors capable of aggravating autoimmunity are abnormally expressed in psoriasis, and there is variant susceptibility both of the major histocompatibility complex and T lymphocyte responses. Psoriasis diagnosis relies on clinical criteria due to the non-availability of any valid markers. Clinical manifestations, disease course and response to therapies are very heterogenous in patients of psoriasis, possibly indicative of differences in molecular mechanisms. The association of specific co-morbidities is also increasingly appreciated. Interaction of complex genetic and environmental factor networks is believed to cause overt disease. Foreign antigen dependent mechanisms activating keratinocytes or misdirecting the immune response to dermal autoantigens, is considered trigger the pathogenesis. Non-immune contribution to immune processes also adds complexity to understanding. The altered expression of

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over 1,300 genes is detected in psoriatic lesions, program-
ing for inflammation and phenotypic change in keratinocytes4. Epigenetic mechanisms altering biomolecules and influencing environmental triggers of pathogenesis are also said to be significant in chronic disease and neoplasia.

Individual health and trait, pharmacotoxicologic profiles of drugs and above all pathogenic mechanisms, are fundamental to comprehend for rational therapeutic address. Uncertainty of success, sustainability and failures of conventional psoriasis therapies reveals an oversimplified rationale, largely palliative intent and continued scope for improvement. Newer biological therapies attempt to intervene at specific steps of understood pathophysiology. The current interest is more on treatment that will be very effective in a particular disease profile, instead of those for all psoriasis cases with inconsistent outcomes and toxicity5. Consensus therapy guidelines incorporate opinions from numerous experts into simple generalizations toward standard care delivery in global perspective. Psoriasis with variegated pathology, merits continued re-examination of effectiveness regarding consensus guidelines in diverse patient populations, toward their refinement and evolution. New scientific knowledge may be incorporated through such very endeavors.

The present study focuses on the most prevalent and relatively stable form, plaque psoriasis. Strata of 150 patients based on the extent of body surface afflicted were studied for response to therapy. Therapeutic outcome was measured by the reduction of the psoriasis area severity index (PASI)6. Reference was made to consensus guidelines for psoriasis therapy7,8. After three months of uninterrupted treatment (without reasons to stop), outcomes were compared in patient groups where the therapeutic decision matched the directives of consensus guidelines with that in patients treated in digression from the guidelines. The responses to therapy were also preliminarily analyzed for the influence of independent traits regarding age, sex, body mass index (BMI), etc. An attempt is made to critically appraise therapeutic needs for specific apparent sets of patients toward optimal outcomes from inferences of observations.

MATERIALS AND METHODS

One hundred ninety-two patients with plaque psoriasis of either sex and any age attending the Dermatology outpatient clinic, Sir Sunderlal Hospital Banaras Hindu University, Varanasi, India, were enrolled in the three month observational study. This study is duly approved by institutional review board and the approval number is dean/2008-09/38.

Forty-two of the enrolled patients were excluded through the course of study on notice of frequent noncompliance to therapeutic instructions and/or failure to report in a timely manner for review. The diagnosis of plaque psoriasis was made clinically by the dermatologist. Clinical criteria for diagnosis were the presence of erythematous papular lesions with adherent silvery white scales. Auspitz’s sign was demonstrated in all the cases9. Relevant personal, disease related and health related history was sought in all cases. Demographic information was also collected.

Direct interaction with patients was adopted for assessment of disease and monitoring of prescribed drug therapy. Cases of plaque psoriasis who had not received any treatment in the past 4 weeks were included in study. The nature of study and its objective were explained and written consent was obtained from the patients, with assurance of not revealing identity. Severity of the presenting disease was determined by calculating the percentage of the involved body surface area (BSA)10,11. Location of the lesions was recorded and PASI score calculations were done6.

The ‘Dermatology Life Quality Index (DLQI)’12 was also elicited to evaluate the overall disease impact on quality of life.

Patients receiving no other treatment except for psoriasis were included in the study. The prescribed treatment regimen was analyzed for consistence or otherwise with prescription guidance for the given severity as per Callen et al.7 After three months of therapy the patient’s condition was reassessed in a follow up session. The PASI score and DLQI score were again determined to calculate therapeutic outcomes for both clinical and in regard to quality of life regarding each drug regimen. A 75% improvement in the PASI score was considered as good response13 at the 3 month follow up.

The cases were categorized into two groups, i.e. those prescribed according to the guideline and others who were not prescribed as per the guideline. The rates of achievers of 75% improvement in the PASI score were used for comparison. The terms mild, moderate and severe psoriasis are used subsequent to employed treatment regimens. Less than 5% of body surface area involvement is considered as mild disease. 5~10% of body surface area involvement is considered as moderate disease. More than 10% of body surface area involvement is considered as severe disease.

Mild, moderate and severe categories were considered...