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Vol 74 | Issue 1 | Jan-Feb 2008

CONTENTS

EDITORIAL REPORT - 2007

IJDVL gets into the Science Citation Index Expanded!
Uday Khopkar 1

EDITORIAL

Registration and reporting of clinical trials
Uday Khopkar, Sushil Pande 2

SPECIALTY INTERFACE

Preventing steroid induced osteoporosis
Jyotsna Oak 5

REVIEW ARTICLE

Molecular diagnostics in genodermatoses - simplified
Ravi N. Hiremagalore, Nagendrachary Nizamabad, Vijayaraghavan Kamasamudram 8

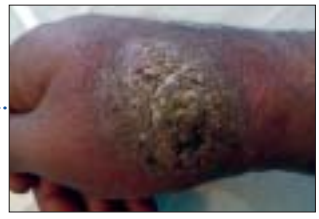
ORIGINAL ARTICLES

A clinicoepidemiological study of polymorphic light eruption
Lata Sharma, A. Basnet 15

A clinico-epidemiological study of PLE was done for a period of one year to include 220 cases of PLE of skin type between IV and VI. The manifestation of PLE was most common in house wives on sun exposed areas. Most of the patients of PLE presented with mild symptoms and rash around neck, lower forearms and arms which was aggravated on exposure to sunlight. PLE was more prevalent in the months of March and September and the disease was recurrent in 31.36% of cases.

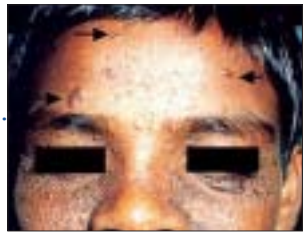
Comparative study of efficacy and safety of hydroxychloroquine and chloroquine in polymorphic light eruption: A randomized, double-blind, multicentric study
Anil Pareek, Uday Khopkar, S. Sacchidanand, Nitin Chandurkar, Geeta S. Naik 18

In a double-blind randomized, comparative multicentric study evaluating efficacy of antimalarials in polymorphic light eruption, a total of 117 patients of PLE were randomized to receive hydroxychloroquine and chloroquine tablets for a period of 2 months (initial twice daily dose was reduced to once daily after 1 month). A significant reduction in severity scores for burning, itching, and erythema was observed in patients treated with hydroxychloroquine as compared to chloroquine. Hydroxychloroquine was found to be a safe antimalarial in the dosage studied with lesser risk of ocular toxicity.



Many faces of cutaneous leishmaniasis
Arfan Ul Bari, Simeen Ber Rahman 23

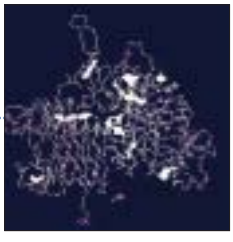
Symptomatic cutaneous leishmaniasis is diverse in its presentation and outcome in a tropical country like Pakistan where the disease is endemic. The study describes the clinical profile and atypical presentations in 41 cases among 718 patients of cutaneous leishmaniasis. Extremity was the most common site of involvement and lupoid cutaneous leishmaniasis was the most common atypical form observed. Authors suggest that clustering of atypical cases in a geographically restricted region could possibly be due to emergence of a new parasite strain.



Forehead plaque: A cutaneous marker of CNS involvement in tuberous sclerosis
G. Raghu Rama Rao, P. V. Krishna Rao, K. V. T. Gopal, Y. Hari Kishan Kumar, B. V. Ramachandra 28

In a retrospective study of 15 patients of tuberous sclerosis, eight patients had central nervous system involvement. Among these 8 cases, 7 cases had forehead plaque. This small study suggests that presence of forehead plaque is significantly associated with CNS involvement.

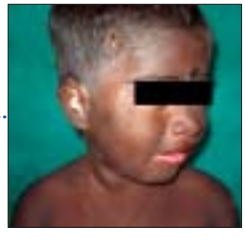
BRIEF REPORTS



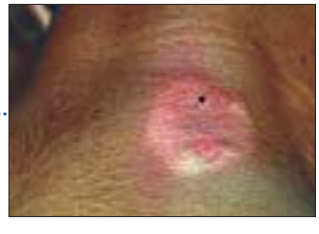
Ligand-binding prediction for ErbB2, a key molecule in the pathogenesis of leprosy
Viroj Wiwanitkit..... 32

SCORTEN: Does it need modification?
Col. S. S. Vaishampayan, Col. A. L. Das, Col. R. Verma 35

CASE REPORTS

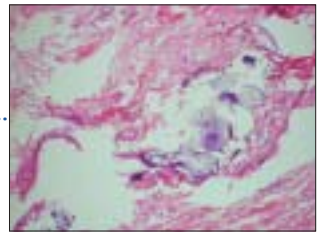


Universal acquired melanosis (Carbon baby)
P. K. Kaviarasan, P. V. S. Prasad, J. M. Joe, N. Nandana, P. Viswanathan 38



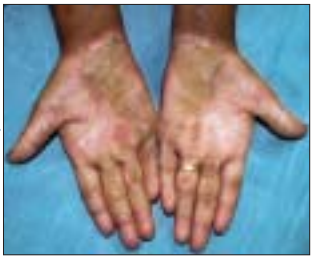
Adult onset, hypopigmented solitary mastocytoma: Report of two cases
D. Pandhi, A. Singal, S. Aggarwal..... 41

Incidental finding of skin deposits of corticosteroids without associated granulomatous inflammation: Report of three cases
Rajiv Joshi 44

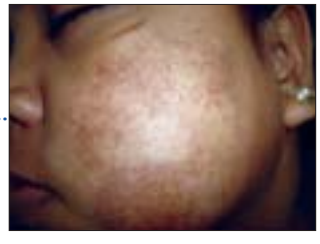


Erythromelanosis follicularis faciei *et* colli: Relationship with keratosis pilaris
M. Augustine, E. Jayaseelan 47

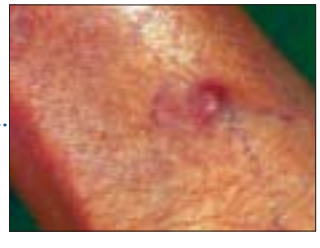
Naxos disease: A rare occurrence of cardiomyopathy with woolly hair and palmoplantar keratoderma
R. Rai, B. Ramachandran, V. S. Sundaram, G. Rajendren, C. R. Srinivas 50



Granular parakeratosis presenting with facial keratotic papules
R. Joshi, A. Taneja 53

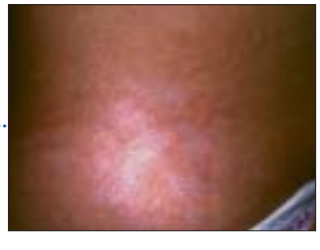


Adult cutaneous myofibroma
V. Patel, V. Kharkar, U. Khopkar 56



LETTERS TO THE EDITOR

Extragenital lichen sclerosus of childhood presenting as erythematous patches
N. G. Stavrianeas, A. C. Katoulis, A. I. Kanelleas, E. Bozi, E. Toumbis-Ioannou ... 59



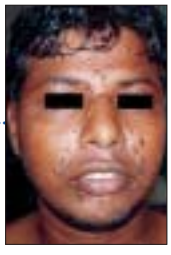
Leukocytoclastic vasculitis during pegylated interferon and ribavirin treatment of hepatitis C virus infection
Esra Adisen, Murat Dizbay, Kenan Hize, Nilsel İlter 60

Poland's syndrome
Saurabh Agarwal, Ajay Arya 62

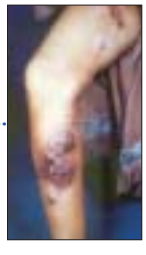
Hereditary leiomyomatosis with renal cell carcinoma
Sachin S. Soni, Swarnalata Gowrishankar, Gopal Kishan Adikey, Anuradha S. Raman 63

Infantile onset of Cockayne syndrome in two siblings
Prerna Batra, Abhijeet Saha, Ashok Kumar 65

Multiple xanthogranulomas in an adult
Surajit Nayak, Basanti Acharjya, Basanti Devi, Manoj Kumar Patra 67

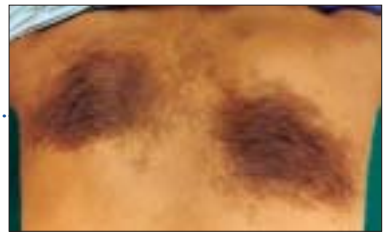


Bullous pyoderma gangrenosum associated with ulcerative colitis
Naik Chandra Lal, Singh Gurcharan, Kumar Lekshman, Lokanatha K 68



Sporotrichoid pattern of malignant melanoma
Ranjan C. Rawal, Kanu Mangla 70

Acitretin for Papillon-Lefèvre syndrome in a five-year-old girl
Didem Didar Balci, Gamze Serarslan, Ozlem Sangun, Seydo Homan 71



Bilateral Becker's nevi
Ramesh Bansal, Rajeev Sen 73

RESIDENTS' PAGE

Madarosis: A dermatological marker
Silonie Sachdeva, Pawan Prasher 74

FOCUS

Botulinum toxin
Preeti Savardekar 77

E-IJDVL

Net Studies

A study of oxidative stress in paucibacillary and multibacillary leprosy
P. Jyothi, Najeeba Riyaz, G. Nandakumar, M. P. Binitha 80

Clinical study of cutaneous drug eruptions in 200 patients
M. Patel Raksha, Y. S. Marfatia 80

Net case

Porokeratosis confined to the genital area: A report of three cases
Sujata Sengupta, Jayanta Kumar Das, Asok Gangopadhyay 80

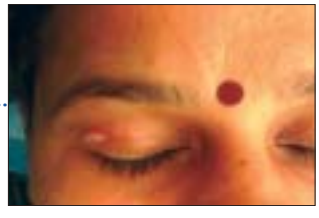
Net Letters

Camisa disease: A rare variant of Vohwinkel's syndrome
T. S. Rajashekar, Gurcharan Singh, Chandra Naik, L. Rajendra Okade 81

Cross reaction between two azoles used for different indications
Arika Bansal, Rashmi Kumari, M. Ramam 81

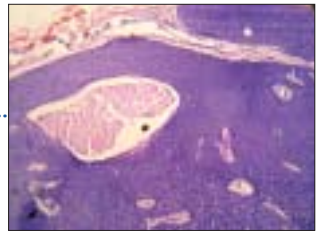
Net Quiz

Asymptomatic erythematous plaque on eyelid
Neeraj Srivastava, Lakhan Singh Solanki, Sanjay Singh 82



QUIZ

A bluish nodule on the arm
Ragunatha S., Arun C. Inamadar, Vamseedhar Annam, B. R. Yelikar 83



REFEREE INDEX-2007

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Registration and reporting of clinical trials

Uday Khopkar, Sushil Pande
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Clinical trials form an integral part of the drug discovery process worldwide. However, registration of clinical trials is not restricted to drug interventions. A clinical trial is defined as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."[1] Interventions include not only drugs but also cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc. A set of guidelines are already in place in India for the ethical conduct of studies to safeguard the interests of patients or volunteers participating in the study. However, there is a need to promote knowledge and awareness of regulatory laws and the more recent phenomenon of registration of clinical trials in India.

INADEQUATE AND SELECTIVE REPORTING

Currently, apart from a few academic clinical trials sponsored by government bodies or NGOs, the majority of clinical trials conducted in India are sponsored, randomized controlled trials. Most of the major hospitals are equipped with appropriately constituted Institutional Ethics Committees (IEC) and Review Boards (IRB). However, the results of clinical trials or their information are not adequately disseminated in many instances. Only selected or positive results might get published which are at risk of being doubted as being biased. Often in such cases, valuable scientific efforts are wasted without yielding desired outcomes. As reports of clinical trials form an important source of information for practitioners, researchers, academicians and the public, it is the moral, ethical and scientific responsibility of researchers to report the results. The so called 'discreetness' of clinical trials defeats the very purpose of scientific research and principles of evidence-based medicine. It may distort the evidence required for making correct clinical decisions. Besides, it deprives trial participants, the general public and fellow researchers of their right to information. It commonly results in duplication of efforts and wastage of vital resources.

CLINICAL TRIAL REGISTRATIION

In order to make clinical data and reports available to all, an online clinical registry has been initiated by the Indian Council of Medical Research (ICMR) for the registration of any interventional trial to ensure the following goals:[2]

1. Transparency and accountability of clinical research
2. Internal validity of clinical trials
3. To oversee the ethical conduct of clinical trials
4. Reporting of results of clinical trials

The clinical trial registry of India (CTRI) is the online registry of prospective clinical trials in India. This is the initiative started by the National Institute of Medical Statistics (NIMS) of the Indian Council of Medical Research and is supported by the Department of Science and Technology (DST) and the World Health Organization (WHO).

CTRI will create a database of prospective clinical trials in India after their registration. The data and reports of these clinical trials and their status will be available to the public and professionals free of cost after formal registration on their website *www.ctri.in* Currently, the registration of clinical trials is only voluntary and not mandatory. With increased

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awareness about this initiative and wide acceptance of the purpose of CT registration, it is likely that it may become mandatory in the future for initiation of clinical trials in India.

It has been affirmed that CT registration should be done before the actual enrollment of study subjects in the trial. The principal investigator or sponsor should share the responsibility of CT registration. In the case of multicentric studies, the lead investigator or sponsor should ensure that the CT is registered.

For the registration of a CT, it is essential to declare 20 items relevant to the CT as determined by the International Clinical Trial Registration Platform (ICTRP) of the World Health Organization (ICRTP-WHO). For registration with the CTRI, additional items related to the EC or IRB's permission and that of Director Controller General of India (DCGI) are included. At the end of a successful registration, each CT is assigned a unique WHO identification number called the Unique Trial Reference Number (UTRN) [Table 1].

Table 1: Registration parameters for Indian registry[2]

- UTRN*
- Registration Number
- Trial Registration Date
- Public title of study*
- Scientific Title of Study (Give Trial Acronym, if any)*
- Secondary IDs, if any
- **Principal Investigator's Name and Address**
- Contact Person (Scientific Query)
- Contact Person (Public Query)
- Funding Source/s
- Primary Sponsor
- Secondary Sponsor
- **Name of Ethics Committee and approval status***
- **Regulatory Clearance obtained from DCGI***
- Date of first enrollment
- **Estimated duration of trial**
- Target sample size
- Health Condition/Problem studied
- Intervention and Comparator agent
- Key inclusion/Exclusion Criteria
- Primary Outcome/s
- Secondary Outcome/s
- Countries of Recruitment
- **Site/s of study**
- Status of Trial*
- **Phase of Trial***
- Study Type
- **Brief Summary**
- **Method of generating randomization sequence**
- **Method of allocation concealment**
- **Blinding and masking**

*Items that are mandatory; bold text indicates additional items required by the ICMR for Indian trials

REGISTRATION OF NONSPONSORED CLINICAL TRIALS

It is widely perceived that the registration requirement for clinical trials refers only to sponsored trials. However, current guidelines for the registration of clinical trials do not make any distinction between sponsored and nonsponsored trials. Enforcement of registration for nonsponsored studies also offers the same advantages as for sponsored trials. Hence, as of today, it is recommended that all clinical trials, sponsored or nonsponsored, be registered at the time of inception. This includes a large number of interventional clinical studies that are conducted in medical colleges as part of postgraduate dissertations. It is particularly important for these to be registered as many of these are duplicated studies and not reporting them leads to wastage of resources.

PUBLICATION OF CLINICAL TRIALS

Although the CTRI is a recent phenomenon, similar registries have been in existence in other countries for some time. As such pretrial registration ensures the authenticity of a clinical trial, medical journal editors prefer a registered clinical trial over an unregistered one. Therefore, registration before the initiation of a trial is a prerequisite for publishing clinical trial data in many medical journals.

Member journals of the International Committee of Medical Journal Editors (ICMJE) declared in a common editorial published in 2004, that their journals will not publish the results of any clinical trial that began recruitment after 1st July 2005 if it was not registered with an authorized registry at the time of inception of the trial.[3] Studies on pharmacokinetics or major toxicity (*e.g*, phase I trials) have been exempted by ICMJE guidelines to ensure protection of original ideas.[4] However, it is mandatory for all the pharma sponsors to make public all their findings within a given framework of time as a part of their responsibility to the public at large.

Thus, clinical trial registration offers unique advantages to researchers in terms of the smooth publication of results

in international and national journals. Apart from this, it encourages researchers to engage in more meaningful and scientifically and ethically sound clinical research. Needless to say, it will build up public confidence in the conduct and authenticity of clinical trials.

Currently, most Indian journals do not enforce the registration for clinical trial reports that are submitted to them for publication. However, with the recent launch of the CTRI website, it may soon become inevitable for them to enforce the registration at the time of inception of a study.

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4. Salvi V. Research trials: Registration, reporting and publication. J Postgrad Med 2005;51:83-4.

Multiple Choice Questions

1. Alternative forms of a particular DNA sequence or a gene is called
   a. Polymorphism, b. Allele, c. Locus, d. Genotype
2. Allelic heterogenicity refers to
   a. Mutations in the same gene causing different clinical entities, b. Mutations in different genes causing same clinical phenotype, c. Loss of heterozygosity, d. All of the above
3. Epidermolysis bullosa is a classical example of
   a. Allelic heterogeneity, b. Locus heterogeneity, c. Loss of heterozygosity, d. None of the above
4. The basic step in any molecular biology experiment is a
   a. Polymerase chain reaction, b. DNA sequencing, c. Genotyping, d. Hybridization
5. Polymerase Chain reaction is used for
   a. Detecting polymorphisms in genes, b. Genetic analysis of complex diseases like psoriasis, c. Detection of microbes in small quantities, d. All of the above, 6. The technique used to study thousands of genes on one platform is, e. Polymerase chain reaction, f. DNA sequencing, g. DNA micro-arrays, h. Southern Blotting.
7. All are true about positional cloning EXCEPT
   a. The first step is chromosomal assignment of the region containing the defective gene by a method called Linkage analysis, b. Genes are identified based on their chromosomal location, c. Prior knowledge of the gene and gene product is necessary, d. A typical example using this approach is Darier's disease
8. All are true about linkage analysis EXCEPT
   a. The aim is to identify the chromosomal region that is transmitted with the disease phenotype and subsequently the disease is linked to the genetic locus which harbors the gene, b. Genome wide scans using several markers are used for this purpose, c. Family pedigrees are required, d. A LOD score of less than 3 suggests linkage.
9. A quantitative method to estimate HIV viral loads is based on
   a. Real Time PCR, b. Reverse Transcriptase PCR, c. DNA sequencing, d. Southern Blotting
10. DNA micro arrays are used for
    a. Genome-based diagnosis of neoplasms, b. Gene expression profiling of inflammatory skin conditions
    c. Mutational analysis of genodermatosis, d. All of the above

ANSWERS:
1-B, 2-A, 3-B, 4-A, 5-D, 6- C, 7- C, 8- D, 9- A,10- D