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# Saving Mucosa with Prophylactic Aloe Vera Therapy

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# Study Overview

- Title of Study: SMAP-AV: Saving Mucosa with Prophylactic Aloe Vera Therapy
  - o The Catholic Health Initiative (CHI) Institute for Research and Innovation  
Institutional Review Board (CHIRB) approved the research project April 23, 2019  
and determined the project to be a full IRB review that was expedited.
- Study Start Date: May 22, 2019
- Study Complete Date: March 14, 2023

# Research Team

- Elizabeth Bright, RN, OCN, Nurse Navigator in the Cancer Treatment Center was the Co-Principal Investigator
- David Pruitt, MD, Radiation Oncologist in the Cancer Treatment Center was the Principal Investigator



# Study Aim

The purpose of this study was to determine if the prophylactic use of Aloe Vera juice in patients receiving external beam radiation therapy specifically for those with a biopsy confirming diagnosis of head or neck cancer:

- Would prevent drastic weight loss ( $>10\%$ )
- Would prevent this patient population from requiring a percutaneous endoscopic gastrostomy (PEG) tube
- Would have this patient population experience 2 or less on the WHO (World Health Organization) oral mucositis scale during their course of radiation

# Literature Review

<sup>1</sup>Puataweepong, Putipun, Mantana Dhanachai, Somjai Dangprasert, Chompron sithatani, Thiti Sawangsilp, Laddawan Narkwong, Parmorn Puttikaran, Tanin Intragumtornchai. "The Efficacy of Oral Aloe Vera Juice for Radiation Induced Mucositis in Head and Neck Cancer Patients: a Double-Blind Placebo-controlled Study." Asian Biomedicine, no. 4. (August 2009): 375-382.

<sup>2</sup>Sahebjamee, Mahnaz, Reza Bekhradi, Arash Mansourian, Sajjad Ashnagar. "Comparative Efficacy of Aloe Vera and Benzydamine Mouthwashes on Radiation – Induced Oral Mucositis: A Triple-Blind". Oral Health & Preventaive Dentistry (November 2014).

<sup>3</sup> Ahmadi, Amirhossein. "Potential Prevention: Aloe Vera Mouthwash May Reduce Radiation-Induced Oral Mucositis in Head and Neck Cancer Patients. Chinese Journal of Integrative Medicine no. 18 (August 2012): 635640.

<sup>4</sup> Lonbro, Simon, Gry Bjerg Peterson, Jens Rikardt Andersen, Jorgen Johansen. Prediction of Critical Weight Loss During Radiation Treatment in Head and Neck Cancer Patients is Dependent on BMI no. 24 (May 2016) 2101-2109.

# Significance of Literature Review

Improving the patient experience of care is important to nursing as patients with head and neck cancer have many difficult side effects that impact their quality of life as well as cause treatment delays that can result in their treatment being less effective. These include but are not limited to pain, problems swallowing, necessary dental procedures prior to the start of radiation (most commonly total mouth extraction).

The cost of care is relevant for this study. The organization looked at:

- Pharmaceuticals vs. over the counter Aloe Vera juice
- PEG tube placement (an extra surgical procedure) vs. no procedure
- The cost of daily tube feedings vs. the cost of normal oral nutrition

# Innovation

This research study produced actionable information for nursing as the proposed mechanism of the Aloe Vera juice is to coat the mucosa. Coating the mucosa decreases irritation to the lining of the throat, thereby allowing the patients to eat and/or drink with less discomfort. Better nutrition will enable the patient to maintain caloric intake to prevent weight loss.

Pruitt reviewed many local Aloe Vera products. The product chosen for this study has a viscosity like water; it is manufactured from the inner gel portion of the Aloe Vera plant. The preparation is Aloe Vera juice and is made from Aloe Vera inner gel or filet. The Aloe Vera will be provided by the investigators for every patient. The ingredients are water, Aloe Vera concentrate, citric acid, and sodium benzoate as a food preservative.

# Study Design

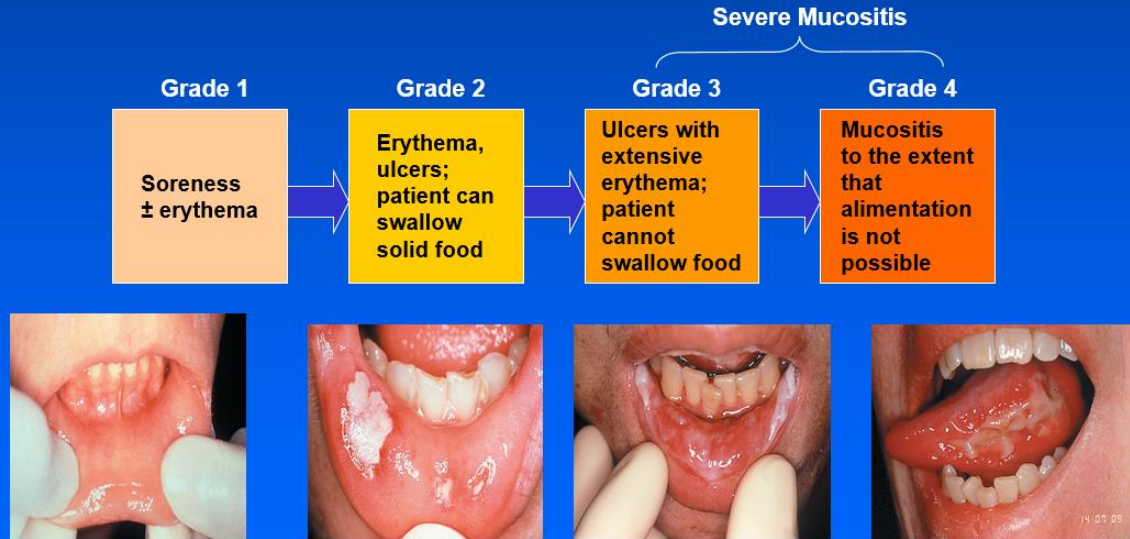
The study follows a quantitative, descriptive design.

The three end-points for SMAP-AV were:

- Patients will not lose greater than 10 percent of their initial body weight during their radiation treatments.
- Patients will not require a PEG tube.
- Patients will experience 2 or less on the WHO (World Health Organization) oral mucositis scale during their course of radiation.

# WHO's Oral Toxicity Scale

## World Health Organization's Oral Toxicity Scale





# Sample Description

The type of sample for this study was a cohort.

Inclusion criteria:

- Patient will have a biopsy confirmed diagnosis of head or neck cancer
- Patient will be receiving external beam radiation therapy + (plus) or - (minus) chemotherapy, with curative intent at CHI St. Vincent Cancer Center - Hot Springs
- P16+ (P16 Positive) or P16- (P16 Negative)
- Smoker or non-smoker
- Male or Female
- Age 20+
  - Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, and 2
  - Patients with Stage I, II, III, or IV head or neck cancers

Exclusion criteria:

- Vulnerable population as defined as:
  - Adults unable to consent; and/or cognitively impaired
  - Individuals who are not yet adults (infants, children, teenagers)
  - Pregnant women
  - Prisoners
  - ECOG performance status of 3 or 4
  - Patients with recurrent head and neck cancer

**30 patients enrolled in the study**

# Location of Study

The research study took place at CHI St. Vincent Hot Springs in the Cancer Treatment Center.



# Study Procedures

- Assessment of oral cavity of the head and neck cancer patients at the new patient consult
- Aloe Vera juice was provided to the patient along with verbal and written instructions for use
- Data collection methods included patients being weighed at baseline and weekly while undergoing treatment or more frequently if weight loss was identified
- Patients were asked to fill out a daily journal recording the time the Aloe Vera juice was taken and any side effects that may have occurred around administration
- Patients met with a Registered Dietician biweekly or more frequently if weight loss was identified

# Results

The results for the three endpoints of the study for the 30 patient sample were:

- 17/30 (57%) of the patients who were compliant with use lost less than 10 percent of their initial body weight  
8/30 (27%) of the patients lost more than 10 percent of their body weight however these patients were not compliant with the use of the Aloe Vera  
5/30 (17%) of the patients did not complete radiation- 1 was hospitalized and never resumed treatment, 3 quit treatment while under study and 1 expired while under treatment due to causes unrelated to the use of Aloe Vera
- 2/30 (7%) of the patients had PEG placement during treatment  
1/30 (3%) of the patients had a PEG placed prior to enrolling in the study but did not disclose that upon admission to the study  
3/30 (10%) of the patients required a PEG after the completion of radiation treatment
- 2/30 (7%) of the patients had a WHO oral mucositis score of 3  
28/30 (93%) of the patients had a WHO oral mucositis score between 0-2 at completion of radiation treatment

# Discussion

- The findings for the IRB and FDA approved research study SMAP-AV were significant
- Findings showed that starting the Aloe Vera juice at the first external beam radiation treatment increased the success of the program
- The patient journals were reviewed during treatment and after treatment was completed
- The implications of the findings were in favor of the organization continuing the prophylactic use of Aloe Vera juice in patients receiving external beam radiation therapy

# Questions

