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Prednisolone Therapy As An Intervention In Terminal Cancer Patients, A Prospective Randomized Double Blind Cross Over Study

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I. Aims And Objectives

This study was designed to assess the efficacy of prednisolone therapy in relation to improving the quality of life in terminal cancer patients.

- To Assess Whether Oral Prednisolone Is An Effective Intervention To Improve The Quality Of Life Of Terminal Cancer Patients
- To Examine The Effects Of Prednisolone On Symptom Clusters Related To Quality Of Life In Patients With Advanced Cancer

II. Materials And Methods

A randomized, prospective, double-blind, cross-over, placebo-controlled, clinical trial where patients were randomized to receive prednisolone 40mg or matching placebo for 14 consecutive days. Study medication was provided in blinded packages which contained packets of either placebo or prednisolone as specified by a computer-generated randomization scheme. After the 14-day, double-blind phase was completed, all patients were given prednisolone for 20 days. The end points of the study were pain, psychiatric status, appetite, nutritional status, daily activity, and performance and were evaluated using FACT-G based questionnaire and VAS.

III. Results And Observations

- There was significant improvement in **overallquality of life** of the study group compared to controls (F=3077.5) ;p<0.01)
- There was significant improvement in **appetite** and cachexic features in study group (F=1277.5) ;p<0.01)
- **Depression** had significantly reduced in the study group (F=2283.7) ;p<0.01)
- Assessed **pain** underwent significant reduction in study group (F=3038.7) ;p<0.01)
- After cross over phase significant majority (80%)of patients **preferred prednisolone over placebo**
- **Total analgesic dose** had a significant reduction in study group

On completion of double blind phase it was observed that mean intensity of pain (VAS) was28.2 +/- 10 after prednisolone treatment and was 60.2 +/- 11 after placebo (P less than 0.01).There was a significant decrease in analgesic dose(80% ,40 of 50 patients) and depression(70% , 35 of 50 patients). 75 %(37 of 50 patients) showed an increase in appetite and almost 80%(39 0f 50 patients) showed an increase in daily activity. After cross over phase 85 per cent (42 of 50 patients) chose prednisolone over placebo. No serious toxicity was found at the dose of prednisolone used.

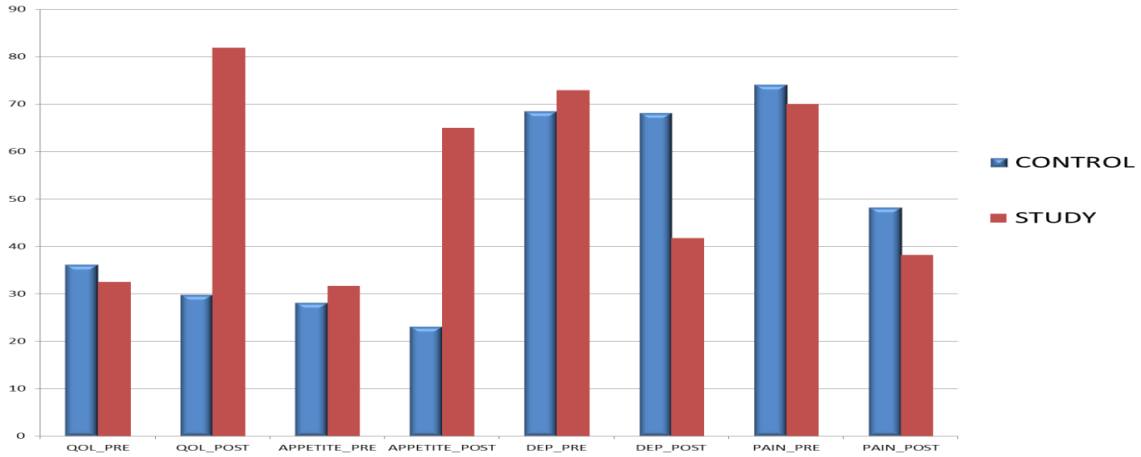

Fig 1 graph showing the quality of life variable pre and post study in the study and control arms

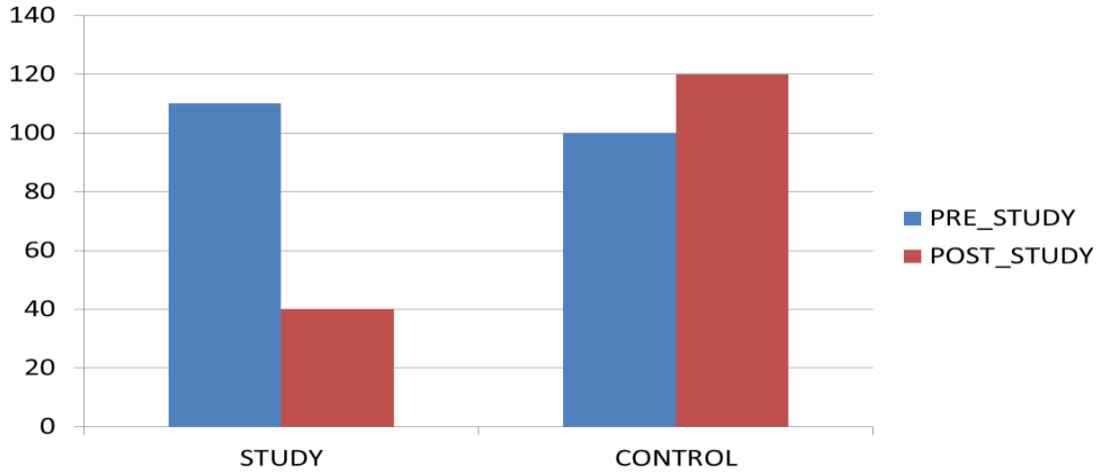

Fig 2 Graph showing change in analgesic dose pre and post study in the study and control arm

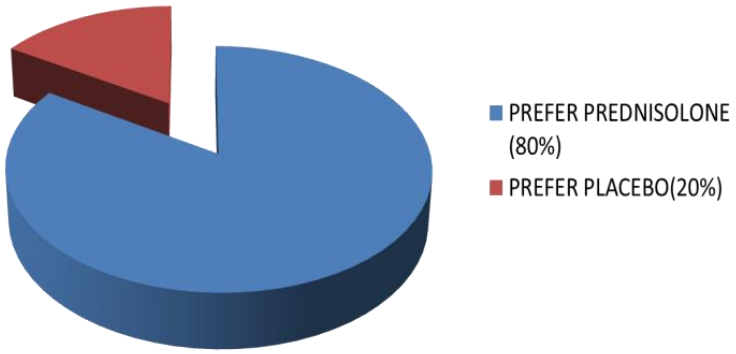

Fig 3 Patient preference after cross over phase

IV. Limitations And Scope For Further Research

- Being an institutional study with limited sample size is a limiting factor
- Assessment was done only at the end of the study , limiting the knowledge on evolution of events
- Questionnaire based assessment could be replaced by more robust clinical assessment

V. Discussion And Conclusion

- There is a recognized need to address the quality of life of cancer patients in the terminal stages of their disease. Therapeutic management with drugs (such as narcotics and sedatives) may provide effective control for pain, but have little or, perhaps, even an adverse effect on nausea, vomiting, alertness, appetite, and the patient' s ability to relate to family members. The results of this study have demonstrated that treatment with oral steroid may be an important adjunct to improving the quality of life in this patient population.

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