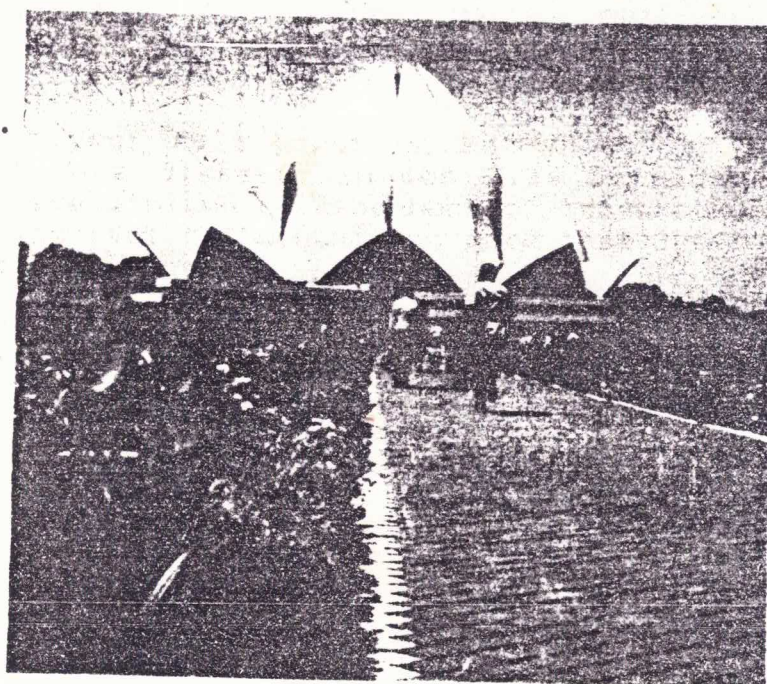




6th INTERNATIONAL CONGRESS ON ORAL CANCER

**February 15-18, 1999
New Delhi, India**

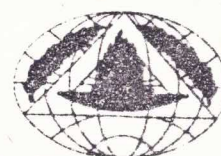
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ABSTRACTS

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USE OF PSORINUM IN THE TREATMENT OF CANCER

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Tumor invasion, metastasis and resistance to chemotherapeutic drugs or radiation are major obstacles for the successful treatment of cancer. This refractoriness of solid tumors to cytotoxic therapies has led to the exploration of new therapeutic modalities and strategies and a region which aims to increase the specificities and efficacy and reduce the toxicity of the anticancer drugs.

Good response was obtained when psorinum was orally administered for the treatment of the terminal cancer patients (ECOG 3 and 4). Out of the 275 patients treated for carcinoma of various organs viz. oral, head & neck, lung, stomach, pancreas, gall bladder, liver etc., the preliminary results are quite encouraging and interesting. About 80 percent of the patient was found responding to this therapy. During the first 6 month of the therapy most of the cases showed gastrointestinal and hepatobiliary symptoms along with improvement in liver function. Haematological picture also indicated satisfactory progress. Along with the psorinum therapy, supportive treatment like blood transfusion, abdominal or pleural paracentesis, analgesic, bronchodilators and stenting of hepato-pancreato-biliary system etc., done as and when required. Significant improvement in ECOG score was obtained, quality of life was improved and life prolonged in most of the cases. Total disappearance of tumor were seen in 45 patients out of which few were oral cancer cases.

The medicine was administered orally and so far no adverse side effects were noticed in any case. Before the start of the therapy informed consent was taken from all the patients.

Though the exact mode of action of Psorinum in regression of tumours is still not known, however, the results suggest that the drug could be a non specific immunomodulator. Biological response modifiers (BRM) with antitumour immunopotential activity, derived from plant, microbial organism, bacterial cell fraction, cytokines and thymic humoral fractions are known to play an important role in cancer immunotherapy. OK-432 (Whole cell preparation from *Streptococcus pyogenes*), PSK (the crude glycoprotein fraction of *coriolus versicolor*), Lentinam (*B*-glucan purified from *schizophyllum commune* fries) are now widely used in Japan. The *B*-glucan moiety is the common active site in the later three BRM.

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USE OF PSORINUM IN THE TREATMENT OF CANCER

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INTRODUCTION

Oral carcinoma is relatively uncommon in most parts of the world. However, in India, it occupies the top rank among male cancers and ranks within the first 5 among female cancer. Oral cancers of India are often linked to the tobacco chewing habit (Gupta, 1993).

Tumour invasion, metastasis and resistance to chemotherapeutic drugs or radiation are major obstacles for the successful treatment of cancer. This refractoriness of many solid tumours to cytotoxic chemotherapy has led to the exploration of new therapeutic modalities viz. immunotherapy, gene therapy, anti angiogenesis, tumour vaccines, biological therapy, development of resistance modifying agent (RMA) and many forms of alternative & complementary cancer therapies all over the world. Immunotherapy does not have a direct cytotoxic effect on the cancer cell but is an attempt to promote rejection of the tumour by the host, chiefly through the cellular arm of the immune system (Quan and Palackdharry 1997). Anti angiogenesis drugs are directed to block the tumour blood vessels through which the tumour get the oxygen and nutrients. Gene therapy aims to replace the defective gene or block the oncogenes. In most of the alternative & complementary cancer therapies the mode of drug action are not exactly known.

Complementary and alternative medicine can be defined as those medicine system, practices, interventions and applications that currently are not part of the dominant or conventional medical system. There are more than 300 topics under the term complementary and alternative medicine that can be divided into seven major categories on the basis of philosophy, approach to the patient, and orientation (Chez and Jonas 1997).

The present study was initiated to see the effect of a conventional drug Psorinum in terminal cancer patients in a non conventional regimen.

MATERIALS & METHODS

Drug : The drug Psorinum is the alcoholic extract of the scabies scrub, slough and pus cells. The drug was administered orally, approx. 0.01 ml/kg body weight per day as a single dose in empty stomach.

Patients: 275 cases suffering from carcinoma of different organs in stage III & IV and performance status (ECOG) of 3 or 4 were taken for the study as a randomized open trial, after informed consent had been obtained from them.

Investigation : Prior to the therapy, all the diagnosed patients were evaluated and staged by routine and special diagnostic techniques including skiagraph, barium meal, fiberoptic endoscopy, ultrasonography, whole body scan and detailed hemogram. The histopathology was reexamined in all the detected cases carcinoma and each case irrespective of clinical stage was evaluated by oncologist whether or not was treated previously by surgery, radio and/or chemotherapy, either alone or in combination according to the merit of the case. In most of the cases conventional therapy was not recommended by oncologist considering poor prognosis and bad treatment outcome. Few were treatment failure cases.

Management : Along with the Psorinum therapy, symptomatic therapy for control of infection, bleeding and nutritional deficiencies were also given. Blood transfusion, abdominal or pleural paracentesis, analgesic, bronchodilators and stenting of the hepato-pancreato-biliary system and palliative relevant surgeries viz. debulking & bypass were done as and when required.

Assessment : Tumour size shrinkage was regularly assessed by physical examination, skiagraph, roentgenogram, sonography or CT scanning as applicable. CT scan was preferred for accurate evaluation of size.

RESULTS

Good response was obtained when psorinum was administered for the treatment of the terminal cancer patients (ECOG 3 and 4). Out of the 275 patients treated for carcinoma of various organs viz. 25 oral / head & neck, 80 lung, 60 stomach, 30 pancreas, 40 gall bladder, 30 liver and 10 colorectal cases, the preliminary results are quite encouraging and interesting. About 80 percent of the patient was found responding to this therapy. During the first 6 month of the therapy most of the cases showed marked remission of presenting symptoms like pain, respiratory, gastrointestinal and hepatobiliary symptoms along with improvement in liver function. Haematological picture also indicated satisfactory progress. Significant improvement in ECOG score was obtained, quality of life was improved and life prolonged in most of the cases.

During the first year, reduction of tumour size more than 70% of the original size were observed in 10 percent of cases. Reduction of approx. 50 percent of the tumour size were observed in 16 percent of cases. In few cases it was observed that the performance status have improved despite very little regression of tumour growth. In 20 percent of cases there were insignificant reduction in size of tumour with waxing and waning of clinical features indicating fluctuating performance status. As many as 13.2 percent of cases died either from infection, bleeding episodes or organ failure.

Complete disappearance of tumour were observed in 45 cases viz. 3 oral, 11 lung, 15 stomach, 7 pancreas, 5 gall bladder, 1 colorectal and 3 liver. No malignant cells were detected histopathologically from the primary site in those cases. Median survival for complete responders was 34 months compared with 9 months for partial responders and 4 months for non responders. The mean survival months for lung, stomach, pancreas, gall bladder, liver and colorectal were 17.0, 22.5, 14.9, 13.0, 7.9 and 30.9 months respectively.

In the patients where the tumour disappeared completely, had a good disease free survival record. And so far no adverse side effects were noticed in any cases.

DISCUSSION

When the trial started the drug psorinum was administered with out any supportive care, hence, though there was considerable shrinkage of the tumours

mass was concerned but the mortality rate remained very high. Later when the supportive treatment was tagged viz. blood transfusion, abdominal or pleural paracentesis, analgesic, bronchodilators and stenting of the hepato-pancreato-biliary system and palliative relevant surgeries etc., there was considerable decline in the mortality rate.

Few cases of cancer of various organs were studied at first, when it was found that psorinum was working good as an anti-cancer drug along with the supportive care (Chatterjee et al. 1995). Few oral cancer were also treated initially with this drug and the results were good. It was then decided that it would be interesting to see the effect of this drug in such cancers where the prognosis is very poor with the conventional treatment and hence, much of the attention was diverted for the cancer of pancreas, liver, lungs, stomach etc.

Researcher both in the United States and other western countries suggest that significant number of people are involved with various form of alternative medicine. However, the reasons for such use are, at present poorly understood. Grothey et al. (1998) reports number of patients treated with conventional oncological regimens also use alternative medicine, most of them because of a polypragmatic attitude to tumour treatment. Alternative medicine was used largely as complementary and not an alternative to conventional medicine. However, in India the scenario is quite different the problem do not only relates to economic conditions but are specific and have very serious implication on the course of treatment. Most of the patient are on two or more therapies at a given time. Despite knowledge patient will present in advance stage, decision making regarding further treatment rest with the family and not with the patient. Opinion of elders in family, are more important than that of a qualified specialist. There is a natural belief of non responsiveness of malignancy, allowing psychologically the relatives to take decisions against treatment, thus making it impossible to run a good trial (Pendharkar 1998). These problems are common for all the tropical countries and do not have relationship to level of education and financial status.

Though the exact mode of action of Psorinum in regression of tumours is still not known, however, the results suggest that the drug could be a non specific immunomodulator. Biological response modifiers (BRM) with antitumour immunopotential activity, derived from plant, microbial organism, bacterial cell fraction, cytokines and thymic humoral fractions are known to play an important role in cancer immunotherapy. OK-432 (Whole cell preparation from *Streptococcus pyogenes*), PSK (the crude glycoprotein fraction of *coriolus versicolor*), Lentinam (β -glucan purified from *schizophyllum commune* fries) are now widely used in Japan. The β -glucan moiety is the common active site in the later three BRM (Tanaka et al. 1998).

CONCLUSION

The Psorinum therapy is quite promising for the treatment of cancer of lungs, stomach, pancreas, gall bladder, liver and colon and is free from any side effects. This therapy could also be effective in oral cancer. It could be safely given to patient of older age groups viz. 60 years and above, where the treatment outcome and prognosis is very poor with the conventional therapy. Detailed investigation is needed to know how and why the entire tumour is slowly disappearing in few cases. In cost effective basis this therapy is very inexpensive and above all the drug is administered orally. Future studies with larger number of cases are needed to assess the exact effectiveness of this therapy. Since there is little information on the long term toxicity and pharmacokinetics of this treatment, detailed investigation are now been initiated in this direction.

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