

**THE EFFECTS OF AN ORAL CARE PROGRAM ON STOMATITIS
IN ACUTE MYELOID LEUKEMIA PATIENTS
UNDERGOING CHEMOTHERAPY**



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THE EFFECTS OF AN ORAL CARE PROGRAM ON STOMATITIS IN ACUTE MYELOID LEUKEMIA PATIENTS UNDERGOING CHEMOTHERAPY.

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ABSTRACT

The purpose of this quasi-experimental research was to study the effects of an oral care program on stomatitis in acute myeloid leukemia patients undergoing chemotherapy. Forty AML patients undergoing chemotherapy were recruited at Siriraj Hospital. The sample was divided into two groups: the control and experimental group. The oral care program included three aspects: a) Providing information and training in oral care skills, b) oral cryotherapy and c) oral supplementation of glutamine. The effects of the oral care program were followed up for 28 days. Oral mucosa was assessed by Oral Assessment Guide (OAG). Data was collected on the number of patients, onset, duration and severity of stomatitis. The data were analyzed by using percentage, mean, Kolmogorov-Smirnov test and t-test.

The results revealed that the number of patients who developed stomatitis in the experimental group was significantly lower than in the control group ($p < .001$), the onset day of stomatitis in the experimental group was significantly later than in the control group ($p < .001$), the duration of stomatitis in the experimental group was significantly shorter than in the control group ($p < .001$) and the severity score of stomatitis in the experimental group was significantly less than in the control group ($p < .001$).

These findings support the hypotheses that an oral care program is effective in preventing stomatitis, delaying its onset, shortening its duration and lessening its severity for AML patients undergoing chemotherapy. Furthermore, the oral care program could be applied with other patients who may be at risk of developing stomatitis.

KEY WORDS : ORAL CARE / STOMATITIS / LEUKEMIA PATIENTS /
CHEMOTHERAPY

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ผลของโปรแกรมการดูแลช่องปากต่ออาการเยื่อช่องปากอักเสบในผู้ป่วยมะเร็งเม็ดเลือดขาวชนิดเฉียบพลันที่ได้รับยาเคมีบำบัด (THE EFFECTS OF AN ORAL CARE PROGRAM ON STOMATITIS IN ACUTE MYELOID LEUKEMIA PATIENTS UNDERGOING CHEMOTHERAPY)

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บทคัดย่อ

การศึกษาครั้งนี้เป็นการวิจัยเชิงกึ่งทดลอง เพื่อศึกษาผลของโปรแกรมการดูแลช่องปากต่ออาการเยื่อช่องปากอักเสบ ในผู้ป่วยมะเร็งเม็ดเลือดขาวชนิดเฉียบพลันที่ได้รับยาเคมีบำบัด กลุ่มตัวอย่างคือผู้ป่วยโรคAMLที่ได้รับยาเคมีบำบัดจำนวน 40 ราย ซึ่งรับไว้ในโรงพยาบาลศิริราช โดยแบ่งออกเป็น 2 กลุ่มคือกลุ่มควบคุมและกลุ่มทดลอง โปรแกรมการดูแลช่องปากประกอบด้วยกิจกรรมการพยาบาล 3 ส่วนคือ 1) การให้ข้อมูลและฝึกทักษะการดูแลช่องปาก 2) การอมน้ำแข็งและ 3) การรับประทานอาหารเสริมกลูตามีน เก็บข้อมูลโดยประเมินสภาพช่องปากของผู้ป่วยโดยใช้ Oral Assessment Guide (OAG) เป็นเวลา 28 วัน ครอบคลุมในเรื่องจำนวนผู้ที่เกิดอาการ, วันที่เกิดอาการ, ระยะเวลาและความรุนแรงของอาการ เยื่อช่องปากอักเสบ นำมาวิเคราะห์ข้อมูลโดยใช้ร้อยละ, ค่าเฉลี่ย, Kolmogorov-Smirnov test และค่าที่

ผลการศึกษาพบว่ากลุ่มทดลองมีจำนวนผู้ป่วยที่เกิดอาการเยื่อช่องปากอักเสบน้อยกว่า, วันที่เกิดอาการช้ากว่า, ระยะเวลาที่มีอาการและความรุนแรงของอาการน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ $p < .001$ ผลการศึกษานี้สนับสนุนสมมติฐานว่าโปรแกรมการดูแลช่องปากมีประสิทธิภาพในการป้องกันอาการเยื่อช่องปากอักเสบ ช่วยชะลอวันที่เกิดอาการ ช่วยให้ระยะเวลาที่มีอาการสั้นลงและลดความรุนแรงของอาการเยื่อช่องปากอักเสบในผู้ป่วยAMLที่ได้รับยาเคมีบำบัด นอกจากนี้โปรแกรมนี้ยังสามารถนำไปประยุกต์ใช้กับผู้ป่วยอื่นๆที่เสี่ยงต่อการเกิดอาการเยื่อช่องปากอักเสบได้

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CHAPTER I

INTRODUCTION

Background and rationale

Cancer is one of the most significant health problems in the world as it is in Thailand. In Thailand, since 1996, cancer has been the third ranked cause of death behind infectious diseases and cardiovascular diseases (Chuprapawan J., 1999: 13; Ministry of Public Health, 1999: 71). Leukemia is a type of cancer has been listed as one of the significant causes of death and threatens patients both physically and psychologically. Acute myeloid leukemia (AML) is a kind of acute leukemia that often occurs in adults. Siriraj Cancer Center reported that new cases of adults diagnosed with AML in the years from 1997 to 2001 were 37, 43, 44, 69 and 48 respectively (Siriraj Cancer Center, 1997-2001). Treatment of acute myeloid leukemia (AML) patients focuses on induction of complete remission (CR). Patients usually receive chemotherapy. The induction regimen used at Siriraj Hospital is a 3+7 regimen consisting of a combination of chemotherapy with cytosine arabinoside and anthracycline, such as doxorubicin, idarubicin and mitozanthrone. Complete remission is achieved in 50-70 percent of patients. Most achieve complete remission after the first course of therapy (Intharakumthonchai T., 1999: 360). However, chemotherapeutic agents have potential benefits in killing cancer cells as well as a potentially toxic effect on normal tissue. Effective management of the expected side effects that accompany aggressive cancer chemotherapy is essential for successful treatment.

The oral cavity is a frequent site of chemotherapy-induced side effects, especially oral mucositis, also called stomatitis. The incidence of stomatitis among adult cancer patients undergoing chemotherapy is about 40 percent (Wilkes G.M. in M.B. Burke, 1996: 118; Wallace K.G., 1997: 35; McGuire D.B., 1998: 387; Faber M.R.V. in B.M. Navidjon, 2000: 311). Patients with hematological malignancies develop stomatitis more often than patients with solid tumors, perhaps because these

patients are functionally myelosuppressed as a consequence of their malignancies (Madeya M.L., 1996: 802).

From the researcher's experience working at Siriraj Hospital, it was found that there has not been a recorded incidence of stomatitis. But it was accepted that stomatitis is a common, debilitating complication of cancer chemotherapy. In a pilot study by the researcher to follow-up five leukemia patients receiving combination chemotherapy "3+7 regimen" for 4 weeks, it was found that all five patients experienced oral mucositis and ulceration. The patients often described a mucosal burning sensation within 5 to 7 days of initiation of the cytoreductive therapy. Erosion and ulceration then developed over the next 3 to 5 days and persisted for 2 to 3 weeks after cessation of cancer chemotherapy. This was consistent with the study by Toowicharanon P. (2000), which examined the effects of chemotherapy and integrated nursing interventions on oral mucositis in leukemia patients. The oral mucositis was followed up for 21 days after chemotherapy administration. It was found that all four patients in the incomplete intervention group, all five patients in the non-intervention group, and two patients from eleven patients in the intervention group developed oral mucositis and ulceration. The mean number of days for onset of mucositis was between 7.5 to 8.5 days, and for ulceration was between 8 to 9 days. Complete resolution of the ulcer varied from 5 to 19.8 days.

The risk of developing stomatitis is associated with a variety of factors for each patient e.g., types of malignancy, age, oral health status before and during therapy, nutrition status, chemotherapeutic agent, and the dosage and schedule of administration. Continuous rather than intermittent administration is more likely to cause stomatitis (Tipton J.M. and Skell R.T. in R.T. Skell (editor), 1999: 565; Madeya M.L., 1996: 801-802). Stomatitis is a dose-limiting toxicity of several chemotherapy agents. Stomatitis following cancer chemotherapy results from two mechanisms: a direct effect of the drug on the oral mucosa (direct stomatotoxicity) and an indirect result of the drug's myelosuppressive action (indirect stomatotoxicity). Direct stomatitis results from the nonspecific effects of cytotoxic drugs on cells undergoing mitosis. Chemotherapeutic agents are unable to distinguish between malignant and normal frequently dividing cells, so the mucosal stem cells are injured directly. Chemotherapy reduces the renewal rate of the mucosa and inflammation. Indirect

stomatotoxicity is a consequence of chemotherapy-induced myelosuppression. Chemotherapeutic agents given to AML patients, such as cytosine arabinoside, doxorubicin, idarubicin and mitozanthrone cause neutropenia and thrombocytopenia. The two most common forms of indirect stomatotoxicity are infection and hemorrhage (Madeya M.L., 1996: 802; Miller M. and Kearney N., 2001: 242; Quilitz R., 2002).

There is evidence of the beginning of tissue damage 5-7 days after chemotherapy administration: this may be pale, dry mucous membrane, burning sensation, dry tongue with raised papillae and ridging of buccal mucosa. This damage may progress to severe inflammation and ulceration with pain. The problems associated with stomatitis are ulceration, pain, decreasing ability to take fluids or food, and chewing, swallowing and taste alteration. For this reason, stomatitis symptoms interfere with adequate oral intake. Stomatitis may contribute to infection and may cause bleeding. AML patients are predisposed to infection caused by organisms found in both normal flora and opportunistic infection. The major pathogens involved in these infections include fungus (e.g., candida albican), viral pathogens (e.g., herpes simplex virus) and bacterial pathogens (e.g., pseudomonas aeruginosa). Infections that originate in the oral cavity are also a major concern because they may progress to systemic infection in myelosuppressed patients and cause death. Furthermore, stomatitis and pain may restrict communication with others, interfere with social interaction, and also cause psychosocial distress. Stomatitis might result in a life threatening situation, diminish quality of life, discourage the patient from continuing treatment, and increase the cost of care (Kenny S.A., 1990: 346; Faber M.R.V. in B.M. Navidjon, 2000: 313; McGuire D.B., 1998: 387).

From past experience in caring for leukemia patients undergoing chemotherapy, the researcher found that most of them were readmitted to hospital due to complications such as; malnutrition, mouth pain, fever and others. From interviewing patients, it was found most of them lack knowledge to perform the appropriate self-care activity and some of them stop the continuation of their treatment, as a result they will be readmitted again when the disease become worse.

In conclusion, stomatitis causes patients distress and also takes 2-3 weeks for a complete resolution. Treatment of stomatitis is primilary supportive. Patients with pain can be managed with local or systemic narcotic analgesics. Xylocaine viscous may be

effective but also may eliminate the sensation of swallowing. Some cases are frequently treated with multiple antibiotics. Patients with stomatitis after high dose chemotherapy frequently require parenteral nutrition due to prolonged inability to eat. These patients may be suffering from the side effects of the analgesic or antibiotics. Therefore, to prevent stomatitis it is necessary for patients to have proper oral assessment and care and to receive relevant information. This approach allows the patients to receive appropriate nursing intervention and will ultimately lead to improvement in the quality of life of AML patients. Nurses occupy a key position in caring for patients and one independent role of nursing is to help individuals to manage unwanted symptoms by education and support according to their needs.

For the reasons mentioned above, it is therefore extremely important that stomatitis be prevented whenever possible, or at least treated to delay its onset, to shorten its duration, and to reduce its severity and possible complications in acute myeloid leukemia patients undergoing chemotherapy. It was found that currently nurses are responsible for a significant increase in the prevention of stomatitis. The researcher was interested in using the supportive-educative nursing care as an intervention and it was selected in order to enhance the knowledge and self-care behaviors of leukemia patients who are receiving chemotherapy to help them perform self-care activities in an appropriate way and right direction. Nurses are well positioned to stimulate and support people's self-care efforts by provision of their knowledge, experience and accessibility. An oral care program was developed and is based on the supportive nursing care, which was developed from Orem's self-care theory, standard nursing care, research utilization and new insights into the pathophysiology of chemotherapy-induced stomatitis. The literature review of interventions for chemotherapy induced stomatitis reveals three distinct groups of studies: a variety of systematic oral care protocols, oral cryotherapy, and oral supplementation of glutamine.

The researcher believed that this method has the potential to increase and equip patients properly with knowledge and to achieve self-care behaviors. Thus, AML patients should develop stomatitis decrease or not have stomatitis totally. At the least, the program should delay its onset, shorten its duration and lessen its severity.

Furthermore, this program may enhance the past studies and confirm the effects of the stomatitis prevention strategies.

Research questions

1. Did the oral care program lower the number of stomatitis cases among acute myeloid leukemia patients, undergoing chemotherapy?
2. Did the oral care program delay the onset of stomatitis in acute myeloid leukemia patients undergoing chemotherapy?
3. Did the oral care program shorten the duration of stomatitis in acute myeloid leukemia patients undergoing chemotherapy?
4. Did the oral care program lessen the severity of stomatitis in acute myeloid leukemia patients undergoing chemotherapy?

Purposes of the study

1. To compare the number of acute myeloid leukemia patients undergoing chemotherapy who developed stomatitis between the group who participated in the oral care program and the group who received routine nursing care.
2. To compare the onset of stomatitis in acute myeloid leukemia patients undergoing chemotherapy between the group who participated in the oral care program and the group who received routine nursing care.
3. To compare the duration of stomatitis in acute myeloid leukemia patients undergoing chemotherapy between the group who participated in the oral care program and the group who received routine nursing care.
4. To compare the severity of stomatitis in acute myeloid leukemia patients undergoing chemotherapy between the group who participated in the oral care program and the group who received routine nursing care.

Conceptual framework

AML patients undergoing chemotherapy are on continuing treatment; however, it will also have an effect on patients' both physical and psychological aspects. Effective management of the expected side effects that accompany aggressive cancer chemotherapy is essential for successful treatment. Thus, the patients need advice how

to do and care on their own for preventing further deviations of oral health and complication that could be occurring. If the patients were lack of knowledge on the drugs' side effects and self-care activities, this may be effect on the effectiveness of treatment and their safety. Self-care is the practice of activities that individuals perform on their own behalf in maintaining and preserving life, health and well-being (Orem, 1995: 104). It is a learned behavior with action and is goal oriented. In leukemia patients undergoing chemotherapy, self-care should aim to promote health and well-being, prevent and decrease complications, prevent recurrences and improve disease free-survival. Orem's theory addresses three nursing systems: wholly compensatory, partly compensatory and supportive-educative.

In this study, the researcher applied the supportive-educative nursing system in the oral care program for AML patients undergoing chemotherapy. For the supportive part, the researcher provided alternative strategies including oral cryotherapy and oral supplementation of glutamine. The researcher prepared the ice chips and oral supplementation of glutamine for every participant. For the educative part, the researcher provided the information and trained the patients in oral care skills. Then, every patient performed oral care strategies themselves. The oral care program included the three aspects of:

1. Providing information and training in oral care skill

Oral care of patients receiving chemotherapy is a major focus for nurses because stomatitis is a frequent and distressing side effect. Existing research does not provide evidence of scientifically based effective oral care regimens. Published reports comment on the use and efficacy of oral care protocol, but do not offer detailed guidance because agents used and frequency of administration varies greatly. Because of this, it was found that many patients must suffer from stomatitis (Coleman S., 1995: 1088; Wilkes G.M. in M.B. Burke, 1996: 120; Madeya M.L., 1996: 809; Miller M. and Kearney N., 2001:250; Armstrong T.S., 1994: 409). Dehydration, poor nutrition and poor oral hygiene impaired integrity of the oral mucous membranes. These three impairments may also be caused by the patient's inability to complete activities of daily living related to chemotherapy-induced fatigue. The oral care program is initiated before the patients begin chemotherapy for one day.

The content and procedures in the program are based on the available scientific literature. It provides only the information that is absolutely essential for patients to use in the care of their mouths. It incorporates the principle of a normal oral cavity, how to care for the mouth, how to examine their mouths and note any changes that deviate from normal. Patients are taught, supervised and evaluated (through a return demonstration) by the researcher. This approach will increase both knowledge and skills. Furthermore, patients who have both knowledge and skills adequately and appropriately, can promote their ability to adapt and learn easily so that will gain much needed confidence, encourage feelings of autonomy and allow the patients to demonstrate their ability to perform correct oral care and incorporate this care into their daily routine. When the participants performed routine oral care, good oral hygiene occurred. Oral hygiene strategies can be helpful in maintaining the moisture and softness in the mouth, removing the debris and reducing the accumulation of plaque and infection. Good oral hygiene has been shown to be important in maintaining integrity of the oral mucosa and could be a strategy to prevent stomatitis (Kenny S.A., 1990: 352).

2. Ice-chips administration, oral cryotherapy

During the patients receiving chemotherapy, continuous intravenous cytosine arabinoside, the plasma levels of cytosine arabinoside increased. Oral mucosal cells that have a high rate of proliferation increase reabsorption of cytosine arabinoside. Cytosine arabinoside reduced the renewal rate of the oral mucosal cells as the integrity of mucosal surface decreased. This can develop into localized or diffuse ulceration of the oral mucosa, and inflammation. Oral cryotherapy is a supportive nursing care provided to the patients. Oral cryotherapy should cause local vasoconstriction, thereby decreasing oral mucosal blood flow. The ice decreases circulation during peak blood flow levels of the chemotherapeutic agents. Oral mucosal cells decreasingly reabsorb cytosine arabinoside; thus, the integrity of the mucosal surface should not be reduced (Mahood, et al., 1991; Rocke, et al., 1993). Ice-chips administration is initiated when the patients begin chemotherapy on the first day until seventh day of cytosine arabinoside administration. In the first day of cytosine arabinoside administration, patients were instructed to place ice-chips in their mouths

for 5 minutes prior to starting the administration of cytosine arabinoside. Patients continuously swish the ice around in their oral cavities, and replenish the ice-chips before the previous ice had completely melted for a total of 30 minutes. In the second dose of cytosine arabinoside (Day 2) until the seventh dose of cytosine arabinoside (Day 7), patients were advised to swish the ice-chips at the same time as the first day and continuously swish the ice around in their mouth for a total of 30 minutes. Patients were asked to remove dentures, if present.

3. Oral supplementation of glutamine

Oral supplementation of glutamine is a supportive nursing care, based on Orem's nursing system theory and researches. Glutamine seems to play a major role in mucosal cellular metabolism. Providing the cells with an optimal nutrient and energy source would enhance the recovery of damaged cells from chemotherapy (Skubitz K.M., and Anderson P.M., 1996: 223-224; Ziegler, et al., 1992). Oral supplementation of glutamine and appropriate oral hygiene management maintain the integrity of the oral mucous membranes. Then oral mucosa minimizes stomatitis. Patients were advised to drink oral supplementation of glutamine initiated on the first day of chemotherapy administration and continued for 28 days. Patients were swishing and swallowing oral supplementation of glutamine. Oral supplementation of glutamine was prepared by mixing 90 grams of dried, non-fat milk or 100 grams of grinded soybean in 200 ml. of warm water. Each patient received 6 grams of glutamine per day.

As mentioned above, the three parts of the oral care program are the nursing practices, and the supportive-educative nursing care, which the researcher expected to reduce the stomatitis, to delay its onset, to shorten its duration and to reduce its severity. At the least, the oral care program may minimize the distress of stomatitis. The oral care program may be an effective guideline in the reduction and relief of stomatitis, which is one of the nursing interventions used to reduce discomfort in leukemia patients receiving chemotherapy.

The conceptual framework of this study is presented in the diagram below.

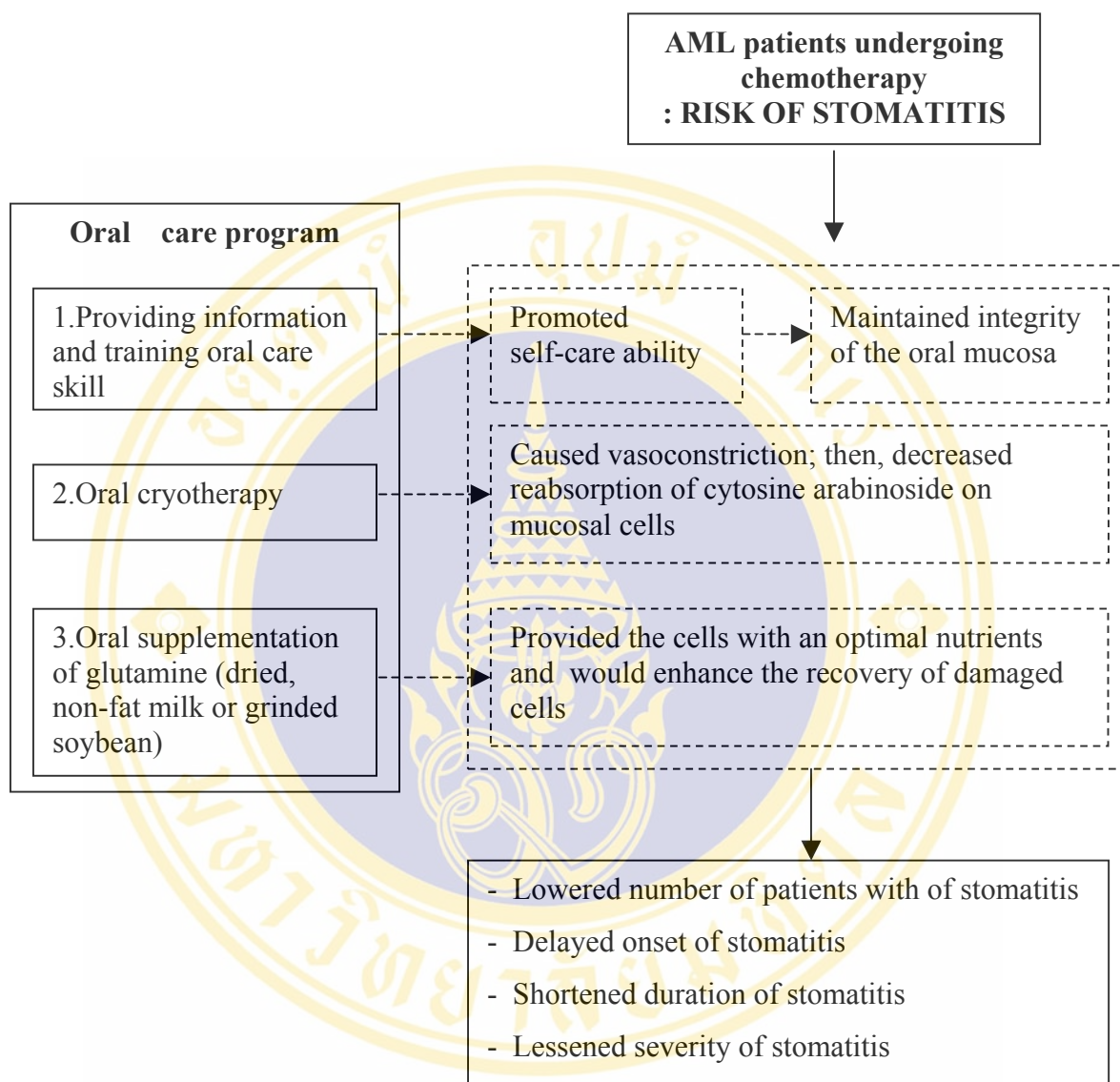


Figure 1 Conceptual framework of the study

Hypotheses

1. After receiving chemotherapy for 28 days, the number of AML patients undergoing chemotherapy who participated in the oral care program would develop stomatitis less than those who received routine nursing care.

2. After receiving chemotherapy for 28 days, the onset of stomatitis in AML patients undergoing chemotherapy who participated in the oral care program would be later than in those who received routine nursing care.

3. After receiving chemotherapy for 28 days, the duration of stomatitis in AML patients undergoing chemotherapy who participated in the oral care program would be shorter than in those who received routine nursing care.

4. After receiving chemotherapy for 28 days, the severity of stomatitis in AML patients undergoing chemotherapy who participated in the oral care program would be less than in those who received routine nursing care.

Scope of the study

This study was a quasi-experimental research to test the effectiveness of an oral care program in lowering the number of acute myeloid leukemia patients undergoing chemotherapy who developed stomatitis, in delaying its onset, in shortening its duration, and in lessening its severity. The AML patients were admitted to the Asdang building on the 6th, 9th, 10th, 11th and 12th floors at Siriraj Hospital, Bangkok. This study was undertaken from January 2003 until August 2003.

Definition of terms

Oral care program is defined as nursing intervention developed for acute myeloid leukemia patients undergoing chemotherapy. The purpose of the oral care program is to prevent stomatitis or at least minimize the effects caused by it. The success of oral care program was measured in 4 aspects including of the number of patients who developed stomatitis and by its onset, duration, and severity. This oral care program includes three aspects as follow:

1) Providing information and training in oral care skills; patients are instructed before they began chemotherapy. The content and procedures in the program are:

- The principles of a normal oral cavity
- How to care for the mouth in either normal status or abnormal status
- Effective brushing technique
- Assessment of the oral cavity and examining the mouth

2) Oral cryotherapy; placing ice-chips in the mouths for 5 minutes prior to the first dose of cytosine arabinoside, continuously swishing the ice around in the oral cavity, and replenishing the ice-chips before the previous ice has completely melted, for a total of 30 minutes. With the second dose of cytosine arabinoside (Day 2) until the seventh dose of cytosine arabinoside (Day 7), patients were advised to swish the ice-chips as on the first day and continuously swish the ice around in their mouth for a total of 30 minutes.

3) Oral supplementation of glutamine either dried, non-fat milk or grinded soybean; patients were advised to drink a glass of oral supplementation twice a day on the first day of chemotherapy administration and continued for 28 days. Patients were to swish and swallow it. Oral supplementation was prepared by mixing 45 grams of dried, non-fat milk or 50 grams of grinded soybean in 200 ml. of warm water, for a total of 6 grams of glutamine received per day. Warm water was prepared from boiled clean water and put into the clean closet until it was warm.

Stomatitis is defined as an inflammation and tissue breakdown of the oral mucous membranes and occurs as direct and indirect consequences of chemotherapy administration. Stomatitis starts with erythema and edema, and may progress to painful ulceration. The extent of stomatitis was assessed and measured according to the Oral Assessment Guide (OAG) of Eilers J., Berger A.M., and Peterson M.C. (1988) which the researcher translated into the Thai language. Stomatitis assessment included the number of patients who developed stomatitis, and its onset, duration and severity.

1) The number of patients who developed stomatitis refers to the number of AML patients undergoing chemotherapy in each group who developed stomatitis (OAG score > 8).

2) Onset refers to the first day that patients developed stomatitis which was assessed by the OAG score > 8.

3) Duration refers to the number of days that patients had stomatitis from its onset until completely resolution.

4) Severity refers to the highest score of stomatitis, which was assessed by the OAG in 28 days- study.

Routine nursing care is defined as nursing care for acute myeloid leukemia patients undergoing chemotherapy admitted at general medicine wards, Asdang 6th, 9th, 10th, 11th, and 12th floors both north and south site. It focused on keeping the mouth moist and clean. The nurses usually asked the patients about abnormal signs in their mouth including mouth pain, sores, bleeding gums, rash, pinpoint dots on the mouth or tongue, odors, dryness, white patches on the tongue and difficulty in swallowing. The patients were instructed to rinse their mouth with normal saline solution (N.S.S) frequently and gently brush their teeth, gums and tongue with fluoride toothpaste. Every patient had a bottle of N.S.S for their own use. The patients who have dentures were instructed to brush or soak dentures with clean water and change the water every 8 hours. Loose dentures can cause irritation in the mouth. If dentures are causing sores, remove the dentures until the sores have healed.

When the patients have mouth pain, the nurses advised the patients to take cotton and dip it into the normal saline solution. Gently clean their gums, teeth, lips and tongue. Lips are coated with lip creams or moisturizing creams. In generally, the nurses consulted the doctors if there is anything the patients can apply directly to the sores and if he or she can prescribe medicine to ease the pain. The doctors may prescribe medical food to maintain patients' nutritional status. Furthermore, every patient saw the dentists before started chemotherapy to assess the patient's mouth, to have their teeth cleaned and to take care of any cavities, abscesses, gum disease, or poorly fitting dentures. However, it was found that the nurses lacked of systematic oral assessment tool and routine assessment.

Expected outcomes and benefits

1. The study will increase understanding of stomatitis and could be used as a guideline for the prevention and relief of stomatitis in leukemia patients undergoing chemotherapy.
2. It will provide more basic knowledge about and management strategies for stomatitis in leukemia patients undergoing chemotherapy for nursing education.
3. The findings could provide basic information and could be used as a guideline for further related research on leukemia patients undergoing chemotherapy.

CHAPTER II

LITERATURE REVIEW

This study is concerned with the study of the effects of oral care program on stomatitis in AML patients undergoing chemotherapy. It is necessary to know about the profile of the samples, chemotherapy induced-stomatitis, self-care ability in AML patients undergoing chemotherapy and the oral care program. In order to understand the topic clearly, theoretical and empirical literature has been reviewed on the following topics:

1. Stomatitis in acute myeloid leukemia patients undergoing chemotherapy
 - 1.1 Chemotherapy administration in acute myeloid leukemia patients
 - 1.2 Risk factor for developing stomatitis
 - 1.3 Stomatotoxicity in AML patients
 - 1.4 The responses of the oral cavity
2. Self-care ability in AML patients undergoing chemotherapy
 - 2.1 Orem's self-care concept
 - 2.2 Oral care program
 - 2.2.1 Providing information and training in oral care skill
 - 2.2.1.1 Assessment of the oral cavity
 - 2.2.1.2 Oral hygiene strategies
 - 2.2.2 Oral cryotherapy
 - 2.2.3 Oral supplementation of glutamine
3. The effects of oral care program on stomatitis

1. Stomatitis in acute myeloid leukemia patients undergoing chemotherapy

Leukemia is a clonal malignant disorder of the blood and blood-forming organs (bone marrow, lymphatic and spleen). Leukemia is due to a loss of cell division, often resulting in an accumulation of abnormal amounts of dysfunctional, immature cells. The common pathologic feature of all forms of leukemias is an uncontrolled

proliferation of leukocytes. The excessive proliferation of the leukemia cells results in an overcrowding of bone marrow, which causes a decreased production and function of normal hematopoietic cells (Mansen et al. In K.L. McCance and S.E. Huether, 1997: 904).

Leukemias are classified as chronic or acute and as either myeloid or lymphoid. The classification system for leukemia is based on structure, number of cells, genetics, identification of surface markers, and histochemical staining. These findings produce important therapeutic and prognostic information (Wujcik D. In S.L. Groenwald, M.H. Frogge, M. Goodman and C.H. Yarbro (Editors), 1993: 1150).

Predominant cell type and the rate at which the affected individual develops clinical symptoms classify the two major forms of leukemia, acute and chronic. The acute leukemias are marked by an abnormal proliferation of immature blood cells with a short natural history (1-5 months). While the chronic leukemias have an excessive accumulation of more mature-appearing but still ineffective cells and a slower progressive course (2-5 years) (Manson et al. In K.L. McCance and S.E. Huether (Eds.), 1997: 904; Wujcik D. In S.L. Groenwald, M.H. Frogge, M. Goodman and C.H. Yarbro (Eds.), 1993: 1150; Crouch M.A. In B.M. Nevidjon and K.W. Sowers (Eds.), 2000: 165).

Acute myelogenous leukemia (AML), also referred to as acute nonlymphocytic leukemia (ANLL or acute myeloid leukemia), is a disease of the pluripotent myeloid stem cell. The malignant clone arises in the myeloid, monocyte, or megakaryocyte lines. The incidence of AML is about 2 to 3 per 100,000 populations per year and increases steadily with age. The median age is 55 to 60 years. There is evidence that AML is associated with certain congenital chromosomal abnormalities such as Down syndrome, Bloom's syndrome, and Fanconi's anemia. Patients with other acquired diseases such as myelodysplastic syndromes, myeloproliferative disorders, and other preleukemic states also have an increased incidence of AML (Crouch M.A. In B.M. Navidjon and K.W. Sowers (Eds.), 2000: 165).

In addition, varieties of environmental factors, both work and treatment related, are known to cause AML. These include exposure to ionizing radiation; chemical exposure to benzene, possibly hydrocarbons, and solvents; and treatment with alkylating agents (e.g. melphalan, cyclophosphamide), and treatment with other drugs

(e.g., Chloramphenicol). In addition, epidemiological research is investigating exposure to various viruses as a potential precursor to AML (Chaney & Jassak cited in M.A. Crouch, 2000: 165-166).

A simplified version of the FAB (French–American–British Co–operative group) classification system is as follows: (Karanes C. and Lachant N.A in R.T. Skell, 1999: 406).

- M0: Myelocytic leukemia without maturation
- M1: Myelocytic leukemia with minimal differentiation
- M2: Myelocytic leukemia with maturation
- M3: Promyelocytic leukemia
- M4: Myelomonocytic leukemia
- M5: Monocytic leukemia
- M6: Erythroleukemia leukemia
- M7: Megakaryoblastic leukemia

1.1 Chemotherapy administration in acute myeloid leukemia patients

The goal of antileukemic treatment for AML is the eradication of the leukemic stem cell. The most important factor in determining survival of AML patients is a complete remission. Complete remission (CR) is defined as the restoration of normal peripheral blood counts, the presence of less than 5% blasts in the bone marrow, and any preexisting adenopathy or organomegaly must be absent. Treatment regimens capable of inducing a complete remission are composed of several drugs, each of which is known to be effective against leukemic myeloblasts.

The course of chemotherapy is divided into two stages: (1) induction to attain a remission and (2) postremission. The goal of remission induction therapy is to eradicate the malignant clone of leukemic blast cells and allow restoration of normal hematopoiesis. Chemotherapy often given as induction therapy for AML is called “3+7 regimen.” It includes a combination of a 7-days of cytarabine (100-200 mg/m²/24 hours) administered by continuous infusion with 3 days of an anthracycline intravenous bolus on day 1 to 3, either doxorubicin, idarubicin, or mitozantrone. The continuous infusion of cytarabine ensures that slowly cycling leukemia cells are adequately exposed to the drug during the synthesis phase of the cell cycle. This

protocol is called “3+7,” but variations include 5-day or 10-day infusion of cytarabine. Complete response rates are now observed in 65% - 80% of patients. Relapse occurs in the remaining cases within 1-2 years. Thus, postremission therapy is essential.

The fact that most patients with AML relapse despite attaining a CR suggests that further postremission therapy is indicated to attempt to eradicate the residual but undetected leukemic clone. Postremission therapies include consolidation, intensification and maintenance. Consolidation therapy refers to therapy given shortly after induction and usually consists of one or two courses of very high doses of the same drugs used for induction. Intensification may be initiated right after remission induction (early intensification) or several months later (late intensification). Different drugs are used with the hope that they will be non-cross-resistant with the induction drugs. Maintenance therapy is treatment with lower doses of the same or other drugs given monthly for a prolonged period of time. (Cheson B.D. In J.S. Macdonald, D.G. Haller and R.J. Mayer (Eds.), 1995:272-275; Wujcik D. In S.L. Groenwald, M.H. Frogge, M. Goodman and C.H. Yarbrow (Eds.), 1993: 1156-1158; Rohatiner A.Z.S. and Lister T.A. In E.S. Henderson and T.A. Lister (Eds.), 1990: 487-499; Crouch M.A. In B.M. Navidjon and K.W. Sowers (Eds.), 2000: 166-167; Karanes C. and Lachant N.A. in R.T. Skell, 1999: 411-423)

Chemotherapeutic regimens often used in AML patients at Siriraj hospital are cytarabine 100 to 200 mg/m²/24 hours continuous infusion on day 1 to day 7, and an anthracycline intravenous bolus on day 1 to 3, either doxorubicin 30-50 mg/m², idarubicin 12 mg/m², or mitoxantrone 12 mg/m².

- **Cytarabine**

Cytarabine (9-β-D-arabinofuranosyl cytosine, cytosine arabinoside, ara-c, and cytosar-u) is a pyrimidine analog antimetabolite that, when phosphorylated to arabinosyl-cytosinetriphosphate (ara-CTP), is a competitive inhibitor of DNA polymerase (Skell R.T., 1999: 94). By deactivating the synthesis of DNA, cytarabine prevents the cells from replicating. Cytarabine is considered to be cell cycle phase-specific and work most often during S phase of the cell cycle. It works best in rapidly dividing cells and fast-growing tumors (Painter J. In B.M. Navidjon, 2000: 201). Oral administration is not effective because of extensive and rapid deamination within the

gut, with less than 20% systemic availability. After intravenous bolus administration, cytarabine is rapidly cleared with biphasic elimination: the initial half-life is 7-20 minutes, while the terminal half-life has been estimated to range from 0.5-2.5 hours. During continuous intravenous administration, steady-state plasma levels of Ara-c increase linearly up to about 5 μM (the range achieved with 100 $\text{mg}/\text{m}^2/\text{hour}$); therefore, deamination is saturated and plasma levels can increase unpredictably (Grem et al In J.S. Macdonald, D.G. Haller and R.J. Mayer, 1995: 117). The most common side effects with cytarabine are stomatitis, myelosuppression, anorexia, nausea, vomiting, alopecia and changes in skin and nails. Conventional doses of cytarabine, 100 to 200 mg/m^2 daily for 7 days as a continuous intravenous infusion, are primarily used in induction therapy of AML.

- **Doxorubicin**

Doxorubicin is an anthracycline glycoside antibiotic. It forms a complex with DNA by intercalation between base pairs, leads to the formation of free radicals, and inhibits topoisomerase II. All of which contribute to inhibition of DNA synthesis and DNA-dependent RNA synthesis. It is a cell cycle phase-non-specific agent. It is widely distributed in plasma and tissues, with a triphasic plasma clearance: 12 minutes, 3.3 hours and 30 hours. The usual doses are 60 to 75 mg/m^2 given intravenously every 21 days for a single dose or 30 to 50 mg/m^2 when combine with other agents. The major acute dose-limiting toxicity is hematological; leukopenia has a median nadir at 10 to 15 days. Stomatitis occurs uncommonly with single-dose administration but more frequently on multiple-day schedules. Other side effects are nausea, vomiting, alopecia, hyperpigmentation of the skin, both acute and chronic cardiac toxicity (Grem et al In J.S. Macdonald, D.G. Haller and R.J. Mayer, 1995: 99-100; Skell R.T., 1999: 100).

- **Idarubicin**

Idarubicin (4-demethoxydaunorubicin, IDA, idamycin) is an analogue of daunorubicin, lacking the methoxyl group of the C-4 position of the aglycone. It has a higher therapeutic index than either doxorubicin or daunorubicin. The drug binds to DNA with a marked inhibitory effect on nucleic acid polymerases. It is also a potent inhibitor of topoisomerase II and this along with its ability to form

free radicals certainly contributes to cytotoxicity. Following rapid intravenous injection, the plasma disappearance of idarubicin is triphasic and similar to that seen for doxorubicin, with a terminal half-life of approximately 22 hours. Activity against AML has been shown both as a single agent and in combination with other chemotherapeutic agents. In combination with ara-c in the induction therapy of AML, a dose of 12-13 mg/m² daily for 3 consecutive days; 10-12 mg/m² intravenous daily for 2 days during consolidation. Idarubicin by injection at equally myelosuppressive doses causes less severe nausea, vomiting, alopecia, and mucositis than doxorubicin or daunorubicin, mucositis is common but usually not severe (Grem et al In J.S. Macdonald, D.G. Haller and R.J. Mayer, 1995: 98-99; Skell R.T., 1999: 111).

- **Mitozantrone**

Mitozantrone (novantrone, dihydroxyanthracenedione, DHAD, DHAQ) is a synthetic anthracenedione that has a symmetrical structure consisting of a tricyclic planar chromophore and two basic side chains. Mitozantrone inhibits the activity of topoisomerase II. As a consequence, the drug causes DNA interstrand and intrastrand crosslinking and DNA-protein crosslinks, and inhibits both DNA and RNA synthesis. It is cytotoxic against both cyclic and nonproliferating cells, although rapidly proliferating tissues are more sensitive. It can induce cell cycle arrest in G2 phase. It has rapid initial half-life (ranging from 2.4-15 minutes) due to distribution of drug into erythrocytes, leukocyte, and platelets. The β phase ranges from 17 minutes to 3 hours, and is believed to result from redistribution of drug from blood cells and into various tissues. The terminal half-life is long, and has been reported to vary from 3 to 12 days. Mitozantrone is approved for use in combination with cytarabine in remission induction for AML; the usual dose is 12 mg/m² daily for 3 consecutive days. The principle toxicity of mitozantrone is myelosuppression; granulocytes are primarily affected with a median nadir at day 12. Thrombocytopenia is relatively mild. Other toxicities include nausea, vomiting (mild to moderate), alopecia, occasional mucositis, and, more rarely, elevations in liver function test. One of the major, long-term toxicity is cardiac toxicity (Grem et al In J.S. Macdonald, D.G. Haller and R.J. Mayer, 1995: 106-107; Skell R.T., 1999: 122).

1.2 Risk factor for developing stomatitis

Mucositis refers to an inflammation of the mucous membranes and/or ulceration and destruction of the mucosal cells in the body (Faber M.R.V. in B.M. Navidjon, 2000: 311). Mucositis is further specified as to its anatomic location: when occurs in the oral cavity, it is called *stomatitis*; in the esophagus, *esophagitis*; in the intestine, *mucositis* is usually manifested by diarrhea; and in the rectum, *proctitis* (Wilkes G.M. in M.B. Burke, 1996: 116). Approximately 40% of patients who received chemotherapy develop stomatitis (Wilkes G.M. in M.B. Burke, 1996: 118; Wallace et al, 1997: 35; McGuire et al, 1998: 387; Faber M.R.V. in B.M. Navidjon, 2000: 311; Roger B.B., 2001: 745).

The many risk factors for developing stomatitis can be placed in four major categories: (1) cancer and its treatment, (2) side effect of disease and treatment, (3) other medical interventions, and (4) irritants (Faber M.R.V in B.M. Navidjon, 2000: 311-313).

1.2.1 Cancer and its treatment

Cancer itself causes disruptions in the integrity of the mucous membranes. Mucous membranes serve as the body's natural barrier against infection. Once a membrane is inflamed, it is more prone to infection. Much more common causes of stomatitis are the treatments utilized to fight cancer, including chemotherapy, radiation and bone marrow transplantation.

Chemotherapy effects are seen in all rapidly reproducing cells, as it interferes with cellular DNA, RNA, or protein synthesis. This interference causes a decrease in production and differentiation of the mucosal cells and promotes the early demise of the current epithelial cells. These factors impair the integrity of the membrane, which allows infection to occur. The peak effect of the chemotherapy on the mucosal cells is seen approximately 7 to 10 days after treatment. This is the same time during which the chemotherapy has its peak effect on the white blood cell count. This lowered white blood cell count (nadir) further increases the risk for infection, as the body is less able to fight against infecting agents.

Chemotherapy could categorized by toxic to the mucous membrane as follow: the antimetabolites (e.g., 5-FU, methotrexate, 6-MP, 6-TG and cytosine arabinoside),

antibiotics (e.g., actinomycin D, doxorubicin, idarubicin, daunomycin, mitoxantrone, bleomycin sulfate and mitomycin C), alkylating agents (e.g., cyclophosphamide), and plant alkaloids (e.g., vinblastine and vincristine) (Rogers B.B., 2001: 747; Faber M.R.V. in B.M. Navidjon, 2000: 313).

1.2.2 Side effects of disease and treatment

Dehydration, poor nutrition and poor oral hygiene are among the side effect of cancer due to the discomfort associated with the impaired integrity of the oral mucous membranes. These three impairments may also be caused by the patient's inability to complete activities of daily living related to chemotherapy-induced fatigue. Dehydration causes dryness and cracking of the lips and mucous membranes, which increase the chance of infection and inflammation. Poor nutrition delay wound healing and increases the chance of infection. Poor oral hygiene can lead to infection due to the increased chance for bacteria to breed. Good oral hygiene actually stimulates circulation in the mouth, decreasing the chance for infection.

1.2.3 Other medical interventions

Patients who are on oxygen therapy during their cancer treatment may need humidified oxygen to prevent drying of the mucous membranes. Many patients take medications that can increase their risk for stomatitis. For example, anticholinergics and antihistamines can dry the mucous membranes, which promotes in these categories, if possible; otherwise, be sure that the patient is performing careful and frequent mouth care.

1.2.4 Irritants

Alcohol; cigarette and cigar smoke; hot, acidic, and spicy foods; and ill-fitting dental appliances, among other things, are irritants for everyone. Cancer patients, however, are more susceptible than most people to irritation of the mucosa, which leads to inflammation and increases the risk of infection (Faber M.R.V. in B.M. Navidjon, 2000: 311-313).

Not only that, patients with hematological malignancies develop stomatitis more often than patients with solid tumors, perhaps because these patients are functionally myelosuppressed as a consequence of their malignancies. Patients younger than age 20

tend to develop oral complications more frequently than older patients. This may be attributable to the higher incidence of hematological malignancies in the younger group and the decreased rate of cell renewal in older patients. Concomitant diseases (e.g., diabetes, AIDS, cardiovascular disease, kidney disease) also may increase the risk (Madeya M.L., 1996: 802).



Figure 2 Physiological components of oral mucosa (from Armstrong T.S., 1994: 404)

A baseline understanding of mucosal cell reproduction is important in understanding how cancer and its treatment cause stomatitis. The lining of the oral cavity is composed of three layers (Figure 2). The inner layer is termed the submucosa and is composed of connective tissue that varies in thickness in accordance with the

function of specific anatomic site. The lamina propria consists of fibrous fingerlike projections that extend into the epithelium and contain the blood vessels, nerves and glandular ducts. The outer layer consists of stratified, squamous epithelium. The outer and middle layers are separated by a basement membrane. It is at this junction that stem cells of the deepest layer of the squamous epithelium replicate. The epithelial cells lining inside of the mouth renew rapidly which enables them to replace cells lost from general “wear and tear.” These cells have a life span of 7 days with the outer epithelial layer being entirely replaced every 7 – 14 days. Due to the high proliferation rate, cells of the oral mucosa are particularly vulnerable to attack by cancer chemotherapeutic agents (Armstrong T.S., 1994: 404–406; Faber M.R.V in B.M. Navidjon, 2000: 311).

1.3 Stomatotoxicity in AML patients

Chemotherapy can damage the oral mucosa through direct or indirect toxicity as follow: (Rogers B.B., 2001: 747-748; Faber M.R.V. in B.M. Navidjon, 2000: 313; Wilkes G.M. in M.B. Burke, 1996: 118; Madeya M.L., 1996: 802-803; Miller M. and Kearney N., 2001:242).

1.3.1 Direct stomatotoxicity

Direct stomatotoxicity, a direct effect of the drug on the oral mucosa, results from the nonspecific effects of cytotoxic drugs on cells undergoing mitosis. Many of the chemotherapeutic agents interfere with DNA, RNA, or protein synthesis and cause destruction of cells that are reproducing actively. Cells that have a high rate of proliferation are particularly sensitive to the direct effect of the antineoplastic agents. Chemotherapeutic agents reduces the renewal rate of the basal epithelium cells that results in epithelium thinning, mucosal atrophy, localized or diffuse ulceration of the oral mucosa, and inflammation. The cytotoxic agents primarily associated with stomatitis are mentioned above. The drugs are unable to differentiate between a malignant cell and a normal proliferative cell. Because of this, they interrupt the division of all rapidly dividing cells. The period of greatest damage to the oral mucosa frequently correlates with the white blood cell nadir because gastrointestinal epithelial cells have a cell turnover rate similar to that of leukocytes. Visible signs of inflammation and ulceration can be observed 7-14 days following therapy, prior to the

granulocyte nadir. The secondary effects of stomatitis, such as reduced oral intake and subsequent protein deprivation, increase the severity of stomatitis and decrease patients' healing capacity.

1.3.2 Indirect stomatotoxicity

Indirect stomatotoxicity, an indirect result of the drug's myelosuppressive action, is the result of the effects of chemotherapy on the cells of the bone marrow rather than the oral mucosa. During this time the individual's immune system is suppressed and susceptible to infection. Patients with hematological malignancies or those who have received intensive chemotherapy are most likely to become neutropenic. Indirect stomatotoxicity is associated with the white blood cell count nadir following chemotherapy and most often occurs 12-14 days after drug administration. Neutropenia can be caused by cell loss during maturation, reduction in precursor-cell proliferation, and adhesion of leukocytes to walls of blood vessels during the first stage of inflammation. Because of leukocytes and oral mucosal cells have similar rate of renewal alterations in the oral cavity correlate with the onset of myelosuppression. Stomatitis is observed near the nadir of the leukocytes with subsequent resolution preceding recovery of the bone marrow.

The two most common forms of indirect stomatotoxicity are infection and hemorrhage. Profound granulocytopenia permits oral infections by gram-negative bacilli, gram-positive cocci, fungi such as candida species, and viruses (particularly herpes simplex). These infections usually occur at the site of direct stomatitis or other oral trauma. Alterations in the integrity of the oral mucous membrane and the remainder of the digestive tract provide an entryway for microorganisms. The entry of the microorganisms into the body provides the potential for a systemic infection that spreads through the bloodstream from a local infection in the mouth. As the immune status of the individual is compromised, the likelihood of the oral cavity serving as a portal of entry for a life-threatening systemic infection increases. A patient with thrombocytopenia is at risk for spontaneous bleeding from oropharyngeal ulceration. Stomatotoxicity in AML patients showed in Figure 3

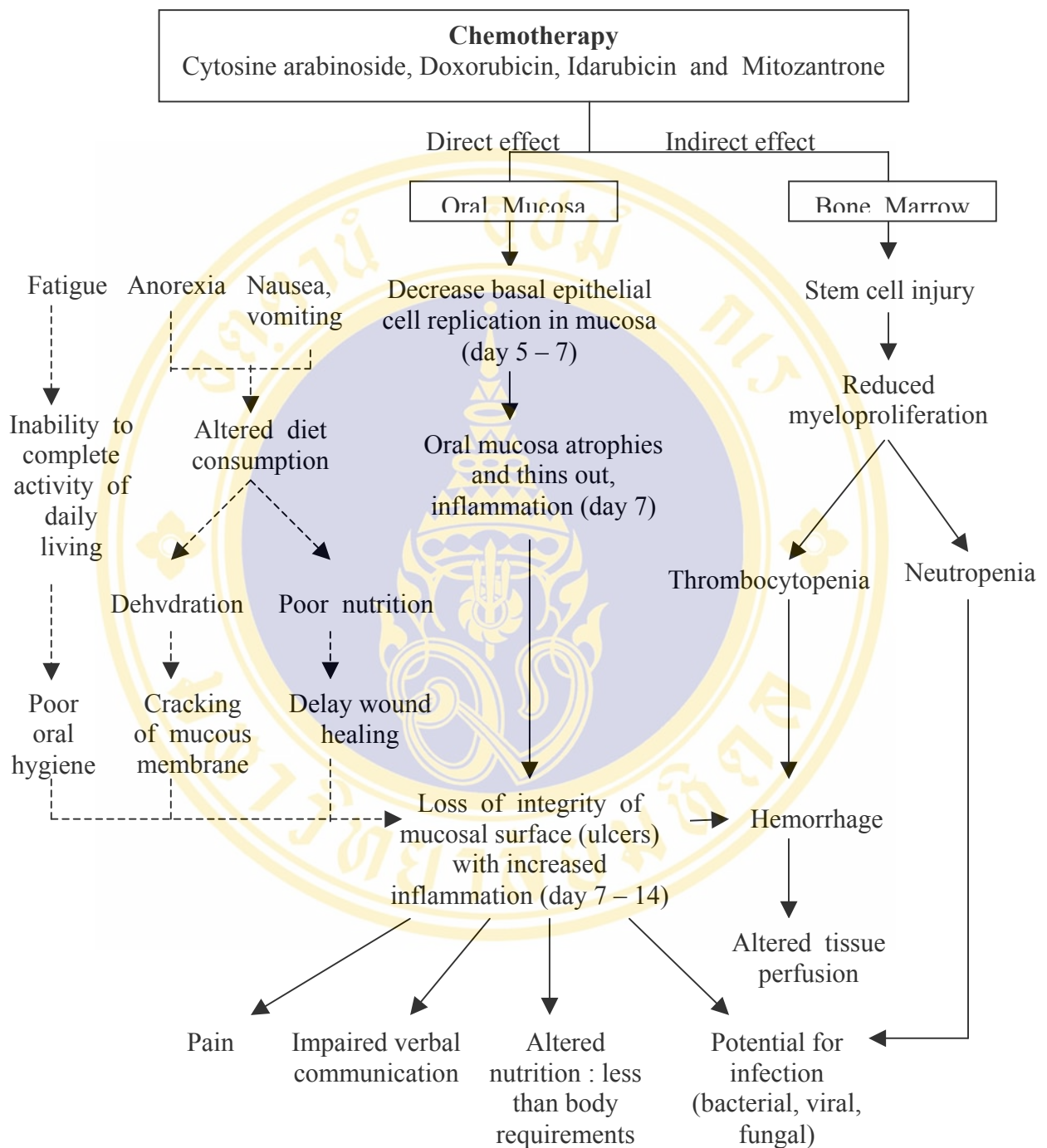


Figure 3 chemotherapy induced-stomatitis (adapted from Madeya M.L., 1996: 802; Wilkes G.M. in M.B. Burke, 1996: 118; Faber M.R.V. in B.M. Navidjon, 2000: 313)

1.4 The responses of the oral cavity

By utilizing a stress response model to describe the responses of the oral cavity from chemotherapy, those are the phases of Alarm, Resistance, Exhaustion, and Recovery. (Wilkes G.M. in M.B. Burke, 1996: 117; Madeya M.L., 1996: 803-804).

The normal healthy oral mucosa is moist, pink, clean, intact mucosa, absence of pain, burning or altered taste perceptions and normal salivary response. During the alarm phase, mild dysfunction phase, the body activates the sympathetic response. The sympathetic response to the stressor of cancer treatment results in pale, dry oral mucosa, a red and enlarged uvula, a dry tongue with raised papillae, and dry lips. Saliva production may increase in an attempt to provide the area with fluid.

Without intervention, the alarm phase quickly progresses to the resistance phase, adaptation or moderate dysfunction phase. During this phase, the body activates the parasympathetic response. Saliva secretion decrease, the oral mucosa becomes red, dry, and wrinkled, and the tongue appears swollen with inflamed papillae. A white coating develops on the tongue to protect the surface. An inflammatory line of demarcation may develop on the tongue, separating damaged tissue from healthy tissue, and blisters may be evident. Adaptation continues until the adaptive reserves are depleted and exhaustion sets in.

The persistent attack from multiple stressors weakens the body's defense to the extent that is cannot adjust further. During the phase of exhaustion, the oral mucosa, tongue, and lips become painfully inflamed, edematous, and ulcerated. Saliva, if present, is thick and ropery. The tongue is dry and may be coated and blistered, bleeding may occur from cracks on the lips and sores on the palate and buccal mucosa. Exhaustion increases the potential for infection and bleeding. The patients experience pain from stomatitis and ulceration. The buccal, labial, soft palatal mucosa, ventral surface of the tongue, and floor of the mouth are most commonly affected. Less commonly involved structures include the hard palate, gingivae, and dorsal surface of the tongue. Painful swallowing and changes in taste perception create significant alterations in nutrition status.

Lastly, the recovery phase, the stomatitis and ulceration improved. Then if no complication on extension occurs, healing takes place over a period ranging from

several days to several weeks (Wilkes G.M. in M.B. Burke, 1996: 117). The inflammation and pain resolved. Recovery occurs within 2-3 weeks without scarring.

Figure 4 illustrates the development of stomatitis utilizing a stress response model. The phases of Alarm, Resistance, Exhaustion, and Recovery are represented over a span of 21 days.

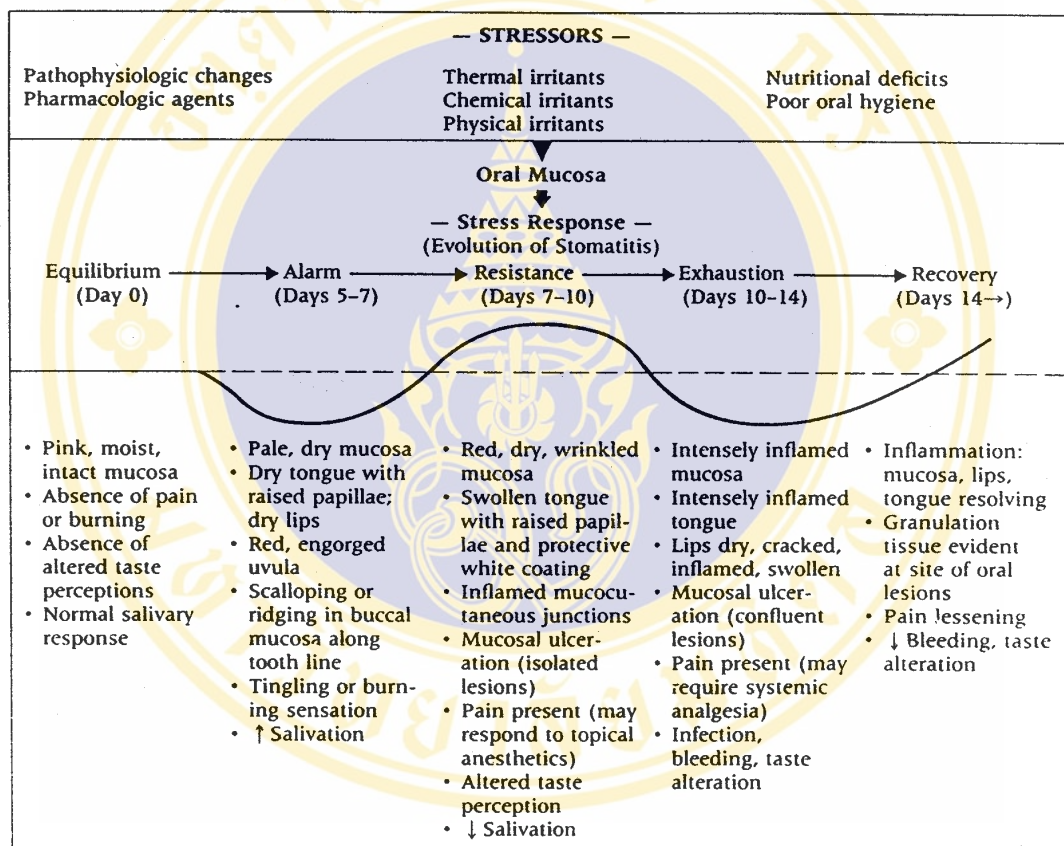


Figure 4 Oral mucosa response to physiological stressors (from Wilkes G.M. in M.B. Burke, 1996: 117).

If stomatitis is not prevented, the problems associated with stomatitis are ulceration, pain, local infection, and decreased ability to take food or fluids, chewing, swallowing and taste alteration. The patients may complain of sensitivity to heat and cold, and to salty and spicy food. Stomatitis can affect the taste receptors and cause unpleasant taste sensations (dysgeusia) or the absence of taste sensations (ageusia).

Xerostomia, or dry mouth, also can occur as a result of stomatitis. The overall impact of these symptoms is altered nutritional status because of the difficulty in taking in adequate nutrients. Stomatitis causes severe pain and distress. Oral pain caused by stomatitis from intensive cancer chemotherapy affects most of patients. This pain can be severe, inhibit nutrition intake, restrict communication with others, and interfere with social interaction and cause psychosocial distress.

Furthermore, patients with damaged oral mucosa and reduced immunity resulting from chemotherapy are prone to opportunistic infections in the mouth and can increase the patients' susceptibility to systemic infection. As the nadir occurs, neutropenia increases the risk of super-infection by normal oral flora. Once injury to the mucosa has occurred, cause infection by bacterial organisms (e.g., gram-positive, gram-negative, and anaerobic organisms), fungal organisms (e.g., candida species), or viral organisms (e.g., herpes simplex virus, cytomegalovirus, varicella zoster or Epstein-Barr virus). The entry of the microorganisms into the body provides the potential for a systemic infection that spreads through the bloodstream from a local infection in the mouth. As the immune status of the individual is compromised, the likelihood of the oral cavity serving as a portal of entry for a life-threatening systemic infection increases. Infection can delay cancer treatment, necessitate a dose reduction, thus jeopardizing treatment effectiveness, prolong hospitalization, increase cost of care and diminish the quality of life.

Stomatitis may compromise patients' response to treatment and/or palliative care. The physician may decide to suspend chemotherapy or to reduce the dosage. This problem may limit the tolerability of chemotherapy, hence its effectiveness and lead to significant compliance problem, often discouraging the patient from continuing treatment. This may have an unfavorable effect on the patient's treatment success. (Kenny S.A., 1990:346; Zerbe et al, 1992: 196-197; Nieweg et al, 1992: 313-314; McGuire et al, 1993: 1494; Wallace et al, 1997: 35; McGuire et al, 1998: 386; Larson et al, 1998: 263; Faber M.R.V. in B.M. Navidjon, 2000: 311; Rogers B.B., 2001: 745-746).

2. Self-care ability in AML patients undergoing chemotherapy

2.1 Orem's self-care concept

Orem's theory should be seen as the “glue” that provided the intervention with a clear structure to make the nursing care given effective and to facilitate descriptions of outcomes. It consists of six core concepts: self-care, self-care agency, therapeutic self-care demand, self-care deficit, nursing agency and nursing system. The nursing methods include the provision of a supportive environment, physical and psychological comforting, and instructions on guiding/ acting/ doing for the patient.

According to Orem (1991: 117), self-care is the practice of activities that individuals initiate and perform on their own behalf in maintaining life, health and well-being. Orem states that health and well-being are interrelated in the sense that well-being when associated with health includes success in personal endeavors and sufficiency of resources. Health is characterized by development as a human being, with bodily and mental functions while well-being concerns spiritual experiences, pleasure, and personal fulfillment. Patients undergoing chemotherapy may experience these elements of well-being under adverse conditions. Chemotherapy nursing care should be aimed at enhancing well-being and quality of life for the patient and family.

Self-care agency is the capability of an individual to perform their own self-care to meet the everyday requirements for care that promotes life, health, and well-being. In chemotherapy, nurses should encourage patients to maximize their self-care agency, since they to a large extent become mainly responsible for their own self-care.

Self-care deficit refers to the relationship between therapeutic self-care demands and self-care agency/action. For example, temporary limitations such as an illness or treatment may cause self-care ability to fall short of the demands for self-care. The limitations may be due to lack of knowledge, skill, motivation or basic conditioning factors such as loss of awareness of self and environment. In chemotherapy nursing it is important for the nurse to assist the patient or the family to identify existing self-care deficits. This approach to care can be used to establish reasonable and appropriate care regimens for the patient.

Orem (1995: 108-109) defines therapeutic self-care demand as activities during a period of time or at specific times for meeting known self-care needs to maintain

health and to promote well-being. Three types of self-care requisites are defined: universal, developmental and health deviation as follow:

1. Universal self-care requisities, which are commonly practiced to all human being during all stages of life cycle, adjusted to age, developmental stage, environment and other factors. There are associated with life process, such as the maintenance of the integrity of human structure and functioning, and general well-being. Universal self-care requisities are the self-care method for promoting and maintaining individual health such as air, water, food condition, balancing daily activities and the rest, balancing single way of life and relation with others, dangerous prevention, promoting welfare and development.

2. Developmental self-care requisities, which are associated with human developmental process, conditions and events that can adversely affect the development. Developmental self-care requisities are the self-care that occurs in developmental stage in human being such as the development and existent for promotion life process, the relation with entertainment.

3. Health-deviation self-care requisities, which are associated with genetic and constitutional defects, human structure, and functional deviations and their effects of medical diagnosis and treatment measures. Health-deviation self-care requisities are the self-care which occur to cripple with abnormal structural and dysfunctional such as seeking for the help, practice under remedy plan diagnosis, rehabilitation, perceive and prevent the side effects of chemotherapy. In chemotherapy nursing the nurse must assess, plan and provide care that is aimed at overcoming the disruption disease and treatment causes health and human development, to liberate the patient as soon as possible from dependence on others.

Orem (1995) considers nursing as a helping service. Nurses assess whether self-care deficits exist. Nursing agency is the power or capacity the nurse has to act, to know, and to help patients meet their therapeutic self-care demands. The nurse assists the patient to minimize or eliminate self-care requisites to promote the latter's self-care agency. The helping methods include acting or doing for others, guiding, physical and psychological support and maintaining an appropriate developmental environment and teaching. The goal of the nursing care is to move patients toward normalcy or full integrity. For the patient undergoing chemotherapy, this move toward normalcy can

consist of easing the suffering from severe side effects while promoting self-care agency and working toward minimizing any self-care deficit.

Following Orem's concept of self-care, it is believed that human beings have the ability to learn, to decide and to have the potential to perform the self-care activities by themselves. Self-care is one of learning behavior, which can be able to develop the people who received the self-care information and health deviation. When the capacity of nursing decreases, it is unavailable to serve as the self-care; therefore, the self-care deficit occurs. The self-care agency must be done.

Nursing system, the type of relationship between nurse and patients, is based on the ability of the patient to perform self-care. The system of nursing care is a helping system. Nurses review and select valid ways of helping individual patients. Orem names three types of nursing systems: the wholly compensatory system (patient totally unable to do self-care: patient is on physical and socially dependent), the partly compensatory (both nurse and patient perform self-care activities), and the supportive-educative nursing system (patient able to perform therapeutic self-care activities but needs the nurse's help or support in learning how to do so).

Whereas nursing system refers to the actual activity of helping patients meet their self-care needs, nursing agency refers to the ability to know and help others to know and meet their therapeutic self-care demands. Thus, agency refers to a set of human abilities for meeting self-care requisites, such as acquiring knowledge, decision making, and taking action for change. The self-care agent takes action through providing self-care or infant, child, or dependent care. The nurse assesses the patient's self-care deficits and either provides the care needed by another person or teaches the patient to do self-care. As nurse and patient relationships are complementary, nurses help patients assume responsibilities for self-care.

Self-care in illness covers the spectrum from disease prevention to disease detection and management. Most people find it easy to visualize self-care behaviors that promote health, such as balance nutrition and stress management. It is more difficult to envision self-care behaviors in illness. However, the client's illness can be a productive time for him or her to begin learning self-care behaviors and techniques.

Another aspect of self-care in illness management involves lifestyle changes in such areas as nutrition, activity and rest. Making lifestyle changes also includes clients

informing from nurses about how they can help in the event of a crisis, as well as carrying any necessary.

2.2 The oral care program

Chemotherapy used in AML patients is focused on the controlling of leukemic cells that trend to cause the side effect, which depends on drug administration and physical health. Furthermore, chemotherapy must cure continuously. Therefore, the patients should know and understand the correct practice in order to prevent the side effect of chemotherapy.

The great majority of patients receiving chemotherapy are expected to engage in self-care practices to promote or maintain their overall health and manage the side effects of their treatment. A patient's ability to perform self-care can be enhanced through mastery of knowledge and skills, and supportive care, which included modeling, persuasion, and feedback. Building on these principles and realities, oral care program was developed to provide adult patients undergoing chemotherapy with the information, skill, and support needed to engage effectively and consistently in prescribed self-care in their daily living. Supportive-educative nursing system was selected when the patients have primary responsibility to perform all self-care actions, with nurses acting as a consultant. The educative/supportive nursing system requires that the patient is competent in self-care and has the required knowledge of the disease or treatment. During the early stages of chemotherapy, for example the patient is capable of self-care, but as the treatment progresses and side effects start to occur. There arises a need for assessing of learning needs that are related to e.g. symptom management.

Once a patient is identified as having the potential to develop stomatitis, nursing intervention begin prior to chemotherapy administration with a focus on preventing stomatitis, delaying its onset, shortening its duration and reducing its severity as well as oral cavity pain and changes in food or fluids intake. Thus, it may decrease breaks or interruptions in chemotherapy treatments and enhance the patient's functional status. The oral care program was a supportive-educative nursing care designed for AML patients undergoing chemotherapy. The oral care program included three dimensions: (a) providing information and training oral care skills, (b) oral

cryotherapy, (c) oral supplementation of glutamine, either dried, non-fat milk or grinded soybean. For supportive part, the researcher provided alternative strategies including oral cryotherapy and oral supplementation of glutamine. For educative part, the researcher providing information and training oral care skills.

2.2.1 Providing information and training in oral care skills.

Orem states that self-care conduct is a learned activity and is learned through interpersonal relation and communications (Orem, 1991). Providing information about oral care is very important. Several studies demonstrate that stomatitis is manifested shortly after chemotherapy begins, which suggests that a preventative approach may be beneficial. Therefore, the oral care program should start before therapy begins and be continually reinforced throughout. The didactic content and procedures in this program are based on the available scientific literature and researches.

It incorporates the principle of a normal oral cavity, how to care for the mouth, how to examine their mouths and detect any changes that deviate from normal. In other view, the information is consisted of assessment of the oral cavity and oral hygiene strategies. It provides only the information that is absolutely essential for patients to use in the care of their mouths. The oral care program emphasizes the importance of helping patients to become proficient in the skills they need to achieve the best symptom management. By targeting specific skill and providing only essential information, practice, and support, nurse help patients gain the confidence they need to carry out a prescribed symptom management strategies. Patients are taught, supervised and evaluated (through a return demonstration) by the researcher on how and when to care for their mouths.

This approach will encourage feelings of autonomy, promote confidence and allow the patients to demonstrate their ability to perform correct oral care and incorporate this care into their daily routine. The nurse teaches patients how to examine their mouths. First, they learn what is normal. Then they are taught the essential aspects of mouth assessment, how to do the prescribed mouth care skills.

The information and skills are designed to provide patients with ability to manage chemotherapy-induced stomatitis. The didactic information and oral care skills are contained in a concise booklet form then patients can be used to reread.

2.2.1.1 Assessment of the oral cavity

The first part of the information is the assessment of the oral cavity. Comprehensive oral assessment does not usually form part of nursing documentation; again this can be compared with skin care, where a pressure sore risk assessment is always done. Eilers et al (1988) developed, tested and applied an Oral Assessment Guide, which seems to be the most valid tool in the literature for patients with stomatitis. It has been adapted for use by several authors and has readily identifiable categories with easily differentiated descriptive ratings for use in both clinical and research settings. The Western Consortium for Cancer Nursing Research (1991) tested several oral assessment tools and found that self report by patients was unreliable as they frequently reported no perceived changes, whilst examination of their mouths revealed definite oral changes.

Heals (1993) demonstrated that an oral assessment tool used on admission improved the oral awareness of nurses and thus improved oral status in patients. The unit subsequently went on to use the oral assessment on a daily basis. Thus, for patients with actual or potential impaired oral integrity, daily assessment of oral status is imperative; this should be systematic and documented to allow daily evaluation of care needs. An oral assessment guide is also a helpful teaching tool for inexperienced staff and can be adapted so that the score indicates the level of intervention required (Feber T, 1995).

Mouth care should be planned daily on the basis of individual patient assessment. Oral assessment should take place at the first meeting with the patients because evidenced suggests that pre-intervention assessment can reduce both the incidence and severity of stomatitis for the patients (Kenny S.A., 1990: 352). A thorough and systematic assessment of the oral cavity should be part of the routine physical examination of the individual with cancer. By carefully and systematically early assessment also increases the likelihood of early detection of treatable oral disease, the nurse can detect alterations in oral status and provide appropriate nursing

interventions. Any protocol for oral care must include individual assessment so that appropriate individualized care can be provided.

The information collected in the patient's pretreatment oral assessment includes age, nutritional status, oral hygiene habits, prior oral and dental diseases, use and fit of oral prosthesis or dentures, other sources of irritation and infection, and previous complications with cancer chemotherapy.

Prior to examining the oral cavity, the nurse or the patients should wash his or her hands and remove any dental appliances from the patient's mouth. The equipment used in an examination includes gloves, flashlight, gauze, tongue blades, or a dental mirror to assist the examination. All mucosal surfaces within the oral cavity should be examined: hard and soft palates, buccal mucosa, dorsal and ventral surface of the tongue, lips, gingival, teeth and saliva. Moisture, color, and texture of the mucosa and debris in the oral cavity are assessed during the examination (Beck, 1979: 187). The mouth is composed of the lips, buccal mucosa, gingiva, teeth, hard and soft palates, and tongue (Figure 5).

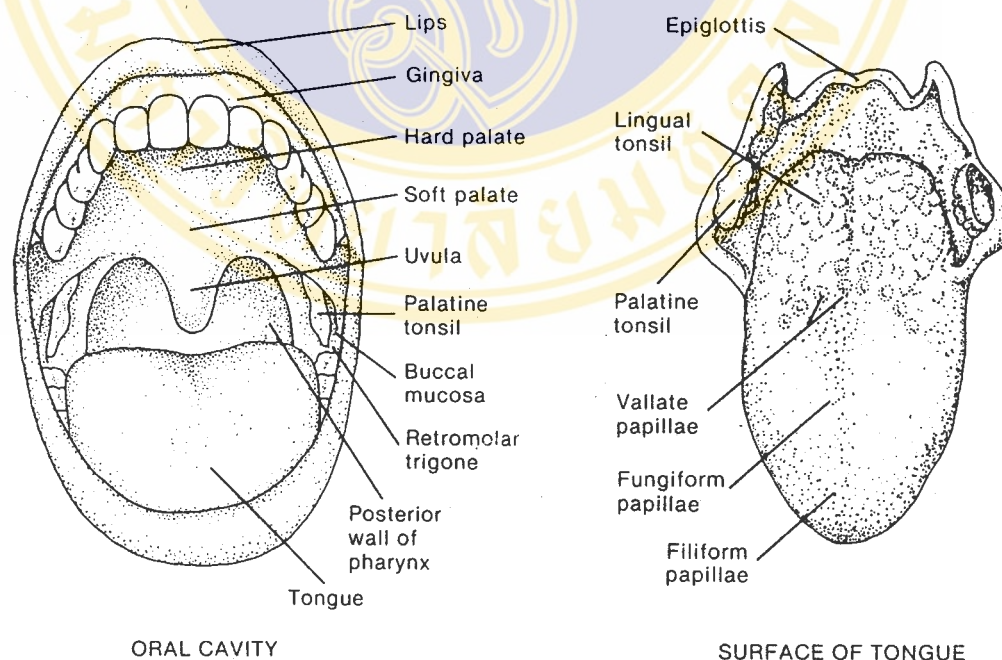


Figure 5 Anatomy of the mouth (from Iwamoto R.R. in S.B. Baird, R.McCorkle, and M. Grant (Eds.), 1991: 743)

A healthy mouth is comfortable, able to maintain nutrition, gives protection against infection, and does not detract from a person's sense of well-being. A normal healthy mouth is moist, pink, clean, soft, intact mucosa, absence of pain, burning or altered taste perceptions and normal salivary response (Wilkes G.M. in M.B. Burke, 1996: 120; Madeya M.L., 1996: 802; Iwamoto R.R. In S.B. Baird, R. McCorkle, and M. Grant (Eds.), 1991: 742; Coleman S., 1995: 1085; Rogers B.B., 2001: 749). Alterations can include changes in color, moisture, integrity (cracks, fissures, ulcers, blisters, or lesions) or cleanliness. Changes in the sensation of taste, hoarseness or a decrease in audible voice tone and strength, difficulty swallowing, and the presence of pain, burning, or stinging are also important alterations found in stomatitis.

All patients receiving chemotherapy should have an initial oral assessment, and the evaluation of oral complications of cancer therapy. The oral cavity should be categorized into specific areas that are scored according to the severity of stomatitis. Another approach may be to stage holistically the stomatitis, including both the functional and objective aspects of stomatitis. These approaches rely on direct visualization of stomatitis and patient-reported functional status.

2.2.1.2 Oral hygiene strategies

The second part of the provided information is oral hygiene strategies. Stomatitis develops in the majority of patients undergoing chemotherapy and nurses need to be aware of current scientific rationales that underpin good practice so that the most effective strategy is delivered. Mouth care is considered one of the most basic nursing activities central to patient comfort and well-being. Adequate oral hygiene has been shown to be important in prevention of stomatitis and is an essential role for nursing staff. Good oral hygiene is needed by teaching patients to care for their mouth correctly. The goal of oral cleansing is to keep the mucosa moist, clean, and without debris so that the mucosal barrier remains infection-free. Good oral hygiene promotes comfort, enhances taste, and stimulates appetite. Oral hygiene strategies consist of tooth brushing and rinsing, which is essential to minimize the risk of developing stomatitis.

- **Mouthwashes or mouth rinse**

Mouthwashes can be helpful in maintaining the moisture and softness in the mouth, removing the debris and reducing the accumulation of plaque and infection. Thus mouth rinses should be nonirritating and nondehydrating to promote the safe removal of debris (Coleman S., 1995: 1088; Wilkes G.M. in M.B. Burke, 1996: 120; Madeya M.L., 1996: 809; Miller M. and Kearney N., 2001:250;). Chlorhexidine mouthwash has the best antibacterial effects (Miller M. and Kearney N., 2001:250; Coleman S., 1995: 1088).

A controlled clinical trial conducted by Dodd et al (1996) examining the efficacy of chlorhexidine and a placebo mouthwash demonstrated that chlorhexidine was no more effective than water in preventing chemotherapy induced stomatitis. They also advocate that nurse should encourage the use of water mouth rinses as a means of reducing costs. Chlorhexidine is associated with black staining of the teeth, which a lot of patients find unacceptable. Furthermore, the unpleasant tasting chlorhexidine can cause burning and stinging because it has an alcohol content of 9.6%. (Coleman S., 1995: 1088; Miller M. and Kearney N., 2001:250; Miligan et al, 2001: 420). Sodium bicarbonate has mucolytic properties (reducing the velocity of oral mucous) and creates an alkaline environment that may actually promote bacterial growth by altering the pH of the oral environment. Patients also report its unpleasant taste (Wilkes G.M. in M.B. Burke, 1996: 120; Miller M. and Kearney N., 2001:250; Miligan et al, 2001: 419).

Hydrogen peroxide has a mechanical cleansing action resulting from the vigorous release of oxygen, which occurs when it comes into contact with the oral mucosa. It also has antimicrobial and deodorant effects. Unfortunately, though, peroxide can break down granulation tissue, and has an unpleasant taste. It has been found to damage the oral mucosa by extensively altering the normal flora of the mouth. Therefore; it is not recommended for mouth care particularly in immunosuppressed patients (Coleman S., 1995: 1088; Wilkes G.M. in M.B. Burke, 1996: 120; Miller M. and Kearney N., 2001:250; Miligan et al, 2001: 419). Lemon glycerin swabs, a combination of lemon and glycerin, should not be used. It possibly due to a direct dehydration effect of glycerin and over-stimulation of salivary glands

by lemon juice, leading to exhaustion (Wilkes G.M. in M.B. Burke, 1996: 120; Miligan et al, 2001: 419).

Povidine-iodine mouthwash is useful for mucosal infections but does not inhibit plaque. It should not be used for more than 2 weeks because a significant amount of iodine is absorbed (Miligan et al, 2001: 420-421). Water is widely used and well accepted as effective mouthwash. It is inexpensive, convenient, may be given warm or cool according to individual taste. Sterile water has been found to be as effective as chlorhexidine at preventing post-chemotherapy mucositis (Dodd et al, 1996) but, it is ineffective at removing subborn coating (Miligan et al, 2001: 420-421).

Normal saline is convenient and inexpensive. It has a mild antiseptic effect and is non-irritant at correct dilution (1 teaspoon of sodium chloride in 500 ml. water = 0.9%). Furthermore it is palatable, although it may be less well tolerated by those with altered taste, damage to the oral mucosa or in patients with severe nausea. It has been shown to be equally or more effective than other solutions, e.g. sodium bicarbonate, hydrogen peroxide, at minimizing radiation-induced mucositis (Miligan et al, 2001: 420). It is thought to aid in the formation of granulation tissue and to promote healing, but has been found to be ineffective alone at removing heavy coating (Wilkes G.M. in M.B. Burke, 1996: 120; Miligan et al, 2001: 420; Miller M. and Kearney N., 2001:250).

From the above has been shown the choice of mouth wash solution for people with advanced cancer. In this study, the researcher choose normal saline because it appears to be a safe, economical, and readily available mouthwash whose use should be promoted and it may be soothe for the aching mucosa. Patients should rinse for one to two minutes using an alternating ballooning and sucking cheek motion to force solution between the teeth. If unable to do this, patients can tilt or rock the head from side to side prior to expectoration (Madeya M.L., 1996: 809).

- **Tooth brushing**

Another category impacting on oral status is brushing. The brushing of the teeth and gingival has been the home care procedure most widely recommended to promote oral cleanliness. Its purpose is to remove oral accumulations of plaque and debris and thereby assist in the prevention of dental disease. When used with an appropriately

abrasive dentifrice, tooth brushing also helps to keep the teeth free of stains that sometimes accumulate (Armstrong T.S., 1994: 409). According to the American Dental Association (ADA), the technique for brushing should be the Modified-Bass Technique. This method is regarded as pretty much the gold standard of brushing techniques and is supported as “best meeting the requirement of proper oral hygiene and as relatively simple for patients to learn.” In this method, a small soft-bristle is placed at a 45-degree angle to the junction between the gingiva and the teeth. Using light pressure, gently jiggle the bristles back and forth at the junction of the gums and teeth. The idea is to remove any plaque and bacteria hiding in the sulcus between the teeth and gums. Brush all of the outside surfaces of the teeth using short back and forth or circular strokes. Brush the inside surfaces using only the tip of the brush. For the front teeth, brush the inside surfaces of the upper and lower jaws by tilting the brush vertically and using up and down strokes with the front part of the brush (Dudjak L.A., 1987: 135).

It has proven its worth both for people with healthy gums and for gingivitis and periodontitis patients. The ADA (1989 cited in Madeya M.L., 1996: 809) states that almost any soft, round-end, bristle toothbrush that is used diligently can be effective in removing plaque. Too hard a brush can cause gum recession and bleeding, allowing bacterial access to the blood stream. Dip the bristles in very warm water to make them softer.

The ADA recommends use of fluoridated toothpastes and gels. Toothpaste requires three key ingredients to be effective: a detergent, a fine abrasive to cleanse the teeth, and fluoride to prevent cavities (Madeya M.L., 1996: 809). Toothpaste is not essential to remove plaque, but as an abrasive agent, it helps the mechanical effect of brushing. It provides topical application of fluoride and its pleasant taste refreshes the mouth. If teeth are sensitive, patients can use desensitizing toothpaste. A pea-sized amount of fluoridated toothpaste is all need.

Although tooth brushing is considered the most effective means of plaque removal, severe stomatitis may make this uncomfortable. Therefore, it is not recommended for patients with thrombocytopenia (platelets < 50,000) (Miller M. and Kearney N., 2001:249). It has been suggested that an alternative method such as using a gloved finger, soft sponge-tipped applicators, or a foam swab may be more

appropriate for patients whom tooth brushing is precluded. For example, when the patients have spontaneous bleeding or pain is present (Wilkes G.M. in M.B. Burke, 1996: 120; Miller M. and Kearney N., 2001: 249).

- **Dental floss**

The toothbrush does **not** remove plaque from areas between the teeth and dental floss can be used to do this. It should be used with care to avoid damaging the gums. Flossing requires manual dexterity. Cut a piece of dental floss 18 inches long. Wrap the ends loosely around the middle fingers, leaving a few inches of floss exposed between those fingers. Guide the floss with the thumbs of both hands to clean the upper teeth and with the index (first) fingers to clean the lower teeth. Gently force the floss between the teeth from your gum line to the top of each tooth. Floss both sides of each tooth using a gently up-and-down motion. It should not be performed if the patient has platelet levels of less than $40,000\text{mm}^3$ (Madeya 1996). This study didn't allow the patients to floss their teeth.

- **Lip care**

Lubricants such as petroleum jelly, and yellow paraffin are often recommended for lips. These should be used with care, as several layers can build up and produce a bolus effect if treatment is being directed onto this area. There is also evidence that their hygroscopic qualities dehydrate the tissues. Moisturising cream is a good alternative.

- **Dentures**

Dentures frequently present a problem in the cancer patient. Alteration to the mouth caused by weight loss means that dentures may no longer fit. Ill fitting dentures can cause trauma and irritation. Great care must be taken as ulcers caused by denture irritation. During chemotherapy, dentures may aggravate mucositis and wearing should be discouraged. An exception must be made for patients wearing resection prostheses and obdurators. Dentures and obdurators become coated with plaque and food debris just like teeth, and can harbour infection (e.g. candida). They; therefore, must be meticulously cleaned using a soft brush and unperfumed soap and water after meals and every time oral care is performed; rinsing and soaking alone will not

remove plaque and debris effectively. Patients should be instructed to remove dentures at night and soak them in a hypochlorite denture cleansing agent 2 or 3 nights per week, after removing all debris with a brush. Hypochlorites can damage the fabric of the dentures and therefore should not be used too often.

The fit of dentures should be checked regularly; if any irritation develops they should be removed immediately and the mouth must be examined by the dental team. Self applied commercial soft linings and denture fixatives should not be used as they may mask problems which need professional dental attention, and they act as a medium for the rapid proliferation of micro-organisms, particularly yeasts (Griffiths & Boyle 1993).

- **Oral hygiene protocols**

Miller M. and Kearney N. (2001) state that the frequency and consistent practice of oral care are rather than agents that minimizes oral complications. As the severity of complication increases, the frequency of oral hygiene also should increase. If the frequency of the oral regimen is too burdensome for the patient, the healthcare team should amend the plan to care (Armstrong T.S., 1994: 409; Madeya M.L., 1996). Beck (1979) studied the impact of frequency on the incidence of stomatitis and recommended oral hygiene every 4 hours for prevention, every 2 hours for mild stomatitis, and every 1-2 hour for severe stomatitis. She found significant improvement ($p < 0.01$) in oral status when the oral care protocol was used.

Based on the review of the literature, an oral care protocol is proposed. All interventions would be initiated before chemotherapy, and frequency of care would be changed based on the oral assessment score. The actual timing or frequency chosen is based on the studies of Beck S. (1979) and Kenny S. (1990). If a patient scored 8 on the OAG, oral care would be performed at least every 4 hours. If the person scored 9-10, care would be performed every 2 hours. If the score was > 10 , care would be performed every 1-2 hour.

Involvement of a dental hygienist and dental team in an oral care protocol is very important to identify risk factors and perform necessary treatment and prophylaxis, particularly before treatment begins. A dental assessment and any necessary extractions should be carried out 2 to 3 weeks prior to chemotherapy to

allow the mucosa to heal. A dental hygienist is an important team member to initiate a comprehensive preventative care program. Fluoride carriers may be made for patients to apply topical fluorides, needed to prevent caries. If the patient is unable to tolerate these, fluoride rinses may be used instead (Madeya M.L.,1996)

An oral care protocol should incorporate written patient education (Dudjak L.A., 1987) as the majority of patients will perform oral care themselves; chemotherapy is generally performed as an outpatient and therefore the patient must be well prepared to manage oral care and side effects at home. Patient education should also include advice and help with smoking cessation, as smoking can increase the severity and duration of mucositis.

2.2.2 Oral cryotherapy

The term cryotherapy is used to describe the application of cold modalities that have a temperature range between 32 °F and 65 °F. During cryotherapy, heat is removed from the body and absorbed by the cold modality, causing the body to respond with a series of local and systemic response. The magnitude of these effects is related to the temperature of the modality, the duration of the treatment, and the surface area exposed to the treatment. The local effects of cold application include vasoconstriction, decreased metabolic rate, decreased inflammation, and decreased pain (Synder M., 1992: 194; Starkey C., 1999: 110). To obtain therapeutic benefits, the skin temperature must be decreased to approximately 57 °F for the optimal decrease in local blood flow to occur (Starkey C., 1999: 110).

Cold causes vasoconstriction with a subsequent decrease in the blood flow to the areas. This effect occurs from the stimulation of cold thermal sensors in the skin; in turn, a reflex excitation of sympathetic adrenergic fibers is initiated resulting in vasoconstriction (Synder M., 1992: 194; Starkey C., 1999: 114). Lehmann J.F. and DeLateur B.J. (1990: 590-632) viewed this action as the principal therapeutic mechanism for the use of cold. Decreasing blood flow to a traumatized area lessens formation of edema. Less histamine is related with less capillary breakdown occurring. Lower of the temperature of tissue decreases cell metabolism and diminishes the oxygen and nutrient needs of the affected tissue cells. Cold is able to reduce pain by

altering the conduction velocity and synaptic activity of peripheral nerves (Snyder M., 1992: 194).

Many modalities are need to apply cold: chipped ice in a bag, frozen gel, chemical ice envelop, ice baths, refrigerant-inflated bladders, ice water, vapocollants, ice massage, and cold packs. The selection of cryotherapy depends on duration, the patient condition and underlying diseases.

The temperature that the skin can tolerate varies among persons and on different parts of the body. Some can tolerate very cold temperatures more safety than others; young children, elderly, diabetic, and individual with circulatory disease have a low tolerance for safety. Cryotherapy is contraindicated in person with cold allergy and impaired circulation such as Raynaud's phenomenon. Wound healing may be impaired by the use of cryotherapy, thus not using cryotherapy during the first two weeks of healing (Snyder M., 1992: 194).

Cryotherapy is used to minimize blood flow and prevent or relieve side effects of chemotherapy such as stomatitis in cancer patients. Stomatitis evidently occurs when the dividing cells of the oral mucosa take up chemotherapeutic agents.

Mahood et al (1991) hypothesized that using oral cryotherapy to reduce blood flow to the oral mucosa during, and shortly following, the administration of 5-FU would reduce the amount of drug delivered to mucosal cells. Oral cryotherapy should cause local vasoconstriction, thereby decreasing oral mucosal blood flow. To test this hypothesis, researchers randomly assigned 95 patients scheduled to receive the first cycle of 5-FU plus leucovorin to either an oral cryotherapy group or a control group. Patients in the cryotherapy group placed ice chips in their mouths five minutes prior to each dose of 5-FU, continuously swished the ice around the oral cavity, and replenished the ice before it melted for a total of 30 minutes. Patients in the treatment group had significantly reduced stomatitis as judged by physicians and by the patients themselves. The researchers concluded using a simple, inexpensive, can decrease that 5-FU induced stomatitis and generally well tolerated therapy. The ice decreases circulation during peak blood flow levels of the 5-FU.

Rocke et al (1993) designed the randomized clinical trial of two different duration of oral cryotherapy for prevention of 5-FU related stomatitis. This trial involved patients who were receiving their first course of a 5-FU plus leucovorin

chemotherapy regimen, for which stomatitis is a major dose-limiting toxicity. These patients were randomized to receive either 30 or 60 minutes of oral cryotherapy given at around the same time as the 5-FU therapy. The results shown that cryotherapy groups had similar degrees of stomatitis, for a total of 178 available patients were studies. The cryotherapy was well tolerated by most patients. Only a few of the subjects discontinued oral cryotherapy prematurely because of unpleasant conditions (e.g., nausea, headache, or chills). Many patients on the 60-minutes treatment arm complained about the duration of cryotherapy, nothing that the 30-minute time period was preferred. Then, the researchers recommended time to use cryotherapy such as ice-chips was a total of 30 minutes.

Natethong T. (1999) designed the change over design to compare the incidence and severity of oral mucositis among cancer patients receiving 5-FU between two periods: the use of ice-chips and the non-use of ice-chips period. In the experimental period, patients placed the ice chips in their oral cavities five minutes before each chemotherapy treatment and continued the ice chips administration for a total of 30 minutes. The results indicated that during the ice chips period the incidence, severity and duration of stomatitis was significantly less than in the control period ($P < .05$, $< .01$ and $< .05$, respectively). The onset of stomatitis during the ice chips period was significantly later than in the control period ($P < .05$).

Toowicharanon P. (2000) studied the effects of chemotherapy and integrated nursing interventions on oral mucositis in leukemia patients. The patients received ice chips administration combine with oral supplementation and oral hygiene management. Ice chips administration, patients placed the ice chips in their oral cavities 5 minutes before each chemotherapy treatment and continuing for a total of 30 minutes for 7 days. The results revealed that nine of eleven patients received complete interventions did not develop stomatitis. Two of them and all patients in other group developed stomatitis.

Ice-chips administration, or oral cryotherapy has been shown to minimize the risk for stomatitis in patients receiving chemotherapy. Cryotherapy is a convenient, practical, and time-efficient method. In this study, Patients were instructed to place ice-chips in their mouths for 5 minutes prior to starting each dose of cytosine arabinoside, continuously swish the ice around in their oral cavities, and replenish the

ice-chips before the previous ice had completely melted for a total of 30 minutes. Patients were asked to remove dentures, if present. Ice-chips administration is initiated when the patients begin chemotherapy on the first day until seventh day of cytosine arabinoside administration.

2.2.3 Oral supplementation of glutamine

Proteins are vital to health because they support the growth and repair of structure and functional components of the body. Amino acids serve as the building blocks for proteins. There are 20 amino acids from which all the proteins that are required by both plants and animals are made. The human body is able to manufacture some of the amino acids for its own protein-building function, but the cells of the body must make nine amino acids. Therefore, these essential amino acids must be eaten in food, digested, absorbed, and then brought to cells by circulating blood. The essential amino acids are histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine. The other eleven are alanine, arginine, aspartic acid, cysteine, cystine, glutamic acid, glutamine, glycine, proline, serine, and tyrosine, are nonessential amino acids (NEAA). The liver can create them as long as structural components, including nitrogen, from other amino acids are available to use for NEAA formation (Grodner M., Anderson S.L., and DeYoung S., 2000: 146-147).

Glutamine is the most abundant amino acid in the blood and in the total body amino acid pool, and there has recently been much interest in its role in nutrition (Lacey S.M., and Wilmore D.W., 1990; Ziegler et al, 1992; Skubitz K.M., and Anderson P.M., 1996). Glutamine has a molecular weight of 146.15 and an elementary composition of carbon (41.09 %), hydrogen (6.90 %), oxygen (32.84 %), and nitrogen (19.17 %) (Lacey S.M., and Wilmore D.W., 1990: 298).

In healthy, non-stressed individuals glutamine is a neutral, non-essential amino acid. Glutamine appears to be a primary fuel for rapidly dividing cells including enterocytes, colonocytes, lymphocytes and fibroblasts; it is as efficient as glucose. Oxidized glutamine provides substrate for the synthesis of purines and pyrimidines needed for DNA, RNA, and mRNA and in the kidneys glutamine is involved in acid-

base balance through ammonia production (Skubitz K.M., and Anderson P.M., 1996: 223-224).

During periods of increased metabolic stress, glutamine is freely released from skeletal muscle and intracellular glutamine concentrations falls rapidly, because glutamine is used for renal ammoniogenesis and serve as an oxidizable fuel for stimulated lymphocytes and macrophages and intestinal mucosal cells (Ziegler et al, 1992: 821). Providing the cells with an optimal nutrient/energy source would enhance the recovery of cells from damage (either chemotherapy-induced or radiation-induced) (Skubitz K.M., and Anderson P.M., 1996: 224). Ziegler et al (1992) found that patients receiving glutamine-supplemented parenteral nutrition after bone marrow transplantation for 4 weeks had improved nitrogen balance, a diminished incidence of clinical infection, lower rates of microbial colonization, and shortened hospital stay composed with patients receiving standard parenteral nutrition.

It is known that the lower gastrointestinal tract obviously absorbs nutrients and can utilize them as they pass through the absorptive cells. Skubitz and Anderson (1996) hypothesized that the local administration of relatively high concentrations of glutamine by “swish and swallow” might result in some local absorption of this nutrient/energy source by the cells could likely utilize these nutrients directly and that would prevent damage and assist recovery from chemotherapy. They published a study describing the effects of supplemental glutamine on chemotherapy-induced mucositis. Patients received a suspension of L-glutamine 4 grams swish and swallow orally twice a day, from day 1 of chemotherapy for 28 days or for 4 days past the resolution of any post-chemotherapy stomatitis. It was found the significant reductions in the grade of stomatitis as well as the duration of the mucositis. Subjectively the patients felt that the mucositis was less severe, important as a quality of life issue.

Numerous clinical trials in human demonstrate that even at high doses, glutamine administration is without side effects and well tolerated, even during times of physiologic stress. Glutamine is administered orally in bulk powder or in encapsulated form. Dosages vary greatly depending on the clinical situation, but are in the range of two to eight grams daily in divided doses for general wound healing and intestinal support. During periods of severe metabolic stress or catabolic insult 20 to 40 grams of glutamine may be required to maintain homeostasis (Decker G.M., 2002:

112-114). People who have Reye's syndrome, kidney disease, cirrhosis of the liver or other illness that cause ammonia to build up in the blood should not take glutamine.

Glutamine is found in plants and animal sources, such as meats, milk, soy proteins, raw spinach, raw parsley, and cabbage, as well as in supplement form. Glutamine content in soybean is 5,777 mg. in 100 grams of edible soybeans and cow milk, dried, non-fat is 6,565 mg. in 100 grams of edible milk (Division of Nutrition, 1990: 17, 34). Thus, oral supplementation of 6 grams of glutamine in the form of 90 grams of edible dried, non-fat milk or 100 grams of grinded soybean per day were used in this study.

3. The effects of oral care program on stomatitis

The oral care program was a supportive-educative nursing care designed for AML patients undergoing chemotherapy. The oral care program included three dimensions: (a) providing information and training in oral care skills, (b) oral cryotherapy, (c) oral supplementation of glutamine, either dried, non-fat milk or grinded soybean.

3.1 Providing information and training in oral care skills

The part of the program emphasizes the importance of helping patients to become proficient in the skills they need to achieve the best symptom management. By targeting specific skill and providing only essential information, practice, and support, nurse help patients gain the confidence they need to carry out a prescribed symptom management strategies. Patients are taught, supervised and evaluated (through a return demonstration) by the researcher on how and when to care for their mouths. This approach will encourage feelings of autonomy, promote confidence and allow the patients to demonstrate their ability to perform correct oral care and incorporate this care into their daily routine. Oral assessment should take place at the first meeting with the patients because evidenced suggests that pre-intervention assessment can reduce both the incidence and severity of stomatitis for the patients (Kenny S.A., 1990: 352). Mouth care should be planned daily on the basis of individual patient assessment. Oral hygiene strategies consist of tooth brushing and rinsing, is essential to minimize the risk of developing stomatitis. Adequate oral

hygiene can be helpful in maintaining the moisture and softness in the mouth, removing the debris and reducing the accumulation of plaque and infection. It has been shown to be important in prevention of stomatitis and is an essential role for nursing staff. Good oral hygiene promotes comfort, enhances taste, and stimulates appetite. Beck (1979) studied the impact of frequency on the incidence of stomatitis and recommended oral hygiene every 4 hours for prevention, every 2 hours for mild stomatitis, and every 1-2 hour for severe stomatitis. She found significant improvement ($p < 0.01$) in oral status when the oral care protocol was used.

3.2. Ice-chips administration, oral cryotherapy

During the continuous intravenous cytosine arabinoside, the plasma levels of cytosine arabinoside increased. Oral mucosal cells that have a high rate of proliferation are increase reabsorption of cytosine arabinoside. Cytosine arabinoside reduced the renewal rate of the oral mucosal cells that the integrity of mucosal surface decreased. It can develop to localized or diffuse ulceration of oral mucosa, and inflammation. Oral cryotherapy is one of the supportive nursing care provided to the patients. Oral cryotherapy should cause local vasoconstriction, thereby decreasing oral mucosal blood flow. The ice decreases circulation during peak blood flow levels of the chemotherapeutic agents. The administration of chemotherapeutic agents would reduce the amount of drug delivered to mucosal cells. Oral mucosal cells decreasingly reabsorb cytosine arabinoside; thus, the integrity of the mucosal surface should not be reduced (Mahood, et al., 1991; Rocke, et al., 1993).

3.3 Oral supplementation of glutamine

Glutamine appears to be a primary fuel for rapidly dividing cells including enterocytes, colonocytes, lymphocytes and fibroblasts; it is as efficient as glucose. Oxidized glutamine provides substrate for the synthesis of purines and pyrimidines needed for DNA, RNA, and mRNA and in the kidneys glutamine is involved in acid-base balance through ammonia production (Skubitz K.M., and Anderson P.M., 1996: 223-224). During periods of increased metabolic stress, glutamine is freely released from skeletal muscle and intracellular glutamine concentrations falls rapidly, because glutamine is used for renal ammoniogenesis and serve as an oxidizable fuel for stimulated lymphocytes and macrophages and intestinal mucosal cells (Ziegler et al,

1992: 821). Providing the cells with glutamine, an optimal nutrient/energy source, would prevent damage and enhance the recovery of cells from damage (either chemotherapy-induced or radiation-induced).

These approaches must be integrated. Then, it would prevent the occurrence of stomatitis, and at least it would delayed the onset of stomatitis, shortened its duration and lessened its severity

Conclusion

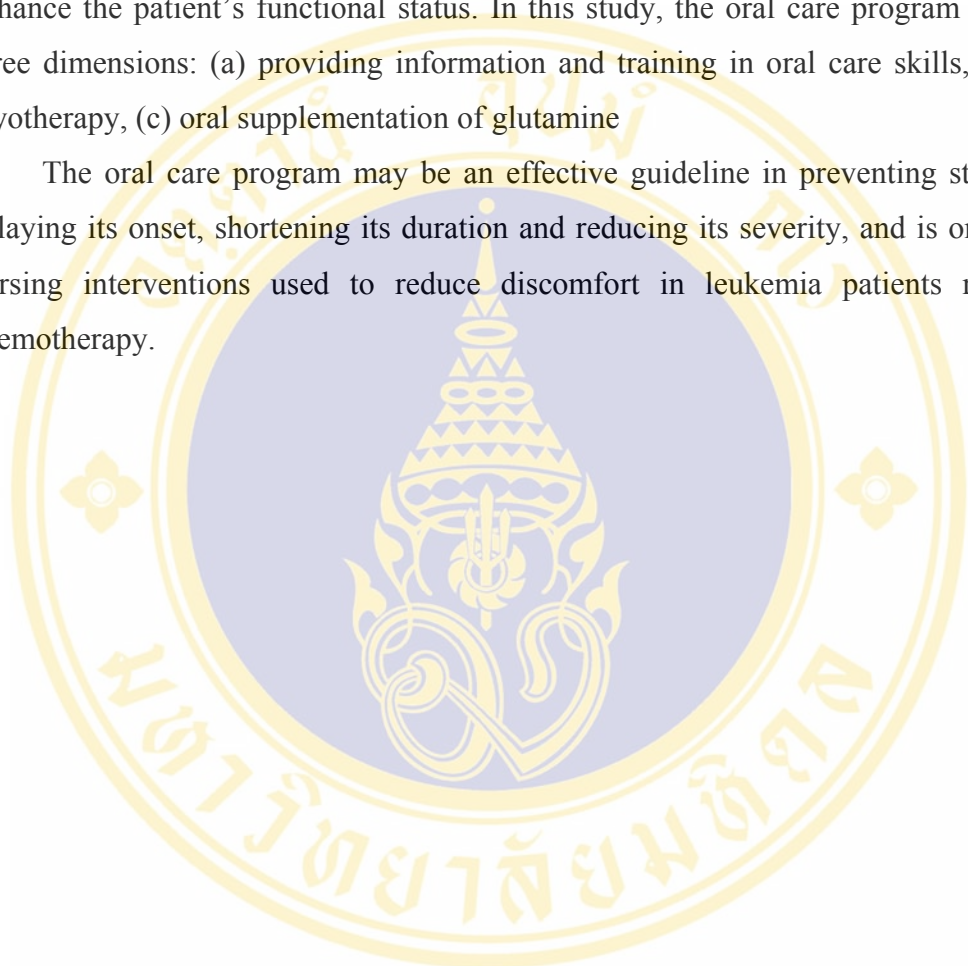
Stomatitis refers to an inflammation of the oral mucous membranes and/or ulceration and destruction of the mucous membranes. Chemotherapy can damage the oral mucosa through direct or indirect toxicity. Direct stomatotoxicity, a direct effect of the drug on the oral mucosa, results from the nonspecific effects of cytotoxic drugs on cells undergoing mitosis. Indirect stomatotoxicity, an indirect result of the drug's myelosuppressive action, is the result of the effects of chemotherapy on the cells of the bone marrow rather than the oral mucosa.

Stomatitis from chemotherapy usually is preceded by pale, dry mucous membranes, burning sensation, dry tongue with raised papillae, and ridging of buccal mucosa. This damage may progress to severe inflammation and ulceration with pain.

The problems associated with stomatitis are ulceration, pain, local infection, and decreased ability to take food or fluids, chewing, swallowing and taste alteration. The overall impact of these symptoms is altered nutritional status because of the difficulty in taking in adequate nutrients. Stomatitis causes severe pain and distress. Oral pain can be severe, inhibit nutrition intake, restrict communication with others, and interfere with social interaction and cause psychosocial distress. Furthermore, patients with damaged oral mucosa and reduced immunity resulting from chemotherapy are prone to opportunistic infections in the mouth and can increase the patients' susceptibility to systemic infection. The entry of the microorganisms into the body provides the potential for a systemic infection that spreads through the bloodstream from a local infection in the mouth. Infection can delay cancer treatment, necessitate a dose reduction, thus jeopardizing treatment effectiveness, prolong hospitalization, increase cost of care and diminish the quality of life.

Once a patient is identified as having the potential to develop stomatitis, nursing intervention should begin prior to chemotherapy administration with a focus on preventing stomatitis, delaying its onset, shortening its duration and reducing its severity. Thus, it may decrease breaks or interruptions in chemotherapy treatments and enhance the patient's functional status. In this study, the oral care program included three dimensions: (a) providing information and training in oral care skills, (b) oral cryotherapy, (c) oral supplementation of glutamine

The oral care program may be an effective guideline in preventing stomatitis, delaying its onset, shortening its duration and reducing its severity, and is one of the nursing interventions used to reduce discomfort in leukemia patients receiving chemotherapy.



CHAPTER III

METHODOLOGY

Research design

This study is a two groups pre-post test design (quasi-experimental study).

Population and samples

The population in this study were acute myeloid leukemia (AML) patients undergoing chemotherapy who were admitted in general medical wards at the Asdang building on the 6th, 9th, 10th, 11th, and 12th floors at Siriraj hospital.

The sample was recruited according to the inclusion criteria as follows:

1. Receiving chemotherapy via treatment regimen for AML at the department of hematology, Siriraj hospital. This regimen is the combination of 7-days of cytarabine (100-200 mg/m²/24 hours) administered by continuous infusion with 3 days of an anthracycline intravenous bolus on day 1 to 3, either doxorubicin, idarubicin, or mitoxantrone.
2. Able to drink oral supplementation of glutamine, either dried, non-fat milk or grinded soybean.

The sample were excluded according to the exclusion criteria as follow:

1. Having oral complications before starting this study (oral assessment guide score > 8).
2. Having a disease that may affect normal tissue during this study, for example, diabetes mellitus and hypertension.
3. Having problems when using cryotherapy, for example, dysfunction of circulatory system, decrease of sensation and hypersensitivity.

The sample size in this study was 40 AML patients who met the above criteria. The samples were divided into two groups. These two groups should have no difference and equal characteristics in their gender and ages (vary less than 5 years). The first twenty participants, the control group, were assigned to receive routine

nursing care. Then, when the researcher collected data in the control group completely, the other group was initiated. The other twenty participants, the experimental group, were assigned to receive the oral care program. To prevent bias during data collection, this study was initiated in the control group until completed; then, the experimental group was started.

The setting of the study

The study site is the general medical wards, Asdang building, Department of medical and psychological nursing, Faculty of Medicine, Siriraj hospital, Mahidol University, Bangkok. It is a tertiary care hospital structuring around 2,000 beds. General medicine wards at the Asdang building have 10 wards, Asdang 6th, 9th, 10th, 11th, and 12th floors both north and south site. These are 5 female wards and 5 male wards. Each ward admitted general patients, aged more than 13 years old. The AML patients were admitted to this building to receive chemotherapy. There were about 150 AML patients admitted in those wards mentioned above for receiving chemotherapy in 2001. It was found that AML patients often developed stomatitis and required advance medical therapeutic intervention.

Routine mouth care in general medicine wards, Asdang 6th, 9th, 10th, 11th, and 12th floors both north and south site, is focussed on keeping the mouth moist and clean. The patients were instructed to rinse their mouth with normal saline solution (N.S.S) frequently. Every patient has a bottle of N.S.S for his or her own used. The nurses usually asked the patients about the abnormal signs in their mouth. When the patients developed stomatitis, the nurses consulted the doctors to order local anesthetic to reduce pain (if presented) or local antibiotics to reduce microorganism in the mouths. Furthermore, the dentists assessed every patient's mouth before they started chemotherapy and solved any oral problem such as decayed tooth or plaque.

Instrumentation

The instruments for this study were composed of two parts as follow:

Part 1 Experimental instruments included:

1.1 Plan for providing information and training in oral care skills, which incorporates the principles of good oral hygiene, how to regularly assess the oral cavity and oral hygiene strategies. The information and skills are designed to provide patients with the ability to manage chemotherapy- induced stomatitis (Appendix C).

1.2 Patient oral care booklet; the didactic information and oral care skills are contained in a concise booklet form that patients can used and reread as needed (Appendix D).

1.3 Oral assessment equipment included: tongue blades, flashlight, tissue paper, mirror, swab (or cotton buds), and mouth care set.

1.4 Ice chips, with a size of one cubic centimeter each, made from boiled drinking water by the researcher. Ice-chips were kept in the clean closed cooler.

1.5 Dried non-fat milk or grinded soybean and warm water. Warm water was prepared from boiled drinking water and kept in the clean closet.

Part 2 Data collection instruments included:

2.1 The personal data record was developed by researcher and composed of basic information and illness data of the participants. The personal data record included demographic data, clinical characteristics, history of oral irritation, previous oral care strategies and other related factors such as body weight, body temperature, absolute neutrophil count and serum albumin (Appendix E).

2.2 The Oral Assessment Guide (OAG) was developed by Eilers, Berger, and Peterson (1988). The OAG uses three levels of descriptors for each of eight oral assessment categories. The eight categories for assessment were voice, swallow, lips, tongue, saliva, mucous membranes, gingiva, and teeth or dentures. Each item was scored from 1 to 3. A score of 1 indicated normal findings; score of 2 indicated mild alterations, and definite compromises of mucosal integrity were assigned a value of 3. Completion of an oral assessment using the OAG yielded a numeric score for oral status. Scores ranged from a total of 8 for normal findings in all categories to a maximum of 24 to indicate definite abnormalities in all categories (Appendix F). OAG

was used to diagnose the stomatitis, and measure the onset, duration and severity of stomatitis.

Permission to use the Oral Assessment Guide, before using the OAG for oral cavity assessment was obtained. The researcher wrote a letter to June Eilers, an oncology clinical nurse specialist at the University of Nebraska Medical Center, to ask her permission as this study needed Oral Assessment Guide. After that, the researcher received a kind response from June Eilers for her copyright permission.

2.3 Patients' comments on receiving the oral care program questionnaire were used to evaluate and describe patient satisfaction, sensation, and the usefulness of the oral care program. The participants would complete the second part of questionnaire on the twenty-eighth day after receiving the oral care program (Appendix E).

Validity and reliability of the instruments

1. Plan for providing information and training in oral care skills and patient oral care booklet.

The researcher made a script of the contents of oral care information. There were five experts who had read the scripts of the plan and booklet who were a clinical nurse specialist, two nursing instructors specialists in oncology nursing, and two nurses in caring for hematologic malignancy patients receiving chemotherapy. After the experts had considered the content validity and appropriate language used, they gave comments and suggestion for the researcher to revise them. The researcher tested it with five similar patients before distribution. The patients conformably understood the content of the information.

2. Oral Assessment Guide (OAG)

The OAG was translated into the Thai language by the researcher. Five bilingual experts retranslated the Thai version back to English. Then, the comparison was made between the retranslated version and the original one to prove the accuracy of translation. The researcher and a registered nurse, who had experience in oncology for more than 10 years, conducted the inter-rater reliability testing. The inter-rater reliability was tested among 5 leukemia patients undergoing chemotherapy, who had

characteristics similar to those of the population. In this study, the value of reliability was 1.00.

Data collection

The researcher consulted the dentists, who cared for patients at Siriraj Hospital and June Eilers, who developed the Oral Assessment Guide, about how to assess the oral cavity and use the OAG accurately. The researcher trained in the observation skills in order to enhance the accuracy of data collection from these dentists. The researcher conducted observations among 5 leukemia patients undergoing chemotherapy, and every patient observation was confirmed by the dentists.

The data were collected after the Faculty of Graduate Studies; Mahidol University approved the research proposal. The process for data collecting were:

1. A letter of introduction was sent to the human subjects committee of Siriraj Hospital to request permission and cooperation in data collection.
2. A permission letter from the Faculty of Graduate Studies, Mahidol University was presented and submitted to the Director of Siriraj Hospital, the Director of Nursing, the Head of Medical and Psychiatric Nursing Division and the Head Nurse of each unit of Asdang Building, Siriraj Hospital.
3. The researcher contacted the supervisor nurse and head nurse of the department of the Asdang 6th, 9th, 10th, 11th, and 12th floors wards both north and south site. Then, the researcher explained the objectives of the study and steps in data collection.
4. For the protection of the patient's rights, the researcher contacted each eligible participant to explain about the objectives of the study and how the intervention will work in order that the patients can decide to participate in this study by themselves. The participants who agreed to participate were requested to sign a consent form in which they can withdraw from the study anytime.
5. At first, the control group was selected to receive routine nursing care until data collection was completed. The twenty patients in the experimental group were then selected to receive the oral care program.

The control group

1. The participants in the control group were recruited from the eligible population.

2. A relationship was established with the participants and the consent forms, the objective of the study and the steps in data collection were explained. The participants had their oral cavity assessed before they were included in this study.

3. The participants were instructed how to self-assess the oral cavity. The oral cavity of the participants were assessed daily by the researcher and the participants for 28 days after receiving initial chemotherapy. The OAG scores were confirmed between the researcher and the patients to ensure that the scores were not different between the researcher and each participant. Thus, the participants have ability to assess the oral cavity by themselves both in the hospital and home. Every patient must be admitted in the hospital for at least 3 weeks (day 1–21). In the case of participants discharged from the hospital before completion of data collection (discharge on day 22–28), the researcher contacted the participants by telephone or postcard to follow-up. If the patients were discharged before day 21, they were dropped out from the study because the researcher did not keep their assessment skills accuracy.

Then, when the researcher had collected data in the control group completely (day 28), the other twenty participants, the experimental group, were initiated.

The experimental group

1. The researcher established the relationship with the participants. The participants' oral cavities were assessed before being included in this study. If the OAG score was more than 8, the participant was excluded from this study. The researcher clarified the consent forms, the objective of the study and the steps in data collection. Every patient in the experimental group would be still received routine mouth care from the ward nurses.

2. The participants were instructed about the oral care program, which could be described in 3 time series; before initiation of chemotherapy (Day 0 of this intervention), undergoing chemotherapy (Day 1-7 of this intervention) and after receiving chemotherapy (Day 8-28 of this intervention).

- **Before initiation of chemotherapy (Day 0 of this intervention)**

This was the time to provide information and training in oral care skills; patients were instructed before chemotherapy began. Providing information and training in oral care skills; patients were instructed and evaluated through a return demonstration before they began chemotherapy. The content and procedures in the program were the principle of normal oral cavities, how to care for and examine their oral cavities, and detect any abnormal signs and symptoms. This approach will encourage feelings of autonomy, promote confidence and allow the patients to demonstrate their ability to perform correct oral care and incorporate this care into their daily routine. In this part, it spent 20-30 minutes since the teaching began until the evaluation of the patient's skills completely.

1.Oral assessment and the evaluation of oral complications of cancer therapy. The oral cavity should be categorized into specific areas that are scored according to the extent of stomatitis. The oral cavities of the participants were assessed daily by the researcher and the participants for 28 days after receiving initial chemotherapy. The OAG scores were confirmed between the researcher and the patients to ensure that the scores were not different between the researcher and each participant. Thus, the participants have the ability to assess the oral cavity by themselves both in the hospital and home.

2.Oral hygiene strategies, patients had the responsibility to perform mouth care in three aspects: First, brush teeth with a soft brush. Use toothpaste containing fluoride, swish and spit normal saline mouthwash and moisturize lips and the oral cavity with a mouth moisturizer as needed. Second, frequencies of mouth care; if a patient scored 8 on the OAG, oral care would be performed at least every 4 hours. If the person scored 9-10, care would be performed every 2 hours. If the score was > 10, care would be performed every 1-2 hours. Finally, additional information; for the patients with dentures, they should remove dentures every time mouth care is performed. If the patient's dentures do not fit well or if the patient experiences any mucosal breakdown, dentures should not be worn. Patients should avoid spicy, acid foods, alcohol and smoking.

- **While undergoing chemotherapy (Day 1-7 of this intervention)**

This was the time for continuing in training and evaluating oral care skills. The participants assessed and cared for their mouth and were psychological supported. The researcher acted as a consultant and resource for the patients. Not only that, while the participants were undergoing chemotherapy (Day 1-7 of this intervention), they received oral cryotherapy and oral supplementation of glutamine, either dried, non-fat milk or grinded soybean

Oral cryotherapy; placing ice-chips in their mouths for 5 minutes prior to each dose of cytosine arabinoside, continuously swish the ice around in their oral cavities, and replenish the ice-chips before the previous ice had completely melted, for a total of 30 minutes per day (day 1-7).

Oral supplementation of glutamine, either dried, non-fat milk or grinded soybean; patients were advised to drink a glass of oral supplementation twice a day initiated on the first day of chemotherapy administration for 28 days (day 1-28). Patients were to swish and swallow the drink. Oral supplementation was prepared by mixing 45 grams of dried, non-fat milk or 50 grams of grinded soybean in 200 ml. of warm water. The warm water used in this study was drinking water boiled and kept in the clean closet.

- **After receiving chemotherapy (Day 8-28 of this intervention)**

After the participants had received chemotherapy (Day 8-28 of this intervention), they were continuing to receive oral supplementation of glutamine, either dried, non-fat milk or grinded soybean. However, It was still the time for continuing in training and evaluating oral care skills. The participants were continuing to assess and care for their mouth.

3. In the case of participants discharged from the hospital before completion of data collection (discharge on day 22–28), the researcher contacted the participants by telephone or postcard to follow-up. If the patients were discharged before day 21, they were dropped out from the study because the researcher did not keep their assessment skills accuracy.

4. After the study had been completed (day 28), the researcher collected the participant comments on receiving oral care program. The researcher informed the

participants what they would like to know about the quality of oral care program. The researcher also assured the participants that all information provided by the participants would be confidential and would never affect their care in the future. The participants were thanked for their participation in the research.

The process of data collection as shown in Figure 7

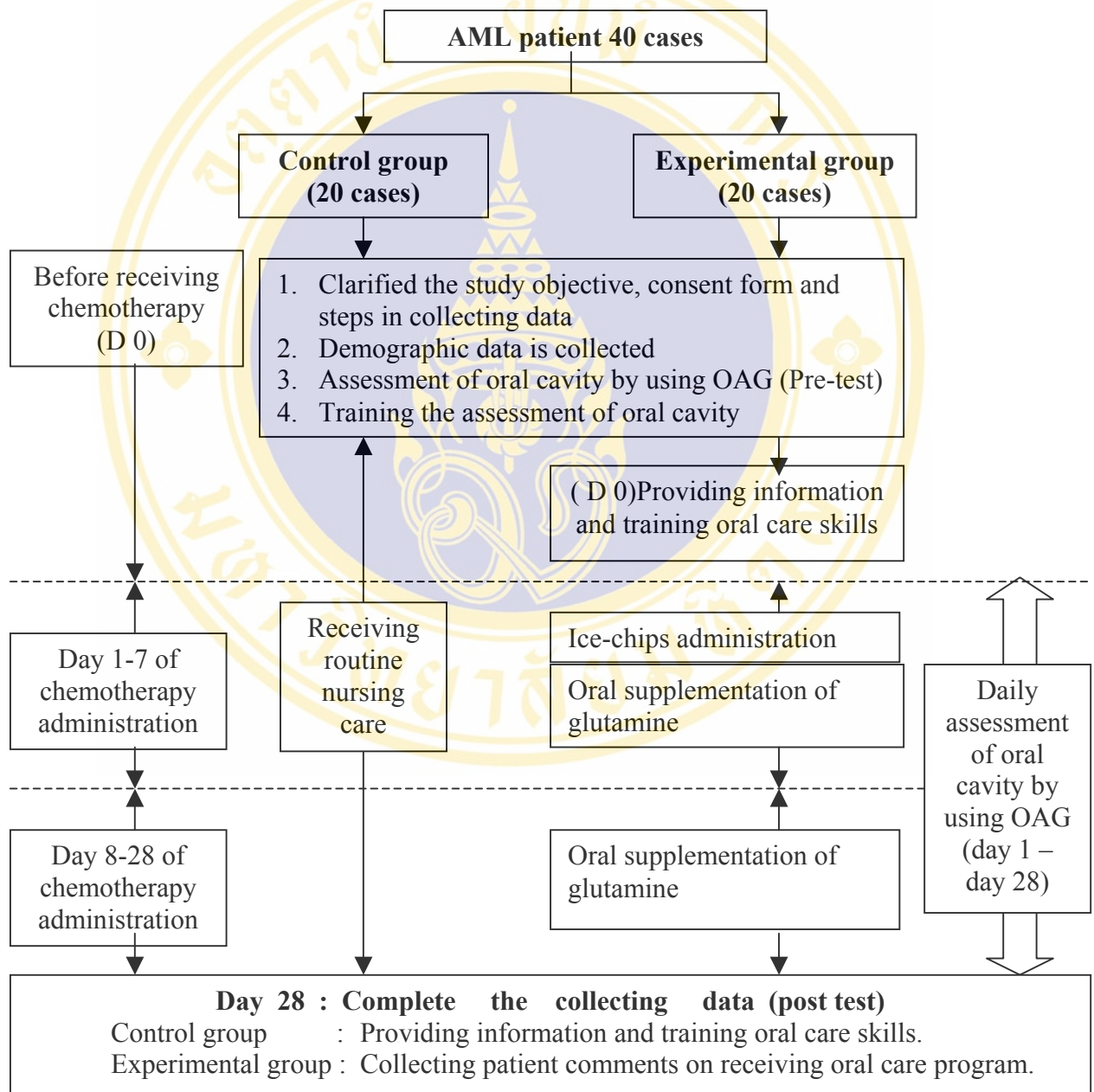


Figure 6 The process of data collection

Condition termination

If the participants had a conditional requirement from the advanced therapy such as, septic shock, cerebral hemorrhage and were on endotracheal tube intubation while receiving the oral care program, the researcher stopped the study immediately and helped the participants to resuscitate.

In this study, 15 eligible subjects were dropped out from the study. In the control group, eight subjects had complication from neutropenia and death before 28 days of data collection and another two had been ceased the chemotherapy administration because they had diagnosed as cerebral hemorrhage. Five subjects in the experimental group were discharged from the hospital before day 21 because the researcher could not keep the intervention accuracy.

Protection of human subjects

Due to the researcher's awareness of ethics in research, data collection was based on human dignity and rights. Before collecting data, the researcher asked for cooperation from the sample groups to obtain consent to perform which indicated the rights and protection of the participants, as well as indicating the purposes of the study.

The sample retained the right to make a decision and whether they were willing to participate in the conduction of the intervention. The samples also had the right to remove themselves from the conduct of the intervention at anytime without any effects on their receiving therapy and nursing care. The sample groups were also informed that any information given would be regarded as confidential. After the samples were informed of these procedures, the researcher could then start the intervention.

In the control group, who received routine nursing care, after the data collection in this group had been completed (day 28), the researcher provided the information and training in oral care skills in order to the control group received the necessary information and appropriate skills in caring their oral cavities.

Data analysis

The data were analyzed through computer by using program of Statistics Package for the Social Science (SPSS for window) in the following steps:

1. Frequency and percentage would be calculated to describe the general characteristics of the participants. Chi-square test and Kolmogorov-Smirnov test were used to test the difference of the sample groups.
2. Kolmogorov-Smirnov test would be used to test the difference of the patients between those who developed stomatitis and those who did not develop stomatitis.
3. Means and standard deviation will be used to analyze the onset, severity and duration of evolution of stomatitis. Using independent t-test compared the difference of mean scores of these variables.
4. Frequency and percentage would be calculated to describe patient's comments on oral care program.

CHAPTER IV

RESULTS

The purpose of this quasi-experimental research was to investigate the effects of an oral care program on stomatitis in acute myeloid leukemia patients undergoing chemotherapy, by measuring the number of patients who develop stomatitis, and its onset, duration, and severity.

There were 55 eligible study subjects participated in this study, 15 eligible subjects were dropped out from the study. In the control group, eight subjects had complication from neutropenia and death before 28 days of data collection and another two had diagnosed as cerebral hemorrhage while receiving chemotherapy (day 1-7) and had been ceased the chemotherapy administration immediately, then these two subjects had not been received complete chemotherapy regimen. Five subjects in the experimental group were discharged from the hospital before day 21 because the researcher could not keep the intervention accuracy. Therefore, a total of 40 subjects remained throughout the study. The participants were separated into two groups, the control group (n = 20) and the experimental group (n = 20). The study started with the control group, and then the experimental group followed. It was conducted at the Asdang building on the 6th, 9th, 10th, 11th, and 12th floors at Siriraj Hospital, Bangkok. The results of the findings were presented in three parts as follows:

Part 1 : The descriptive data of the study population

- 1.1 Demographic data of patients
- 1.2 Clinical characteristics of patients
- 1.3 The history of oral irritation
- 1.4 The previous oral care strategies

Part 2 : The results for Hypotheses testing

- 2.1 The results for Hypotheses 1
- 2.2 The results for Hypotheses 2-4

Part 3 : Patients' opinion on the oral care program

Part 1: The descriptive data of the study population

Part 1 was the descriptive data of the study population including demographic data of patients, their clinical characteristics, the history of oral irritation and the previous oral care strategies.

1.1 Demographic data of patients

Table 1. Frequency and percentage of the sample groups classified by matched gender and age.

Characteristics	Control group (N = 20)		Experimental group (N = 20)	
	n	%	n	%
Gender				
Male	10	50.0	10	50.0
Female	10	50.0	10	50.0
Age				
Adolescent (16-19)	3	15.0	1	5.0
Adult (20-60)	13	65.0	16	80.0
Older adult (61-73)	4	20.0	3	15.0

Table 2. Mean, standard deviation and range of age classified by the control and experimental group. Comparison the mean of age between the control and experimental group by t-test.

Group	Age (years)			t-test
	Mean	SD	Range	
Control group (n = 20)	45.85	17.40	16-73	.111 ^{ns}
Experimental group (n = 20)	45.30	13.68	19-69	

ns = non significant, $p > .05$

Table 3. Frequency and percentage of the sample groups classified by marital status, educational level, type of payment, and occupation. Comparison the data between the samples groups by Kolmogorov-Smirnov test.

Characteristics	Control group (N = 20)		Experimental group (N = 20)		p-value
	n	%	n	%	
Marital status					1.000 ^{ns}
Single	6	30.0	4	20.0	
Married	12	60.0	13	65.0	
Widowed	2	10.0	3	15.0	
Educational level					.978 ^{ns}
Non-attained	2	10.0	3	15.0	
Primary school	7	35.0	7	35.0	
Secondary school	5	25.0	4	20.0	
Diploma	1	5.0	4	20.0	
Bachelor	5	25.0	2	10.0	
Type of payment					1.000 ^{ns}
30 baht	11	55.0	13	65.0	
Government funds	6	30.0	3	15.0	
Life insurance	0	0	2	10.0	
Social security	3	15.0	1	5.0	
Self-pay	0	0	1	5.0	
Occupation					1.000 ^{ns}
Government servant	2	10.0	2	10.0	
Employee	2	10.0	3	15.0	
Merchant	0	0	0	0	
Student	3	15.0	3	15.0	
Unemployed	13	65.0	12	60.0	

ns = non significant, $p > .05$

The demographic characteristics of the participants in both groups are presented in Table 1-3. Table 1 showed that the participants consisted of 20 males and 20 females. The gender distribution was exactly the same, for the two groups, which are 10 males (50%) and 10 females (50%) in each group. The most of the participants was adult (65 % in the control group and 80 % in the experimental group).

Table 2 showed that the age of participants ranged from 16 to 73 years old with the average age of 45.85 years in the control group and ranged from 19 to 69 years old with the average age of 45.30 years in the experimental group. Independent t-test showed that the mean of participant's age between two groups was no significant differences ($p>.05$).

Table 3 showed that many of the participants were married (60 % in the control group and 65% in the experimental group). The most common, educational background was primary school (35% exactly in both group). For methods of medical payment, most commonly they had health insurance or 30 baht scheme (55% in the control group and 65% in the experimental group). A significant number of the participants were unemployed (65% in the control group and 60% in the experimental group). Using Kolmogorov-Smirnov test, there were no significant differences between the two groups ($p>.05$).

1.2 Clinical characteristics of patients

The clinical characteristics of the participants in both groups are presented in Table 4. It showed that the most of the participants in the control group had differentiated on M1 (30%), while the most of the participants in the experimental group had differentiated on M3 (25%). The largest group of them was in the case of their other courses of chemotherapy (55% in the control group and 50% in the experimental group). The largest group of them had been diagnosed as AML less than 1 year (75% in the control group and 80% in the experimental group). Most commonly they received Cytosar with Doxorubicin (60% in the control group and 50% in the experimental group). Using Kolmogorov-Smirnov test, there were no significant differences between two groups ($p>.05$).

Table 4. Frequency and percentage of the sample groups classified by diagnosis, course of chemotherapy, length of time since diagnosis, and drug used in treatment regimen. Comparison the data between the samples groups by Kolmogorov-Smirnov test.

Characteristics	Control group (N = 20)		Experimental group (N = 20)		p-value
	n	%	n	%	
Diagnosis					1.000 ^{ns}
M1	6	30.0	4	20.0	
M2	2	10.0	3	15.0	
M3	3	15.0	5	25.0	
M4	5	25.0	4	20.0	
M5	3	15.0	3	15.0	
M6	1	5.0	1	5.0	
Course of chemotherapy					.978 ^{ns}
First course	9	45.0	10	50.0	
Other course	11	55.0	10	50.0	
Length of time since diagnosis					.819 ^{ns}
< 1 year	15	75.0	16	80.0	
1-2 years	5	25.0	4	20.0	
Drug used in treatment regimen					1.000 ^{ns}
Cytosar+Doxorubicin	12	60.0	10	50.0	
Cytosar+Idarubicin	8	40.0	10	50.0	

ns = non significant, $p > .05$

1.3 The history of oral irritation

The data of the history of oral irritation are presented in Table 5. It showed that the largest group of the participants did not smoke (80% and 70% in the control and the experimental group, respectively), did not drink alcohol (80% and 70% in the

control and the experimental group, respectively). Many of the participants wore the dentures (60% and 50% in the control and the experimental group respectively). The most of the participants did not chew arena, with only one participant in the control group was chewing arena. The data of the history of oral irritation between the two groups when analyzed by Kolmogorov-Smirnov test showed no significant differences ($p>.05$).

Table 5. Frequency and percentage of the sample groups classified by smoking, drinking alcohol, dentures and arena chewing. Comparison the data between the samples groups by Kolmogorov-Smirnov test.

Characteristics	Control group (N = 20)		Experimental group (N = 20)		p-value
	n	%	n	%	
Smoking					1.000 ^{ns}
Non-smokers	16	80.0	14	70.0	
Ex-smokers	3	15.0	4	20.0	
Current smokers	1	5.0	2	10.0	
Alcohol drinking					1.000 ^{ns}
Non-drinkers	16	80.0	14	70.0	
Ex-drinkers	3	15.0	4	20.0	
Current drinkers	1	5.0	2	10.0	
Dentures					1.000 ^{ns}
No	8	40.0	10	50.0	
Yes	12	60.0	10	50.0	
Arena chewing					1.000 ^{ns}
No	19	95.0	20	100.0	
Yes	1	5.0	0	0	

ns = non significant, $p>.05$

1.4 The previous oral care strategies

Table 6. Frequency and percentage of the sample groups classified by frequency of tooth brushing and history of applied mouthwash solution. Comparison the data between the samples groups by Kolmogorov-Smirnov test.

Characteristics	Control group (N = 20)		Experimental group (N = 20)		p-value
	n	%	n	%	
Tooth brushing					1.000 ^{ns}
Twice a day	20	100.0	20	100.0	
Mouthrinse solution					1.000 ^{ns}
Not used	16	80.0	15	75.0	
Used N.S.S	4	20.0	5	25.0	

ns = non significant, $p > .05$

The data of the previous oral care strategies are presented in Table 6. It showed that all of the participants brushed their teeth twice a day, in the morning and at bedtime. Many of the participants did not use a mouthrinse solution (80% and 75% in the control and the experimental group, respectively). The data of the previous oral care strategies between the two groups when analyzed by Kolmogorov-Smirnov test showed no significant differences ($p > .05$).

Part 2 : The results for Hypotheses testing

2.1 Testing the Hypothesis 1

Hypothesis 1 stated that “After receiving chemotherapy for 28 days, the number of AML patients undergoing chemotherapy who participated in the oral care program would develop stomatitis less than those who received routine nursing care.”

In this study, stomatitis were assessed by the Oral Assessment Guide (OAG). Table 7 showed that all of the participants in the control group developed stomatitis, while many of the participants in the experimental group did not develop stomatitis. Kolmogorov-Smirnov test showed that the number of patients who developed

stomatitis in the experimental group was significantly lower than in the control group ($p < .001$). These results supported Hypothesis 1.

Table 7. Comparison the number of the patients with and without stomatitis between the control and experimental group by Kolmogorov-Smirnov test.

Sample group	Stomatitis		p-value
	Yes	No	
Control group	20	0	.000***
Experimental group	2	18	

*** $p < 0.001$

2.2 Testing the Hypotheses 2-4

- Hypothesis 2 stated that “After receiving chemotherapy for 28 days, the onset of stomatitis in AML patients undergoing chemotherapy who participated in the oral care program would be later than in those who received routine nursing care.”
- Hypothesis 3 stated that “After receiving chemotherapy for 28 days, the duration of stomatitis in AML patients undergoing chemotherapy who participated in the oral care program would be shorter than in those who received routine nursing care.”
- Hypothesis 4 stated that “After receiving chemotherapy for 28 days, the severity of stomatitis in AML patients undergoing chemotherapy who participated in the oral care program would be less than in those who received routine nursing care.”

Table 8 showed that the average of the stomatitis onset day was 3.95 (S.D. 1.79) in the control group and 9.00 (S.D. 1.41) in the experimental group. Independent t-test showed that the onset day of stomatitis in the experimental group was significantly later than in the control group ($p < .001$). These results supported Hypothesis 2.

The average of the duration of stomatitis was 21.90 days (S.D. 4.45) in the control group and 10.00 days (S.D. 2.83) in the experimental group. Independent t-test showed that the duration of stomatitis in the experimental group was significantly shorter than in the control group ($p < .001$). These results supported Hypothesis 3.

The average of the severity score of stomatitis was 16.35 (S.D. 3.38) in the control group and 10.50 (S.D. 0.71) in the experimental group. Independent t-test showed that the severity score of stomatitis in the experimental group was significantly less than in the control group ($p<.001$). These results supported Hypothesis 4.

Table 8. Comparison of the mean scores and standard deviation of onset, duration and severity of stomatitis in AML patients undergoing chemotherapy between the control and experimental group by independent t-test.

Sample group	n	Mean	S.D.	t- test
Onset				
Control group	20	3.95	1.79	-3.838***
Experimental group	20	9.00	1.41	
Duration				
Control group	20	21.90	4.45	3.663***
Experimental group	20	10.00	2.83	
Severity				
Control group	20	16.35	3.38	2.394***
Experimental group	20	10.50	0.71	

*** $p<0.001$

Part 3 : Patients' opinion on the oral care program

In the aspect of satisfaction with the oral care program that the participants received, this program focused on providing information and training in oral care skills, oral cryotherapy and oral supplementation of glutamine. Table 9 showed that the satisfaction level of the patients who received the oral care program were high and moderate. Most of the patients had a high level of satisfaction in all part of the program; this was 100% in the part of providing information and training in oral care

skill, 75% in the part of oral cryotherapy and 70% in the part of oral supplementation of glutamine.

Table 9. Satisfaction level of the patients receiving oral care program during 28 days of chemotherapy administration (N = 20)

Satisfaction level	n	%
1. Providing information and training oral care skill		
High	20	100
Moderate	0	0
Low	0	0
2. Oral cryotherapy		
High	15	75
Moderate	5	25
Low	0	0
3. Oral supplementation of glutamine		
High	14	70
Moderate	6	30
Low	0	0

Table 10. The number and percentage of the advantages of the oral care program (N = 20)

Advantages of the oral care program	Number	Percentage
Prevention of stomatitis	18	90
Increased oral intake	17	85
Lessened the extent of stomatitis	16	80
Refreshing the mouth	15	75

*More than one number was permitted

Table 11. The number and percentage of the disadvantages of the oral care program
(N = 20)

Disadvantages of the oral care program	Number	Percentage
Patients was boring with drinking oral supplementation of glutamine	15	75
Toothache from sucking ice-chips	3	15

* More than one number was permitted

The advantage of the oral care program while undergoing chemotherapy was presented in number and percentage. While using the oral care program, Table 10 showed that the most advantages that the patients commented were prevention of stomatitis (90%), increased oral intake (85%), lessened the extent of stomatitis (80%), and it refreshed their mouth (75%). However, some disadvantages that the patients commented on were patients was boring with drinking oral supplementation of glutamine for 28 days and had toothache from sucking ice-chips (Table 11).

Additional finding

This section was about laboratory parameters of body weight, serum albumin, body temperature, absolute neutrophil count, and oral and systemic infection of AML patients who received the oral care program and routine nursing care.

1. Body weight

Patients were measured body weight before starting the oral care program before initial chemotherapy (baseline data) and measured once a week later four times. Figure 7 showed that, the mean of body weight of the control group before initial chemotherapy, after the first week, after the second week, after the third week and after the fourth week were 59.475 (SD 10.385), 58.850 (SD 10.273), 57.550 (SD 10.252), 56.575 (SD 9.966), 55.925 (SD 9.797), respectively. The mean body weight of the experimental group before initial chemotherapy, after the first week, after the second week, after the third week and after the forth week were 55.975 (SD 10.144),

55.440 (SD 10.199), 54.840 (SD 9.961), 54.575 (SD 10.153), 54.725 (SD 10.099), respectively.

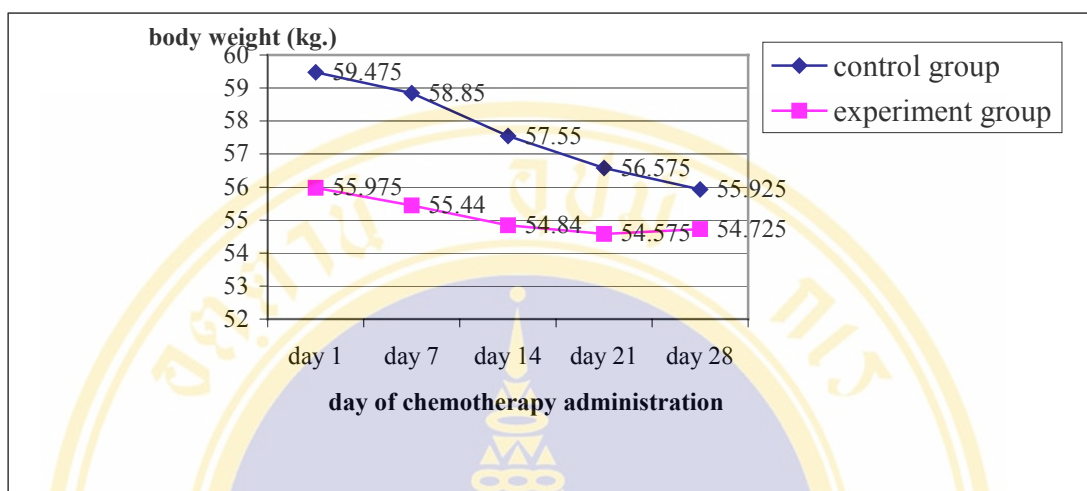


Figure 7. The mean number of body weight of the control and experimental group before initial chemotherapy and measured once a week later for four times.

2. Serum albumin

Table 12. Comparison of the mean scores and standard deviation of serum albumin level of the AML patients undergoing chemotherapy between the control and experimental group and before and after the study by independent t-test.

Sample group	n	Mean	S.D.	t- test
Serum albumin level before chemotherapy administration				
Control group	20	3.716	0.412	0.127 ^{ns}
Experimental group	20	3.700	0.384	
Serum albumin level after 28 days of the study				
Control group	20	2.965	0.490	-3.662 [*]
Experimental group	20	3.480	0.394	

ns = non significant, $p > .05$

* $p < 0.05$

The data of serum albumin level was presented in Table 12. It showed that the mean of serum albumin level before chemotherapy administration in the control group was 3.716 gm./dl. and 3.716 gm./dl. in the experimental group. Independent t-test showed that the mean of serum albumin level before chemotherapy administration between two groups was no significant differences ($p>.05$). It was found that the AML patients, after they received chemotherapy, had lower levels of albumin than before they received chemotherapy. The mean of serum albumin level after 28 days of the study in the control group was 2.965 gm./dl. and 3.480 gm./dl. in the experimental group. Independent t-test showed that the mean of serum albumin level after 28 days of the study in the control group was significantly lower than in the experimental group ($p<.05$).

3. Body temperature

Table 13 showed that the average of time (days) which the AML patients undergoing chemotherapy had body temperature more than 38.3°C were 16.90 (S.D. 6.81) in the control group and 7.30 (S.D. 3.91) in the experimental group. Independent t-test showed that time (days), which the AML patients undergoing chemotherapy had oral temperature more than 38.3°C, in the experimental group was significantly shorter than in the control group ($p<.001$).

Table 13. Comparison of the mean scores and standard deviation of time (days) which the AML patients undergoing chemotherapy had oral temperature more than 38.3°C between the control and experimental group by independent t-test.

Sample group	n	Mean	S.D.	t- test
Control group	20	16.90	6.81	5.466***
Experimental group	20	7.30	3.91	

*** $p<0.001$

4. Absolute neutrophil count (ANC)

Table 14 showed that the average of time (days) which the AML patients undergoing chemotherapy had an absolute neutrophil count less than 500/mm³ were 20.45 (S.D. 4.83) in the control group and 11.10 (S.D. 2.57) in the experimental group.

Independent t-test showed that time (days), which the AML patients undergoing chemotherapy had an absolute neutrophil count less than $500/\text{mm}^3$ in the experimental group was significantly shorter than in the control group ($p<.001$).

Table 14. Comparison of the mean scores and standard deviation of time (days) which the AML patients undergoing chemotherapy had absolute neutrophil count less than $500/\text{mm}^3$ between the control and experimental group by independent t-test.

Sample group	n	Mean	S.D.	t- test
Control group	20	20.45	4.83	7.643***
Experimental group	20	11.10	2.57	

*** $p<0.001$

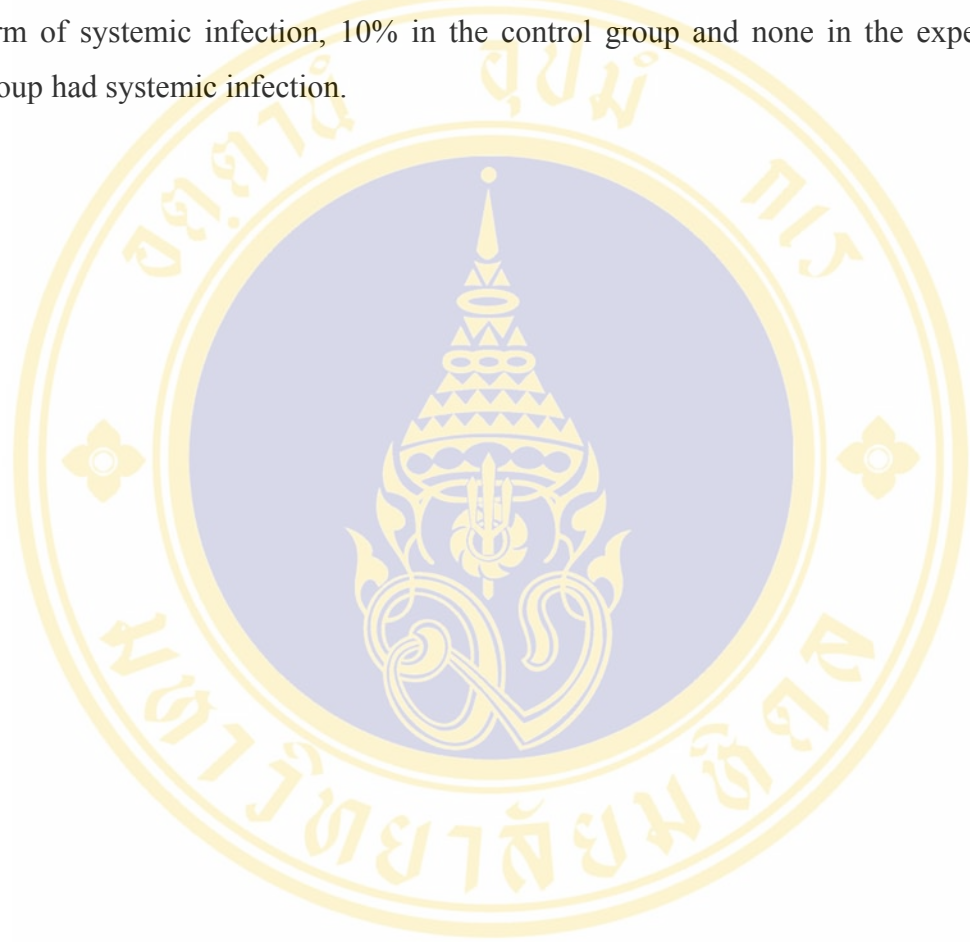
5. Oral and systemic infection

Table 15. Frequency and percentage of the number of the patients with and without oral and systemic infection. Comparison the data between the samples groups by Kolmogorov-Smirnov test.

Characteristics	Control group (N = 20)		Experimental group (N = 20)		p-value
	n	%	n	%	
Oral infection					0.819 ^{ns}
Negative	16	80.0	20	100.0	
Positive	4	20.0	0	0	
Systemic infection					1.000 ^{ns}
Negative	18	90.0	20	100.0	
Positive	2	10.0	0	0	

ns = non significant, $p>.05$

The data of the oral infection were derived from the culture of the oral thrush, while the data of the systemic infection was derived from the blood culture. The data of the oral and systemic infection were showed in Table 15. It showed that the most of the participants did not have oral and systemic infection. In the term of oral infection, 20% in the control group and none in the experimental group had oral infection. In the term of systemic infection, 10% in the control group and none in the experimental group had systemic infection.



CHAPTER V

DISCUSSION

This chapter was the discussion of the results of the study; in which the main purpose was to investigate the effects of an oral care program on stomatitis in AML patients undergoing chemotherapy. There were two groups of patients, the control group and the experimental group. The design of this study started with the control group, and after data collection in the control group was completed, continued with the experimental group. The researcher tried to prevent the contamination of the experimental intervention for the control group that could have caused feelings of inequality of services. The researcher tried to prevent inequality between the study groups by matching their gender and age. Other related factors were confirmed by Kolmogorov-Smirnov test to show that they were not different. From the study, the demographic data, the clinical characteristics, the history of oral irritation and the previous oral care strategies of the patients showed no significant difference (Table 1-6). This helped increase the equality between groups and reduce factors that could interfere with the effects of the intervention program.

The effects of an oral care program on stomatitis

The oral care program consisted of three interventions used, a) providing information and training in oral care skills, b) oral cryotherapy, and c) oral supplementation of glutamine. These three interventions cooperated in decreasing the number of patients who develop stomatitis, delaying the onset, shortening the duration and decreasing the severity of stomatitis. Thus, the results derived from this study strongly support all Hypotheses. The discussion of the effects of the oral care program could not split out because the oral care program was an integration nursing intervention and cooperate in decreasing the number of patients who develop stomatitis, delaying the onset, shortening the duration and lessening the severity of stomatitis.

In the aspects of the number of patients who developed stomatitis and the onset day of stomatitis, it was found that all of the participants in the control group developed stomatitis while 2 participants in the experimental group developed stomatitis. Hypothesis I, it was found that the number of AML patients who developed stomatitis in the experimental group was significantly lower than in the control group ($p<.001$) (Table 7). Thus, Hypothesis 1 was supported, the oral care program could prevent stomatitis. Furthermore, it was found that the average of the stomatitis onset day was 3.95 (S.D. 1.79) in the control group and 9.00 (S.D. 1.41) in the experimental group. Independent t-test showed that the onset day of stomatitis in the experimental group was significantly later than in the control group ($p<.001$) (Table 8). These results supported Hypothesis 2. The lower number of patients who developed stomatitis and the delayed onset day of stomatitis in the experimental group were described as follow:

Firstly, swishing ice-chips or oral cryotherapy was placing ice-chips in the mouths for 5 minutes prior to each dose of cytosine arabinoside, and continuously swishing the ice around in their oral cavities for a total of 30 minutes and replenished the ice-chips before the previous ice had completely melted for a total of 30 minutes per day (day 1-7). Oral cryotherapy should cause local vasoconstriction, thereby decreasing oral mucosal blood flow. The ice decreased circulation during peak blood flow levels of the chemotherapeutic agents. The peak blood flow level of continuous intravenous infusion of cytosine arabinoside was 7-20 minutes (Grem et al In J.S. Macdonald, D.G. Haller and R.J. Mayer, 1995: 117). Oral cryotherapy caused local vasoconstriction in the time of peak blood flow levels of chemotherapeutic agents, so the oral mucosal cells could reduce reabsorption of cytosine arabinoside. Thus, oral mucosal cells were less damaged by chemotherapy. The integrity of the mucosal surface should not be decreased.

Next, oral supplementation of glutamine, either dried, non-fat milk or grinded soybean, a part of the oral care program, could be a primary fuel for rapidly dividing cells including lymphocytes and colonocytes. Providing the cells with an optimal nutrients/energy source such as glutamine in edible food of dried, non-fat milk or grinded soybean were used. Ninety grams of dried, non-fat milk or one hundred grams of grinded soybean consisted of 6 mg.glutamine per day, a large amount of glutamine,

which might be used to prolong the lifetime and strengthen the oral mucosa. The oral mucosal cells of the experimental group may be stronger than the control group.

And lastly, the providing information and training in oral care skills could increase both knowledge and skills. Patients were instructed before chemotherapy began. Patients who had both knowledge and skills adequately and appropriately, could be promote their ability to adapt and learn easily, so that would be gain much needed confidence, encourage feelings of autonomy. Furthermore, both knowledge and skills allowed the patients to demonstrate their ability to perform correct oral care and incorporated this care into their daily routine. The experimental group, who received the oral care program, always took care of their oral cavity. Oral hygiene strategies promoted cleanliness of the oral cavity and could be helpful in maintaining the moisture, refreshment and softness in the mouth, removing the debris and reducing the accumulation of plaque and infection, so that the mucosal barrier remained infection-free. When the participants performed routine oral care, oral hygiene strategies, good oral hygiene occurred. Good oral hygiene had been shown to be important in maintaining integrity of the oral mucosa and could be a strategy to prevent stomatitis. (Kenny S.A., 1990: 352). Furthermore, careful and systematical early assessment also increased the likelihood of early detection of treatable oral abnormal signs, so the researcher could be provided appropriate nursing interventions.

The oral care program which consisted of three nursing interventions could be important in maintaining integrity of the oral mucosa, so chemotherapy might harm the oral mucosa in lower or later chance, thus causing stomatitis did not occur and a delay in the onset day of stomatitis. These three interventions in the oral care program must be integrated. Then, it would prevent the chemotherapy-induced stomatitis and delayed the onset of stomatitis. In conclusion, this study found that the experimental group had lower number of patients who developed stomatitis, as well as prevention of stomatitis, and later onset day of stomatitis than in the control group.

In the aspects of the duration of stomatitis, in this study, the average of the duration of stomatitis was 21.90 days (S.D. 4.45) in the control group and 10.00 days (S.D. 2.83) in the experimental group. Independent t-test showed that the duration of stomatitis in the experimental group was significantly shorter than in the control group ($p < .001$) (Table 8). These results supported Hypothesis 3. In the aspects of the severity

of stomatitis, in this study, the mean of the severity score of stomatitis was 16.35 (S.D. 3.38) in the control group and 10.50 (S.D. 0.71) in the experimental group. Independent t-test showed that the severity score of stomatitis in the experimental group was significantly less than in the control group ($p < .001$) (Table 8). These results supported Hypothesis 4.

The patients in the experimental group developed stomatitis on the ninth day (onset), after receiving chemotherapy. They were continuing to receive oral supplementation of glutamine, either dried, non-fat milk or grinded soybean. However, it was still the time for continuing in training and evaluating oral care skills. The participants were continuing to assess and care for their mouth. Thus, the shorter duration and less severity of stomatitis in the experimental group, who received the oral care program, were the effects of oral supplementation of glutamine and oral care strategies. Ninety grams of dried, non-fat milk or one hundred grams of grinded soybean provided a large amount of protein and energy, which might be support the nutritional status of the patients. From this study, it was found that the reduction of body weight and serum albumin level in the experimental group were less than in the control group. It was found that the mean of body weight of the control group before initial chemotherapy, after the first week, after the second week, after the third week and after the fourth week were 59.475 (SD 10.385), 58.850 (SD 10.273), 57.550 (SD 10.252), 56.575 (SD 9.966), 55.925 (SD 9.797), respectively. The mean body weight of the experimental group before initial chemotherapy, after the first week, after the second week, after the third week and after the fourth week were 55.975 (SD 10.144), 55.440 (SD 10.199), 54.840 (SD 9.961), 54.575 (SD 10.153), 54.725 (SD 10.099), respectively (Figure 7). From these results, it was found that the reduction of body weight in the experimental group was less than the control group.

In the term of serum albumin level, it was found that the mean of serum albumin level before chemotherapy administration in the control group was 3.716 gm./dl. and 3.716 gm./dl. in the experimental group. The mean of the serum albumin level in both groups before they received chemotherapy (day 0) was in the acceptable range. Independent t-test showed that the mean of serum albumin level before chemotherapy administration between two groups was no significant differences ($p > .05$). It was found that the AML patients, after they received chemotherapy, had lower level of

albumin than before they received chemotherapy. The mean of serum albumin level after 28 days of the study in the control group was 2.965 gm./dl. and 3.480 gm./dl. in the experimental group. Independent t-test showed that the mean of serum albumin level after 28 days of the study in the control group was significantly lower than in the experimental group ($p<.05$) (Table 12). It was found that the reduction of the serum albumin level of the experimental group was less than the control group. However, the body weight and serum albumin level of the patients decreased because chemotherapy caused various problems; for examples, a dry mouth, sore throat, altered taste and smell sensations, nausea and vomiting, which resulted in a form of low nutritional intake. Thus, the oral supplementation of glutamine could maintain the nutritional status of AML patients undergoing chemotherapy. Then, the reduction of body weight and serum albumin level in the experimental group were less than in the control group, who received routine nursing care.

Furthermore, the oral supplementation of glutamine provided substrate for the synthesis of purines and pyrimidines needed for DNA, RNA, and mRNA (Skubitz K.M., and Anderson P.M., 1996: 223-224) and stimulated lymphocytes, macrophages and intestinal mucosal cells (Ziegler et al, 1992: 821). Thus, it might be result in enhancement of the recovery of neutrophil from chemotherapy. From this study, it was found that the average and standard deviation of time (days) which the AML patients undergoing chemotherapy had an absolute neutrophil count less than $500/\text{mm}^3$ in the control group was more than the experimental group. It was found that the average of time (days) which the AML patients undergoing chemotherapy had an absolute neutrophil count less than $500/\text{mm}^3$ were 20.45 (S.D. 4.83) in the control group and 11.10 (S.D. 2.57) in the experimental group. Independent t-test showed that time (days) which the AML patients undergoing chemotherapy had an absolute neutrophil count less than $500/\text{mm}^3$ in the experimental group was significantly lower than in the control group ($p<.001$) (Table 14).

And lastly, the providing information and training in oral care skills can promote their ability to perform routine oral care, which good oral hygiene occurred. Oral hygiene strategies promoted cleanliness of the oral cavity and can be helpful in maintaining the moisture, refreshment and softness in the mouth, removing the debris and reducing the accumulation of plaque and infection. Good oral hygiene actually

stimulates circulation in the mouth, decreasing the chance for infection. Furthermore, careful and systematical early assessment also increases the likelihood of early detection of treatable oral abnormal signs, so the researcher could provide appropriate nursing interventions. From this study, it was found that the average of time (days) which the AML patients undergoing chemotherapy had body temperature of more than 38.3°C were 16.90 (S.D. 6.81) in the control group and 7.30 (S.D. 3.91) in the experimental group. Independent t-test showed that time (days) which, the AML patients undergoing chemotherapy, had oral temperature of more than 38.3°C in the experimental group was significantly lower than in the control group ($p < .001$) (Table 13). The data of the oral infection were derived from the culture of the oral thrush, while the data of the systemic infection was derived from the blood culture. It was found that the most of the participants did not have oral and systemic infection. In the term of oral infection, 20% in the control group and none in the experimental group had oral infection. In the term of systemic infection, 10% in the control group and none in the experimental group had systemic infection (Table 15). In addition, good oral hygiene and careful and systematical early assessment had been shown to be important in increasing the taste sensation, which increasing the patient's appetite, then it could maintain the nutritional status of AML patients undergoing chemotherapy.

From this study, it was found that the providing of information and training in oral care skills and oral supplementation of glutamine could effect on the body weight, serum albumin level, the duration of time (days) which, the patients had oral temperature of more than 38.3°C, absolute neutrophil count less than 500/mm³, and oral and systemic infection. The patients in the experimental group, who received the oral care program had lower reduction of body weight and serum albumin level, the shorter duration of time (days) which, the patients had oral temperature of more than 38.3°C, had absolute neutrophil count less than 500/mm³, and less oral and systemic infection than in the control group. Consequently, the better nutritional status and immune function could promote wound healing, reduced the infection, and caused rapid resolution. Thus, in this study, the experimental group had shorter duration and less severity of stomatitis than in the control group.

From the reason mentioned above, AML patients undergoing chemotherapy who received an oral care program had lower number of patients who developed stomatitis, later onset, shorter duration and less severity of stomatitis. However, each intervention had been approved by previous studies as followed:

In the part of providing information and training in oral care skill, the findings found in this study were similar to the study of Kenny S.A. (1990: 352), who suggests that pre-intervention assessment can reduce the incidence and severity of stomatitis.

In the part of oral supplementation of glutamine, the findings found in this study were similar to the studies of Skubitz and Anderson (1996), who studied the effects of supplemental glutamine on chemotherapy-induced mucositis. Patients received a suspension of L-glutamine 4 grams swished and swallowed orally twice a day, from day 1 of chemotherapy for 28 days or for 4 days past the resolution of any post-chemotherapy stomatitis. They found significant reductions in the grade of stomatitis as well as the duration of the mucositis. Subjectively the patients felt that the mucositis was less severe, which was important as a quality of life issue.

In the part of oral cryotherapy, the findings found in this study were similar to the studies of Mahood et al, (1991) and Natethong T. (1999), patients in the cryotherapy group placed ice chips in their mouths five minutes prior to each dose of 5-FU, continuously swished the ice around the oral cavity, and replenished the ice before it melted for a total of 30 minutes. Patients in the treatment group had significantly reduced stomatitis as judged by physicians and by the patients themselves.

In the aspect of combination intervention, the results from this study were consistency with the previous studies of Toowicharanon P. (2000), which studied the effects of chemotherapy and integrated nursing interventions on oral mucositis in leukemia patients. The patients received ice chips administration combined with oral supplementation of dried, non-fat milk and oral hygiene management. The results revealed that the patients who received complete intervention had lower occurrence of stomatitis, later onset, shorter duration, and less extent of erythema and ulcers.

In addition to this study revealed the effects of an oral care program on stomatitis, the researcher asked the patients about the satisfaction level of the oral care program, too. In this study, the satisfaction level of the patients who received the oral

care program was high and moderate. Most of the patients had a high level of satisfaction in all part of the program; these were 100%, 75% and 70% in the part of providing information and training in oral care skill, oral cryotherapy and oral supplementation of glutamine, respectively. While using the oral care program, the most advantage that the patients commented were prevention of stomatitis, increased oral intake, lessened the extent of stomatitis, and it refreshed their mouth. However, some disadvantages that the patients commented on were patients was boring with drinking oral supplementation of glutamine for 28 days and had toothache from sucking ice-chips. The various levels of satisfaction might be due to the willingness to be alive of the patients because the patients with willingness to be alive had willpower to perform self-care. In addition to the prior experience of stomatitis might be affecting the patients to realize the suffering of the stomatitis and attempt to prevent the stomatitis. When the researcher suggested the patients to perform the oral care program, they were extremely rejoiced to do.

In reality, the improvement of the patients depends upon various factors such as type and dosage of chemotherapy, the responses of the patients to the chemotherapy and appropriate nursing intervention. The researcher realizes that it is essential for nurses to utilize various methods. This study revealed that the AML patients undergoing chemotherapy who received the oral care program, which consisted of a) providing information and training in oral care skills, b) oral cryotherapy and c) oral supplementation of glutamine, had the lower numbers of patients who developed stomatitis, and had delayed onset, shortened duration and lessened severity of stomatitis. Thus, these three interventions consisted in the oral care program must be integrated. Then, the oral care program was important for preventing the chemotherapy-induced stomatitis, delaying the onset, shortening the duration and lessening the severity of stomatitis. The most of the patients was satisfied in the oral care program, which was a nursing intervention to promote well being, too.

CHAPTER VI

CONCLUSION

This chapter is organized into two sections. The first section is the summary of the study. The second section focuses on the implications and applications of the research findings and recommendations

Summary of the study

This study aimed to explore the effects of an oral care program on stomatitis in AML patients undergoing chemotherapy. The program was measured the number of patients who developed stomatitis, and its onset, duration and severity. The study was conducted between January to May 2003, at the Asdang building on the 6th, 9th, 10th, 11th, and 12th floors at Siriraj Hospital, Bangkok.

The participants were 40 AML patients receiving chemotherapy. The participants were divided into two groups. The first twenty participants, the control group, were assigned to receive routine nursing care. The other twenty participants, the experimental group, were assigned to receive the oral care program. The oral care program was designed based on the supportive-educative nursing system of Orem's theory.

The intervention for the experimental group consisted of (1) providing information and training in oral care skills, (2) Oral cryotherapy, and (3) Oral supplementation of glutamine. Stomatitis was assessed and measured according to the Oral Assessment Guide (OAG) of Eilers J., Berger A.M., and Peterson M.C. (1988). The researcher received a kind response from June Eilers for her copyright permission.

Data collection was started with the control group and the experimental group followed. The participants in both group were instructed how to self-assess the oral cavity. The oral cavities of the participants were assessed daily by the researcher and the participants for 28 days after receiving initial chemotherapy. The OAG scores were confirmed between the researcher and the patients to ensure that the scores were not different between the researcher and each participant. Thus, the participants have

the ability to assess the oral cavity by themselves both in the hospital and home. In the case of participants discharged from the hospital before complete data collection, the researcher contacted the participants by telephone or postcard to follow-up.

Data were analyzed by computer by using the program of Statistics Package for the Social Science (SPSS for window). Comparison the difference of the participant's characteristics and the number of patients who developed stomatitis were done by using Kolmogorov-Smirnov test. The difference of mean scores at the onset, duration and severity of stomatitis were compared between the two groups by using independent t-test. The findings are summarized as follows

1. The descriptive data of the study population

The results of this study revealed that the demographic data of patients, their clinical characteristics, the history of oral irritation and the previous oral care strategies had no significant difference between the two groups ($p > .05$) (Table 1-6).

2. The results for hypotheses testing

The results of the study showed that the number of AML patients who developed stomatitis in the experimental group was significantly lower than in the control group ($p < .001$) (Table 7). In the aspect of onset, it was found that the onset day of stomatitis in the experimental group was significantly later than in the control group ($p < .001$). In the aspect of duration, it was found that the duration of stomatitis in the experimental group was significantly shorter than in the control group ($p < .001$). And in the aspect of severity, it was found that the severity score of stomatitis in the experimental group was significantly less than in the control group ($p < .001$) (Table 8).

3. Satisfaction with the oral care program

The patients had a high level of satisfaction in all part of the program (100% in the part of providing information and training in oral care skill, 75% in the part of oral cryotherapy and 70% in the part of oral supplementation of glutamine). The advantage of the oral care program while undergoing chemotherapy was it prevented stomatitis, increased oral intake, lessened the extent of stomatitis, and refreshed the mouth (Table 10). However, some disadvantages that the patients

commented on were patients were boring with drinking oral supplementation of glutamine for 28 days and had toothache from sucking ice-chips (Table 11).

Implications and applications of the research findings to nursing practice

The researcher believes that the supportive-educative nursing system in the oral care program is necessary, useful, essential and important for every AML patient as follows

1. This program could be used as a nursing guideline for AML patients for minimizing the side effects of chemotherapy on the oral cavity and could be utilized as a model for other patients who received chemotherapy too. But for the effective use, all of the nursing staff should be trained and organized to develop the knowledge and basic understanding of this program, such as oral assessment skills and oral hygiene strategies.
2. The information and oral care skills should be contained in a concise booklet form then the patients can be used to reread.
3. Giving the necessary information and skills enabled patients to perform and accomplish the self-care practice constantly. Then, it should be provided whenever the nurses met the patients and should be evaluated until it was accuracy. Thus, it will decrease absent time, encourage the patients to continue their treatment, control the cost of care and prevent the infection that could occur.
4. Oral supplementation of glutamine used in this study was dried, non-fat milk and grinded soybean. It was found that some patients were boring with this. It may be recommended that patients eat other kinds of food, which contain glutamine such as eggs. But the appropriate amount of glutamine received must be controlled.
5. The patients undergoing chemotherapy were immuno-suppressed, then the cleanliness should be strongly aware such as water, ice-chips, oral supplementation of glutamine, food container and equipment used in the oral assessment and mouth care.
6. The equipment used in the oral assessment and mouth care procedures included flashlight, gauze, tongue blades, tissue paper, mirror, swab and mouth care set, must be prepared and available for every patient.
7. When the patients could perform oral care by themselves correctly, the nurses should give positive reinforcement, such as appreciation, and empower the patients to

incorporate this care into their daily routine. Because the giving appreciation or compliment to patient will yield willpower and be proud, thus enabling them to perform and accomplish the self-care practice constantly.

8. The follow-up visits were also designed to evaluate patient's performance on oral care skills and assess the oral cavities through exchange of opinions and collaboration on how to encounter and solve problems.

9. A multidisciplinary team approach to oral care for cancer patients undergoing chemotherapy should be provided and encouraged. Nurses are leaders in recognizing early changes in patient's problems, and providing oral care and close collaboration with physicians and practical nurses.

Recommendations for further study

This study had some weak points, so the researcher recommends for further study as follows

1. Further research should investigate other clinical outcomes, such as anthropometric measurement, serum electrolytes and creatinine.
2. Since chemotherapy is a frequent treatment of malignancies, the findings could be applied to other malignancies. However, further study is needed to ensure the effectiveness of the oral care program in different groups of cancer patients.
3. Further research should use a large sample size of AML patients undergoing chemotherapy and randomized control trial recommendation for more representation and better generalization of study.

Limitations of the study

In Siriraj Hospital, it was accepted that stomatitis is a common, debilitating complication of cancer chemotherapy. But it was found that there has not been a recorded incidence of stomatitis. In the period of data collecting, especially in the control group, there was showed the high occurrence of stomatitis and the patients were usually suffering from stomatitis, too. According to the nursing department, Siriraj Hospital, had working hard in quality control in nursing care, which the side effect of chemotherapy was one of the measurement criteria, then the nurses were interesting in this situation increasingly, such as assessed the oral cavity, discussed about the problem and strategies and collaborated with the doctor to care the oral cavity.

When the experimental group was initiated, many nursing staff appreciated about the effectiveness of the oral care program and interesting in caring oral cavity increase. Then, the experimental group received both the oral care program from the researcher and the continuing care from the ward nurses. The researcher could not forbid them to involve the intervention. Thus, the results in the experimental group may be better than actuality.



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วิทยานิพนธ์หลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต (พยาบาลศาสตร์) มหาวิทยาลัยมหิดล.

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APPENDIX A

NAMES OF VALIDATORS

Names of Validators

The names of qualified experts who kindly examine in verifying the validity of the instrument of this study

1. Assist. Prof. Thipapun Sungkapong

Department of medical nursing
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2. Assist. Prof. Chuanpit Norradechanont

Department of obstetric and gynecologic nursing
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4. Miss Sujit Kitbuncha

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5. Miss Prapimpan Toowicharanon

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Mahidol University.



APPENDIX B

THE CONSENT FORM

เอกสารพิทักษ์สิทธิ (สำหรับกลุ่มทดลอง)

ดิฉันนางสาววิมลวรรณ เลิศวงศ์เผ่าพันธุ์ นักศึกษาปริญญาโท สาขาการพยาบาลผู้ใหญ่ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล สนใจที่จะศึกษาอาการเยื่อช่องปากอักเสบในผู้ป่วย มะเร็งเม็ดเลือดขาวที่ได้รับยาเคมีบำบัด โดยมีวัตถุประสงค์เพื่อเป็นแนวทางในการดูแลช่องปากในผู้ป่วย มะเร็งเม็ดเลือดขาวที่ได้รับยาเคมีบำบัด

อย่างไรก็ตามการศึกษานี้จะสำเร็จไปไม่ได้เลยหากไม่ได้รับความร่วมมือจากท่าน จึงใคร่ขอความร่วมมือจากท่านในการเข้าร่วมกิจกรรมตามโปรแกรมการดูแลช่องปาก ซึ่งใช้เวลาทั้งสิ้น 28 วัน โดยมีกิจกรรมดังนี้คือท่านต้องตอบแบบสอบถามข้อมูลทั่วไป ซึ่งใช้เวลาประมาณ 15-20 นาที ตลอดจนได้รับข้อมูลและการฝึกทักษะการดูแลช่องปากด้วยตนเองจากนักวิจัย ท่านจะได้รับคู่มือการดูแลช่องปากด้วยตนเอง ท่านต้องอมน้ำแข็งในปากอย่างต่อเนื่องกันนานวันละ 30 นาที ขณะที่ได้รับยาเคมีบำบัดรวมทั้งสิ้นเป็นเวลา 7 วัน และดื่มนมวันละ 2 ครั้ง ครั้งละ 200 มิลลิลิตร เป็นเวลา 28 วันนับจากวันที่ท่านได้รับยาเคมีบำบัดวันแรก ซึ่งตลอดระยะเวลาทั้ง 28 วันนับตั้งแต่วันที่ท่านได้รับยาเคมีบำบัด ท่านจะได้รับการตรวจประเมินสภาพช่องปากวันละ 1 ครั้งจากนักวิจัยหลังจากนั้นท่านต้องตอบแบบประเมินความคิดเห็นเกี่ยวกับโปรแกรมการดูแลช่องปาก ซึ่งจะถือว่าเสร็จสิ้นการเข้าร่วมโครงการวิจัย

การศึกษานี้ขึ้นอยู่กับความสมัครใจของท่าน ไม่ว่าท่านจะเข้าร่วมการวิจัยหรือไม่ก็ตาม จะไม่มีผลกระทบต่อท่านและการรักษาพยาบาลที่ท่านได้รับแต่อย่างใด แม้ท่านยินดีเข้าร่วมการวิจัยและภายหลังเกิดการเปลี่ยนใจ ท่านมีสิทธิ์จะขอถอนตัวได้โดยไม่มีข้อแม้ใดๆ นอกจากนี้ ข้อมูลที่ได้จากท่านทั้งหมดจะถือเป็นความลับ และแสดงผลการศึกษาเป็นภาพรวมเท่านั้น ในระหว่างเข้าร่วมการวิจัย ถ้ามีข้อสงสัยใดๆ ดิฉันยินดีตอบข้อสงสัยของท่านตลอดเวลาและขอขอบคุณที่กรุณาให้ความร่วมมือ

วิมลวรรณ เลิศวงศ์เผ่าพันธุ์

ผู้วิจัย

เอกสารพิทักษ์สิทธิ (สำหรับกลุ่มควบคุม)

ดิฉันนางสาววิมลวรรณ เลิศวงศ์เผ่าพันธุ์ นักศึกษาปริญญาโท สาขาการพยาบาลผู้ใหญ่ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล สนใจที่จะศึกษาอาการเยื่อช่องปากอักเสบในผู้ป่วย มะเร็งเม็ดเลือดขาวที่ได้รับยาเคมีบำบัด โดยมีวัตถุประสงค์เพื่อเป็นแนวทางในการดูแลช่องปากในผู้ป่วย มะเร็งเม็ดเลือดขาวที่ได้รับยาเคมีบำบัด

อย่างไรก็ตามการศึกษาในครั้งนี้จะสำเร็จไปไม่ได้เลยหากไม่ได้รับความร่วมมือจากท่าน จึงใคร่ขอความร่วมมือจากท่านในการเข้าร่วมกิจกรรมตามโปรแกรมการดูแลช่องปาก ซึ่งใช้เวลาทั้งสิ้น 28 วัน โดยมีกิจกรรมดังนี้คือท่านต้องตอบแบบสอบถามข้อมูลทั่วไป ซึ่งใช้เวลาประมาณ 15-20 นาที และตลอดระยะเวลาทั้ง 28 วันนับตั้งแต่ท่านได้รับยาเคมีบำบัด ท่านจะได้รับการตรวจประเมินสภาพช่องปากวันละ 1 ครั้งจากนักวิจัย จึงจะถือว่าเสร็จสิ้นการเข้าร่วมโครงการวิจัย

การศึกษาในครั้งนี้ขึ้นอยู่กับความสมัครใจของท่าน ไม่ว่าท่านจะเข้าร่วมการวิจัยหรือไม่ก็ตาม จะไม่มีผลกระทบต่อท่านและการรักษาพยาบาลที่ท่านได้รับแต่อย่างใด แม้ท่านยินดีเข้าร่วมการวิจัยและภายหลังเกิดการเปลี่ยนใจ ท่านมีสิทธิ์จะถอนตัวได้โดยไม่มีข้อแม้ใดๆ นอกจากนี้ ข้อมูลที่ได้จากท่านทั้งหมดจะถือเป็นความลับ และแสดงผลการศึกษาเป็นภาพรวมเท่านั้น ในระหว่างเข้าร่วมการวิจัย ถ้ามีข้อสงสัยใดๆ ดิฉันยินดีตอบข้อสงสัยของท่านตลอดเวลาและขอขอบคุณที่กรุณาให้ความร่วมมือ

วิมลวรรณ เลิศวงศ์เผ่าพันธุ์
ผู้วิจัย



APPENDIX C

แผนการให้ข้อมูลและฝึกทักษะ

เรื่อง : การดูแลช่องปากด้วยตนเองในผู้ป่วยมะเร็งเม็ดเลือดขาวที่ได้รับยาเคมีบำบัด

โดย : นางสาววิมลวรรณ เลิศวงศ์แผ่พันธุ์
นักศึกษาหลักสูตรพยาบาลศาสตรมหาบัณฑิต คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล

วัตถุประสงค์:

เพื่อให้ผู้ป่วยมะเร็งเม็ดเลือดขาวที่ได้รับยาเคมีบำบัดมีความรู้ความเข้าใจเกี่ยวกับการดูแลช่องปากด้วยตนเอง และสามารถปฏิบัติตนก่อน / ระหว่าง และภายหลังการรักษาด้วยยาเคมีบำบัดได้อย่างมีประสิทธิภาพ

กิจกรรมการสอน : สนทนา ซักถาม และ สาธิต โดยทำการสอนเป็นรายบุคคล หรือกลุ่มย่อยประมาณ 3 – 5 คน

สื่อการสอน : แผ่นพับ

ขั้นตอนการสอน:

- 1.สร้างสัมพันธภาพ
- 2.ประเมินความรู้ของผู้ป่วยก่อนทำการสอน
- 3.สอน อธิบาย และเปิดโอกาสให้ผู้ป่วยซักถาม เมื่อมีข้อสงสัยเป็นระยะ ๆ
- 4.ประเมินผลการสอนโดยใช้การสอบถาม และให้ผู้ป่วยลองทำให้อู

ระยะเวลา : 15 – 30 นาที

วิธีการประเมิน : การสังเกตและการซักถาม

ขอบเขตเนื้อหา

- 1.ความสำคัญของการดูแลช่องปาก
- 2.วิธีการตรวจสอบสุขภาพช่องปากด้วยตนเอง
- 3.การดูแลสุขภาพภายในช่องปาก
- 4.เรื่องของการใส่ฟันปลอม
- 5.คำแนะนำทั่วไปเกี่ยวกับช่องปากและฟันปลอม
- 6.การดูแลฟันปลอม
- 7.หลักในการดูแลช่องปาก
 - สภาพช่องปากปกติ (ช่องปากชุ่มชื้น มีสีชมพู ไม่มีอาการอักเสบ หรือบวม หรือแดงเลย)
 - ช่องปากอักเสบเล็กน้อย (เริ่มมีอาการบวม หรือแดง):
 - ช่องปากอักเสบปานกลางถึงรุนแรง :
- 8.เรื่องน่ารู้



APPENDIX D

PATIENT ORAL CARE BOOKLET

การดูแลช่องปากด้วยตนเอง
ในผู้ป่วยมะเร็งเม็ดเลือดขาวที่ได้รับยาเคมีบำบัด



โดย

นางสาววิมลวรรณ เลิศวงศ์เผ่าพันธุ์
นักศึกษาหลักสูตรพยาบาลศาสตรมหาบัณฑิต
คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล



APPENDIX E

INSTRUMENT

แบบสอบถามข้อมูลส่วนบุคคล

คำชี้แจง กรุณาเติมคำตอบลงในช่องว่าง (.....) หรือทำเครื่องหมาย X ลงใน () ที่ตรงกับความจริงมากที่สุด

ตอนที่ 1 ข้อมูลทั่วไป

1. เพศ () ชาย () หญิง
2. อายุ.....ปี
3. สถานภาพสมรส () โสด () คู่
() หม้าย, หย่า, แยก
4. ระดับการศึกษา () ไม่ได้เรียนหนังสือ () ประถมศึกษา
() มัธยมศึกษา () ปวช., ปวส.
() ปริญญาตรี () สูงกว่าปริญญาตรี
5. ประเภทของการรับบริการทางสุขภาพ
() บัณฑิตประกันสุขภาพ (30 บาท) () เบิกต้นสังกัด
() ประกันชีวิต () ประกันสังคม
() จ่ายค่ารักษาพยาบาลเอง
6. อาชีพปัจจุบัน () รับราชการ () รับจ้าง
() ค้าขาย () นักเรียน / นักศึกษา
() อื่น ๆ โปรดระบุ.....

ตอนที่ 2 ข้อมูลเกี่ยวกับการรักษา**1. การวินิจฉัยโรค**

- () M1 () M2 () M3 () M4
 () M5 () M6 () M7

2. ครั้งนี้ได้รับยาเคมีบำบัดเป็นครั้งที่**3. ระยะเวลาที่ได้รับการวินิจฉัยว่าเป็น AML****4. ยาเคมีบำบัดที่ได้รับ**

- () cytarabine $\text{mg/m}^2/24 \text{ hours}$ ร่วมกับ doxorubicin mg/m^2
 () cytarabine $\text{mg/m}^2/24 \text{ hours}$ ร่วมกับ idarubicin mg/m^2
 () cytarabine $\text{mg/m}^2/24 \text{ hours}$ ร่วมกับ mitozantrone mg/m^2

ตอนที่ 3 ประวัติการระคายเคืองภายในช่องปาก**1. บุหรี**

- () ไม่สือบุหรี
 () เคยสือบุหรีจำนวน / วัน
 ปัจจุบัน () เลิกสือบุหรีแล้ว () ยังสือบุหรีอยู่จำนวน / วัน

2. เครื่องดื่มที่มีแอลกอฮอล์

- () ไม่ดื่มเครื่องดื่มที่มีแอลกอฮอล์
 () เคยดื่มเครื่องดื่มที่มีแอลกอฮอล์ปริมาณ / วัน
 ปัจจุบัน () เลิกดื่มแล้ว () ยังดื่มอยู่ปริมาณ / วัน

3. กินหมาก

- () ไม่กิน () กิน โปรตีนระยะเวลาและปริมาณ.....

4. ฟันปลอม

- () ไม่มี () มี โปรตีนชนิดและจำนวนซี่.....

ตอนที่ 4 ประวัติการดูแลช่องปาก

1. แปรงฟัน.....ครั้ง / วัน คือ เวลา
2. การใช้น้ำยาบ้วนปาก
 - () ไม่ใช้
 - () ใช้ โปรดระบุชนิดและจำนวนครั้งต่อวัน

ตอนที่ 5 แบบประเมินผลโปรแกรมการดูแลช่องปาก

1.การให้ข้อมูลและการฝึกทักษะการดูแลช่องปาก

1.1 ท่านมีความพึงพอใจในระดับใด

- | | |
|----------|-------------|
| () มาก | () ปานกลาง |
| () น้อย | () ไม่พอใจ |

1.2 ประโยชน์ที่ได้รับ

.....

.....

1.3 ข้อเสีย

.....

.....

1.4 ข้อเสนอแนะ

.....

.....

2.การอมน้ำแข็ง

2.1 ท่านมีความพึงพอใจในระดับใด

- | | |
|----------|-------------|
| () มาก | () ปานกลาง |
| () น้อย | () ไม่พอใจ |

2.2 ประโยชน์ที่ได้รับ

.....

.....

2.3 ข้อเสีย

.....

2.4 ข้อเสนอแนะ

.....

3. การดื่มอาหารเสริม

3.1 ท่านมีความพึงพอใจในระดับใด

- | | |
|----------|-------------|
| () มาก | () ปานกลาง |
| () น้อย | () ไม่พอใจ |

3.2 ประโยชน์ที่ได้รับ

.....

3.3 ข้อเสีย

.....

3.4 ข้อเสนอแนะ

.....

ตอนที่ 6 แบบบันทึกข้อมูลจากการตรวจร่างกายและผลการตรวจทางห้องปฏิบัติการ

1. น้ำหนัก

Day 0

Day 7

Day 14

Day 21

Day 28

2. Serum albumin

ก่อนได้รับยาเคมีบำบัด

ภายหลังได้รับยาเคมีบำบัด

3. Absolute neutrophil count (ANC)

ANC	วันที่															
ผล																

4. Temperature

temperature	วันที่						วันที่						วันที่					
	2	6	10	14	18	22	2	6	10	14	18	22	2	6	10	14	18	22
ผล																		

ตอนที่ 7 แบบบันทึกการประเมินสภาพช่องปาก

คำชี้แจง ให้ผู้ป่วยทำเครื่องหมาย (✓) ลงในช่องว่างที่ตรงกับสภาพช่องปากของตนเองในแต่ละวัน และรวมคะแนนการประเมินสภาพช่องปากที่ประเมินได้ในช่องคะแนนรวม

องค์ประกอบ ในการ ประเมิน	ลักษณะ	หมายเลข	ได้รับยาเคมีบำบัดเป็นวันที่			
			1	2	.	.
เสียง	ปกติ	1				
	เสียงแหบ	2				
	พูดคุยได้ลำบากหรือมีอาการเจ็บปวดมาก	3				
การกลืน	การกลืนปกติ	1				
	เจ็บปวดเล็กน้อยเวลากลืน	2				
	ไม่สามารถกลืนอาหารได้	3				
ริมฝีปาก	นุ่ม มีสีชมพู และชุ่มชื้น	1				
	แห้งหรือแตก	2				
	มีแผลหรือมีเลือดออก	3				
ลิ้น	สีชมพู ชุ่มชื้น และมองเห็นปุ่มบนลิ้น	1				
	มีคราบเกาะที่ลิ้นหรือไม่พบปุ่มบนลิ้น ลิ้นเงา โดยมีหรือไม่มีอาการแดง	2				
	มีตุ่มพองหรือแผลแตก	3				
ต่อมน้ำลาย	น้ำลายใส	1				
	น้ำลายเหนียวหรือข้น	2				
	ไม่มีน้ำลาย	3				
เยื่อในปาก	สีชมพู และชุ่มชื้น	1				
	มีสีแดงมากขึ้นหรือมีคราบเกาะสีขาวมากขึ้น โดยที่ไม่มีแผล	2				
	มีแผล โดยมีหรือไม่มีเลือดออกก็ได้	3				
เหงือก	สีชมพู เป็นเงา และอ่อนนุ่ม	1				
	บวม โดยมีหรือไม่มีอาการแดงก็ได้	2				
	มีเลือดออกเองหรือมีเลือดออกจากการกระทบกระแทก	3				
ฟันหรือฟันปลอม (หรือเนื้อเยื่อบริเวณที่สัมผัสกับฟันปลอม)	สะอาดและไม่มีคราบ	1				
	มีคราบหินปูนหรือหินน้ำลายเกาะบริเวณซอกฟัน	2				
	มีคราบหินปูนหรือหินน้ำลายเกาะโดยทั่วไปตลอดแนวเหงือกหรือบริเวณที่ใส่ฟันปลอม	3				
คะแนนรวม						



APPENDIX F
ORAL ASSESSMENT GUIDE

ORAL ASSESSMENT GUIDE

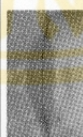
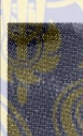
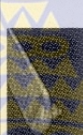
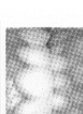
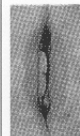
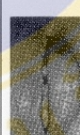
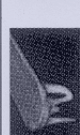
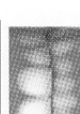
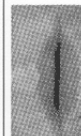
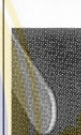
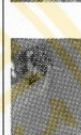
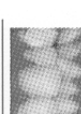
CATEGORY	TOOLS FOR ASSESSMENT	METHODS OF MEASUREMENT	NUMERICAL AND DESCRIPTIVE RATINGS		
			1	2	3
VOICE	Auditory	Converse with patient	Normal	Deeper or raspy	Difficulty talking or painful
SWALLOW	Observation	Ask patient to swallow. To test gag reflex, gently place blade on back of tongue and depress	Normal swallow	Some pain on swallow	Unable to swallow
LIPS	Visual/palpatory	Observe and feel tissue	Smooth and pink and moist	Dry or cracked	Ulcerated or bleeding
TONGUE	Visual/palpatory	Feel and observe appearance of tissue	Pink and moist and papillae present	Coated or loss of papillae with a shiny appearance with or without redness	Blistered or cracked
SALIVA	Tongue blade	Insert blade into mouth, touching the center of the tongue and the floor of the mouth	Watery	Thick orropy	Absent
MUCOUS MEMBRANES	Visual	Observe appearance of tissue.	Pink and moist	Reddened or coated (increased whiteness) without ulcerations	Ulcerations with or without bleeding
GINGIVA	Tongue blade and visual	Gently press tissue with tip of blade	Pink and stippled and firm	Edematous with or without redness	Spontaneous bleeding or bleeding with pressure
TEETH OR DENTURES (or denture bearing area)	Visual	Observe appearance of teeth or denture bearing area	Clean and no debris	Plaque or debris in localized areas (between teeth if present)	Plaque or debris generalized along gum line or denture bearing area

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MEDICAL CENTER
J. Eilers RN, MSN, 83 Rev 2-84, 5-84, 4-85, 11-85, 4-86

Oral Assessment Guide*

Developed by
the University of Nebraska
Medical Center

Category	Voice	Swallow	Lips	Tongue	Saliva	Mucous membranes	Gingiva	Teeth, Dentures, or denture bearing area
Tools for Assessment	Auditory assessment	Observation	Visual/palpatory	Visual/palpatory	Tongue blade	Visual assessment	Tongue blade and visual assessment	Visual assessment
Methods of Measurement	Converse with patient	Ask patient to swallow. To test gag reflex, gently place blade on back of tongue and depress	Observe and feel tissue	Feel and observe appearance of tissue	Insert blade into mouth, touching the center of the tongue and the floor of the mouth	Observe appearance of tissue	Gently press tissue with tip of blade	Observe appearance of teeth or denture bearing area
1								
	Normal	Normal swallow	Smooth and pink and moist	Pink and moist and papillae present	Watery	Pink and moist	Pink and stippled and firm	Clean and no debris
2								
	Deeper or raspy	Some pain on swallow	Dry or cracked	Coated or less of papillae with shiny appearance with or without redness	Thick orropy	Reddened or coated (increased whiteness) without ulcerations	Edematous with or without redness	Plaque or debris in localized areas (between teeth if present)
3								
	Difficulty talking or painful	Unable to swallow	Ulcerated or bleeding	Blistered or cracked	Absent	Ulcerations with or without bleeding	Spontaneous bleeding or bleeding with pressure	Plaque or debris generalized along gum line or denture bearing area

* J. Ellis, RN, MSN et al 2-04 Rev 5-04, 4-05, 11-05
Photographs courtesy of Simon W. Rosenberg, DMD,
Memorial Sloan-Kettering Cancer Center

Special thanks to the personnel of the University of
Nebraska Medical Center and to Simon W. Rosenberg, DMD,
Memorial Sloan-Kettering Cancer Center

© 1989/1995 June Ellis,
University of Nebraska Medical Center
600 So. 46th St., Omaha, NE 68198-2445

Faculty of Nursing
Mahidol University
Bangkoknoi, Bangkok 10700 Thailand

November 12, 2002

Dear, Dr. June Eilers,

I would like to introduce myself that my name is Wimonwan Lertwongpaopun. I am an RN and currently studying in the Master Degree Program in Adult Nursing at the Faculty of Nursing, Mahidol University in second year. My thesis proposal is entitled "The effects of oral care program on stomatitis in acute leukemia patients undergoing chemotherapy." To complete my thesis research, I aim to use an Oral Assessment Guide to assess an effectiveness of my intervention for the leukemia patients. I would like to request your permission to allow me to use your Oral Assessment Guide printed in the text as follow:

Eiler J., Berger A.M., and Peterson M.C. Development, Testing, and Application of the Oral Assessment Guide, Oncology Nursing Forum, 1988, 15(3), 325-330.

Your Oral Assessment Guide would be a great help for me to carry on data collection from the acute leukemia patients in Siriraj Hospital. I am looking forward to hearing from you soon. Thank you.

Yours Sincerely,

Wimonwan Lertwongpaopun.

Wimonwan Lertwongpaopun
e-mail: g4437007@student.mahidol.ac.th
tuiyui_ka@thaimail.com

Signature of Thesis Advisor

Pensri Rabiab.

Assoc. Prof. Pensri Rabiab, M.S.



December 6, 2002

Dear Wimonwan Lertwongpaopun,

Thank you for your letter of request to use the Oral Assessment Guide(OAG) in your study "The effects of oral care program on stomatitis in acute leukemia patients undergoing chemotherapy".

When we first worked on the OAG, our intent was to develop an instrument that would be clear, concise, and clinically useful for nurses providing direct care. We have been very pleased with the response to the OAG by nurses throughout the world.

Please accept this as permission to use the instrument. I wish you well in your academic endeavors and would be very interested in hearing the results of your study as well as your experience with the OAG. If you have specific questions or need additional information, do not hesitate to contact me.

I am enclosing a colored version of the OAG as well as a text only version. We have found that it is extremely helpful for nurses to understand the simplicity of the tool. The rating scale is set up so that a value of a "1" is for normal findings and it is fairly easy to teach this finding, or nurses already know it. Next, it helps to discuss the "3" rating, which indicates "broken" or "loss of function". For example "unable to swallow", saliva - "absent", and ulcerations or bleeding indicating a breakdown in this protective membrane. If the assessment indicates the area is not "normal" or "broken", then the rating would be a "2". In that way, once a nurse learns the eight categories to assess the individual does not require a copy of the OAG when doing the assessment. I hope you find this brief explanation helpful.

Sincerely,

A handwritten signature in black ink, which appears to read 'June Eilers', is written over a horizontal line.

June Eilers PhD, APRN, BC
Oncology Clinical Nurse Specialist
Clinical Nurse Researcher





บันทึกข้อความ

1389

คณะพยาบาลศาสตร์	
เลขรับ.....	2647
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ส่วนราชการ คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล โทร. 0 2419 8940 ต่อ 6614

ที่ ทม 0807/ 337 วันที่ 13 มกราคม 2546

เรื่อง ยินดีให้ความอนุเคราะห์ข้อมูลประกอบการทำวิทยานิพนธ์

เรียน คณบดีคณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล

ตามที่ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล มีความประสงค์ให้ นางสาววิมลวรรณ เลิศวงศ์เผ่าพันธุ์ นักศึกษาหลักสูตรพยาบาลศาสตรมหาบัณฑิต สาขาการพยาบาลผู้ใหญ่ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล เข้าเก็บข้อมูลเพื่อประกอบการทำวิทยานิพนธ์เรื่อง "ผลของการใช้โปรแกรมการดูแลช่องปากต่ออาการเยื่อช่องปากอักเสบ ในผู้ป่วยมะเร็งเม็ดเลือดขาวชนิดเฉียบพลันที่ได้รับยาเคมีบำบัด" โดยการเก็บข้อมูลจากแฟ้มประวัติการเจ็บป่วย การสัมภาษณ์ และการตอบแบบสอบถามจากผู้ป่วยที่เข้ารับการรักษาที่ตึกอักษุรักษ์ และตึก 72 ปี โรงพยาบาลศิริราช ความละเอียดดังแจ้งแล้วนั้น

คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล พิจารณาแล้วยินยอมให้ นางสาววิมลวรรณ เลิศวงศ์เผ่าพันธุ์ ดำเนินการเก็บข้อมูลที่ตึกอักษุรักษ์ตามที่เสนอขอได้ ยกเว้นตึก 72 ปี เนื่องจากภาควิชารังสีวิทยา แจ้งว่าไม่มีผู้ป่วยมะเร็งเม็ดเลือดขาวที่รับยาเคมีบำบัดเข้ารับการรักษา แต่ทั้งนี้จะต้องได้รับการพิจารณาอนุมัติจาก คณะกรรมการจริยธรรมการวิจัยในคน ของคณะแพทยศาสตร์ศิริราชพยาบาล เรียบร้อยแล้ว จึงจะดำเนินการเก็บข้อมูลได้

ขอได้โปรดติดต่อสำนักงานคณะกรรมการจริยธรรมการวิจัยในคน โทร. 0 2419 8940 ต่อ 6405-6 เพื่อขอรับ การพิจารณาจากคณะกรรมการจริยธรรมการวิจัยในคน ของคณะแพทยศาสตร์ศิริราชพยาบาล ต่อไป

จึงเรียนมาเพื่อโปรดทราบ

เรียน รองคณบดีฝ่ายบัณฑิตศึกษา

เพื่อโปรดทราบ

เรื่องส่ง.....

Onke o
14 มี.ค. 46

ทอม + อภิสิทธิ์

(รองศาสตราจารย์สายพิน เกษมกิจวัฒนา)

รองคณบดีฝ่ายบัณฑิตศึกษา

ปฏิบัติราชการแทน คณบดีคณะพยาบาลศาสตร์

14 มี.ค. 2546

(รองศาสตราจารย์นายแพทย์สรนิต ศิลธรรม)

รองคณบดีฝ่ายบริหาร คณะแพทยศาสตร์ศิริราชพยาบาล

ปฏิบัติราชการแทนคณบดี

14 มี.ค. 46

ห้องรองคณบดี คณะพยาบาลศาสตร์
วันที่รับ..... 14 มี.ค. 2546 เวลา.....



บันทึกข้อความ

ส่วนราชการ สำนักงานคณะกรรมการการวิจัยการวิจัยในคน ตึกอดุลยเดชวิกรม ชั้น ๕ โทร. ๖๔๐๕-๖

ที่ ทม. ๐๔๐๗/ ๕๓๓/

วันที่ ๘ มกราคม ๒๕๕๖

เรื่อง แจ้งผลการพิจารณาโครงการวิจัย

เรียน นางสาววิมลวรรณ เลิศวงศ์เผ่าพันธุ์

ตามที่ท่านได้ส่งโครงการวิจัยเรื่อง “ ผลของการใช้โปรแกรมการดูแลช่องปากต่ออาการเยื่อ
ช่องปากอักเสบในผู้ป่วยมะเร็งเม็ดเลือดขาวชนิดเฉียบพลันที่ได้รับยาเคมีบำบัด ” ซึ่งท่านเป็นหัวหน้าโครงการ
เพื่อขอรับการพิจารณาด้านจริยธรรม

คณะกรรมการการวิจัยการวิจัยในคน ได้พิจารณาด้านจริยธรรมของโครงการดังกล่าวแล้ว
เมื่อวันที่ ๓ มกราคม ๒๕๕๖ และมีมติรับรอง

จึงเรียนมาเพื่อทราบ และได้ส่งเอกสารมาพร้อมนี้

(ศาสตราจารย์แพทย์หญิงสุมาลี นิมนานนิตย์)
ประธานคณะกรรมการการวิจัยการวิจัยในคน

๒ ถนนพหลโยธิน บางกอกน้อย กรุงเทพฯ ๑๐๓๐๐
 โทร. (๐๖-๒) ๔๑๑-๑๔๒๙, ๔๑๑-๓๒๕๓
 โทรสาร. (๐๖-๒) ๔๑๒-๑๓๗๑



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Faculty of Medicine Siriraj Hospital
 Mahidol University

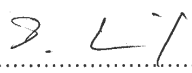
The Ethical Committee on Research Involving Human Subject
 Faculty of Medicine Siriraj Hospital, Mahidol University

No. 3/2003

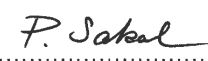
Protocol Title	The effects of oral care program on stomatitis in acute leukemia patients undergoing chemotherapy
Protocol Number	-----
Principal Investigator	Miss. Wimonwan Lertwongpaopun
Name of Department	Faculty of Nursing

The aforementioned project and informed consent have been reviewed and approved by the Ethical Committee, Faculty of Medicine Siriraj Hospital, Mahidol University, based on the Declaration of Helsinki on January 3, 2003

Signature of Chairman


 (Prof. Sumalee Nimmannit)

Signature of Dean


 (Clin. Prof. Piyasakol Sakolsatayadorn)

BIOGRAPHY

NAME	Miss Wimonwan Lertwongpaopun
DATE OF BIRTH	19 June 1977
PLACE OF BIRTH	Bangkok, Thailand
INSTITUTIONS ATTENDED	Mahidol University, 1995-1999 Bachelor degree of Nursing Mahidol University, 2001-2003 Master degree of Nursing Science (Adult Nursing)
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