

RANDOMIZED DOUBLE-BLIND PROSPECTIVE CLINICAL TRIAL ON EFFECTIVENESS OF A HERBAL PREPARATION IN IMPROVING THE PROGNOSIS OF ORAL CANCER

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Background: In Sri Lanka, oral cancer (OSCC) is the most common cancer among males and ranks sixth among women, reported to account for 12.9% of total malignancies in the country. The buccal mucosa and tongue are the commonest sites involved. Present study was focused on secondary chemoprevention.

Aim: The objective of the present study was to determine whether *Emblica officinalis* (Nelli) and *Tinospora cordifolia* (Rasakinda) has a prognostic effect in the treatment of oral cancer.

Method: The study was a randomized double blind prospective clinical trial comprised 114 consecutive patients with OSCC of buccal mucosa and tongue who had treatment in our unit during 2005 to 2015. Of this 70 had carcinoma in the buccal mucosa and 44 in the tongue. After conventional treatment, they were randomly assigned. 51 were in the trial group and 63 in the control. 7 were young (<45) 70 were in middle (46-65) and 37 were in old (>66) age groups. 15 females and 99 were males. 73 were an early (stage 1&2) and 41 were in late (stage 3&4a) stages.

The Trial group was given 10gms of equal quantity of above herbs twice a day in powdered form for three months postoperatively. The Control was given a placebo (Viva milk powder) instead.

Efficacy of herbal regime was determined by recurrence free survival and incidence of recurrence. SPSS software and chi square statistical method was used.

Results: Recurrence OSCC buccal mucosa were greatly reduced in the trial group showing statistically significant ($p = 0.02$) for local recurrence and ($p = 0.05$) for overall recurrence. Nodal and overall recurrences of trial group of OSCC tongue was reduced highly statistically significantly ($p = 0.01$).

Five-year recurrence-free survival of the trial groups of both carcinoma together, was 62.7% compared to 42.3% in the control ($p = 0.031$) and statistically significant.

Conclusion: It is justifiable to conclude that *Emblica officinalis* (Nelli) and *Tinospora cordifolia* (Rasakinda) prevented cancer recurrence of trial groups and improvement in the survival rate.

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