



Effect of Aloe Vera Mouthwash on Radiation Induced Oral Mucositis



GROUP 8 Gavila P.; Siripornkitti W.; Thaveetermsakul N.; Umpreecha C.

Introduction



Oral mucositis is a common side effect of radiation therapy in head and neck cancer patient.⁽¹⁾



Patient's QoL ↓



Pain and Dysphagia



Cannot eat solid food/ weight loss



Infection



Hospitalization and discontinued on RT⁽²⁾

Standard oral care protocol⁽³⁾



Aloe vera (*Aloe barbadensis miller*)

has "medical properties" by its wound healing effect and anti-inflammatory mechanism.



Research Design



1 Sample Size Calculation

Using N4studies: Using 2-sided type I error of 0.05 and 80% power, total sample size of 220 subjects (110 subjects per group)

2 Sample selection



INCLUSION

- ✓ Dx with H&N cancer
- ✓ 35-60 years old
- ✓ Non-smoking
- ✓ BMI ≥ 18
- ✓ Normal renal function.
- ✓ Radiotherapy: 50-70 Gy.
- ✓ Oral cavity exposed to radiation.
- ✓ The KPS ≤ 80%.

EXCLUSION

- ✗ History of RT within the past year
- ✗ Conjugated Tx. with CT
- ✗ Allergy to Food and Aloe vera,
- ✗ Existing lesion in the oral cavity
- ✗ History of smoking
- ✗ Unwilling to participate

⚡ Allergic test to Aloe vera
 ⚡ Treat Oral Disease
 ⚡ Controlled Oral hygiene (OHI-S) ≤ 3

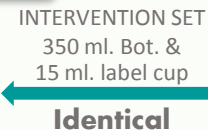
3 Experiment Design

First Oral exam: Prior First RT within 10 days

Start RT (1st Fraction)



Aloe vera Group n=110



Normal Saline Group n=110

INTERVENTION SET
350 ml. Bot. & 15 ml. label cup
Identical

4 Data Collection

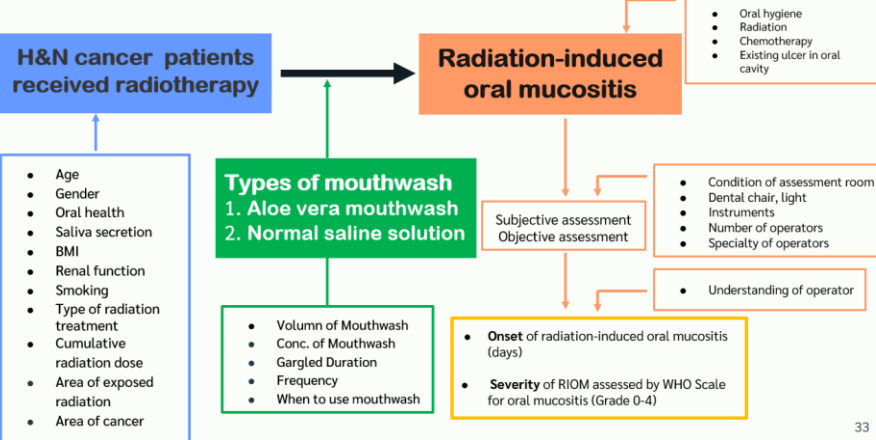


2 Oral Medicine Specialist
 Severity of RIOM By WHO Grading System (0-4)
 🔴 Soreness
 🔴 Ulcer
 🔴 Food Intake
 🔴 Frequency of MW.
 🔴 OHI-S

5 Outcome

WHO scale	Onset (days)
1	
2	
3	
4	

Conceptual Framework



Research Question and Hypothesis



- **RQ:** Does aloe vera mouthwash delay onset of radiation-induced oral mucositis compared with normal saline solution?
- **Hypothesis:** There is difference between Aloe vera mouthwash and normal saline solution in delaying onset of radiation-induced oral mucositis.

Research Objective



To evaluate the efficacy of Aloe vera mouthwash on delaying onset of radiation-induced oral mucositis compared with normal saline solution.

Statistic Analysis



Statistic analysis of data will be perform using the SPSS software, Version 22.0. For Comparison of the outcome variable between two group (Aloe vera and normal saline) Independent t-test is used at P<0.05

Time and Budget



- Start from August,2020 until August, 2022
- Budget approximately 60,000 THB

Keyword

- Aloe vera
- Oral mucositis
- Radiotherapy
- Head and neck cancer

Reference :

1. Trotti A, Bellm LA, Epstein JB, et al. Mucositis incidence, severity and associated outcomes in patients with head and neck cancer receiving radiotherapy with or without chemotherapy: a systematic literature review. *Radiother Oncol.* 2003; 66: 253–62.
2. Muanza TM, Cotrim AP, McAuliffe M, Sowers AL, Baum BJ, Cook JA, et al. Evaluation of radiation-induced oral mucositis by optical coherence tomography. *Clin Cancer Res* (2005) 11(14):5121–7
3. Lalla RV, Bowen J, Barasch A, Elting L, Epstein J, Keefe DM, et al. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. *Cancer* (2014) 120(10):1453–61.
4. Puataweepong P, Dhanachai M, Dangprasert S, Sithatani C, Narkwong L, Puttikaran P, et al. The efficacy of oral Aloe vera juice for radiation induced mucositis in head and neck cancer patients: A double-blind placebo-controlled study. *Asian Biomed* 2009;3:375–82.
5. McGuire DB, Fulton JS, Park J, Brown CG, Correa MEP, Eilers J, et al. Systematic review of basic oral care for the management of oral mucositis in cancer patients. *Supportive Care in Cancer.* 2013;21(11):3165–77