

A Prospective study to compare the efficacy between povidone-iodine gargling and benzydamine hydrochloride (Diffiam®) for mucositis prevention from chemoradiotherapy in head and neck cancers, preliminary analysis.

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Background: Head and neck cancer (HNC) is one of the top ten cancer incidences in Thailand. Curative treatment approaches were included surgery, radiation, and systemic therapy. Radiation-induced oral mucositis (RIOM) is an important treatment limited toxicity which has been found in 40-80% of patient receiving concurrent chemoradiotherapy. Benzydamine hydrochloride or Diffiam® was recommended by MASCC/ISOO to prevent oral mucositis. Povidone-iodine had also been adopted to use as oral rinse to prevent mucositis.

Objective: This study compared the efficacy between benzydamine hydrochloride and povidone-iodine to prevent RIOM in HNC patients who received concurrent chemoradiation (CCRT).

Methods: We conducted a randomized study in HNC patients who were undergoing CCRT for curative intention. The stratification factors were primary site of disease, fashion of treatment (adjuvant vs. definitive), regimen of chemotherapy (cisplatin vs. carboplatin) and schedule of chemotherapy (weekly vs. 3 - week). The primary outcome was RIOM assessed by Oral Mucositis Assessment Scale (OMAS). Secondary outcomes were included RIOM assessed by NCI-CTCAE v.5, analgesic use rate, antibiotics use rate, anti-fungal use rate and hospitalization rate.

Results: We reported a preliminary study of 44 of 70 participants. Demographic characteristics were well-balanced between both arms. Median OMAS scores were significant different between 4th -6th week of treatment indicated toxicity from CCRT. There was no significant difference in median OMAS score in any time point of treatment (0.99, 0.37, 0.47, 0.99, 0.99, 0.63, 0.65, and 0.08). The worst CTCAE score were also similar in both arms. Rates of analgesic, antibiotics, anti-fungal usage, NG insertion and hospitalization were also not different between both arms. Furthermore, mean compliance of gargling treatments was not difference; compose of 81.53% in benzydamine hydrochloride and 75.22% in povidone-iodine.

Conclusions: This preliminary study could not demonstrate superior efficacy of povidone-iodine gargle over benzydamine hydrochloride but seem equal efficacy in mucositis prevention for HNC patients who received CCRT.
