Prevention of chemoradiation related mucositis in patients with head and neck cancer using dexamethasone based mouthwash (Miracle mouthwash): A phase II randomized double blind, placebo controlled study

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**Background:** Oral mucositis (OM) is the most common adverse event in patients with head and neck cancer (HNC) who are treated with chemoradiotherapy (CRT). Normal saline/ or benzydamine hydrochloride oral rinse might reduce OM incidence and severity. However, the need for interruption of CRT may occurred. A phase II study of steroid solution for stomatitis prophylaxis has been reported in patients with advanced stage breast cancer who was treated with mTOR inhibitor. We aimed to assess the efficacy of dexamethasone-based mouthwash for prevention of oral mucositis (OM) in HNC patients who were receiving with CRT.

**Patients & Methods:** In this phase 2, double-blind, placebo-controlled study, we enrolled 27 patients with HNC who were treated with CRT. Those patients were randomized (1:1) to received dexamethasone-based mouthwash (0.5 mg in 10 ml of normal saline solution) (n=14) versus placebo plus normal saline solution (n=13) at a day before starting in CRT schedule (rinse for 2 min and spit, four time daily for 10 weeks). The primary endpoint was incidence- and severity of OM, which focused on pain score by 10 weeks evaluated in the full analysis.

**Results:** There was statistically significant difference in the incidence of WHO grade 2 OM at 3 weeks after randomization (23.1% placebo group vs 0% in dexamethasone-based solution group, p-value=0.003). At 6 weeks, 84.6% of patients in placebo group developed grade 2 or higher OM, and only 7.1% in dexamethasone-based solution group (p-value <0.001). Furthermore, pain score in patient with dexamethasone-based solution group was lower than placebo group significantly at 3 weeks until complete treatment.

**Conclusions:** Dexamethasone-based solution mouthwash significantly reduced the incidence and severity of oral mucositis in head and neck cancer patients receiving chemoradiotherapy, and could be a new standard of care for prevention of oral mucositis from chemoradiation treatment.