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Assessment of indomethacin oral spray for the treatment of anticancer therapy induced severe oral and oropharyngeal mucositis

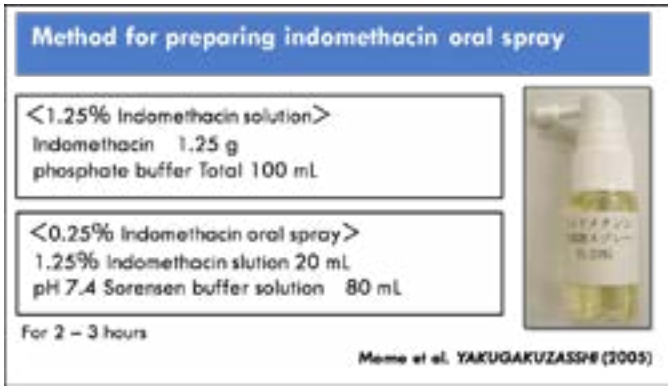
Kenji Momo
Teikyo Heisei University, Japan

Statement of the Problem: Oropharyngeal mucositis (OM) and Oral mucositis is an adversity of chemo- and radio-therapy and is accompanied by severe throat and oral pain in patients with CTCAE grades of over 3, which includes 30% of cancer patients treated with radio-therapy. OM often impairs quality of life (QOL) and leads to discontinuation of chemo- and radio-therapy because severe pain compromises oral intake and nutritional status. In this study, we tried to use the Indomethacin oral spray (IM-OS) preparation to relief the pain that induced cancer therapy.

Methods: We observed 35 patients (male/female: 20/15, 53 ± 17 y) with oropharyngeal mucositis, who treated with IM-OS preparation for pain relief at University of Tsukuba hospital, Japan. Analgesic effects were assessed using the six-grade face scale for pain in 28 patients at the start of IM oral spray treatment. Systemic exposure was assessed by determining urinary excretions of IM in seven patients.

Results: Pain relief was achieved in 26 (93%) patients at 25 (5–60) min after applying the IM-OS preparation (15.6 ± 3.4 μg/kg) and analgesic effects were maintained for 120 (10–360) min. The pain was significantly decreased after using the spray (3.6 ± 0.7 vs. 2.4 ± 0.9, $p < 0.01$). Moreover, urinary IM excretion rates after applying the IM spray preparation were 1.8 ± 0.8% of the IM oral spray dose (130.5 ± 77.7 μg/kg/day), which was markedly lower than that following oral administration of IM (60%). No adverse events were observed following application of the spray.

Conclusions: The present IM spray is an effective and safe for pain relief and can be used as an alternative therapeutic option for oropharyngeal mucositis in cancer patients.



Biography

Kenji Momo from Japan has his expertise of the drug formulations, pharmacokinetics and pharmacoepidemiology. He worked at Tsukuba-university hospital in Japan for 13 years as a clinical pharmacist belonged to palliative care team. From 2016, he moved to Teikyo Heisei University (faculty of pharmaceutical sciences) as an associate professor. Indomethacin spray preparation that introduce in this session, used in Japan as an alternative therapeutic optionfor uncontrollable pain for the oral mucositis and oropharyngeal mucositis caused by cancer therapy. He is trying to develop this indomethacin spray to commercially based drug.

k.momo@thu.ac.jp