

# STUDY THE EFFICACY OF THE TOPICAL CHINESE MEDICINE, ANGELICA ALOE VERA GEL, ON THE TREATMENT OF RADIATION DERMATITIS

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Radiotherapy is the main method for the treatment of head and neck cancer; however, patients suffer from substantial side effects of radiation dermatitis that may affect the course of treatment. There is no consistent medical treatment program for the management of radiation dermatitis. Nonetheless, topical steroids have proved effective in the treatment of radiation dermatitis; however, several side effects from steroid use have been reported. This study proposes using the Chinese herbal medicine “Angelica aloe vera gel” as a possible alternative treatment for radiation dermatitis. In this study, 70 patients were enrolled and randomly divided into 2 groups of 35 patients each. The 35 patients in the first group used Western medicine as the treatment for radiation dermatitis, whereas the patients in the second group used Chinese herbal medicine as the treatment. Seven patients dropped out of the study because of personal reasons 3 from the group using Western medicine and 4 from the group using Chinese medicine. During the study, patients were evaluated using the Criteria for Adverse Events Version 4.0 (CTCAE v4) of the National Cancer Institute Common Terminology, and skin symptom including pain, itching, tightness, comfort, peeling, and quality of life were evaluated. The study findings showed that CTCAE results from the group of patients using Chinese medicine compared to the group of patients using Western medicine were significant ( $P = 0.012$ ). Further comparison of the skin symptoms using 54 Grays to 68 Grays of radiotherapy showed a lower rate of desquamation in the group of patients using Chinese medicine with a significant difference compared to the group of patients using Western medicine. In conclusion, using Chinese medicine is not inferior to using topical steroids in the treatment of radiation dermatitis.

**Key words:** radiation dermatitis, Chinese medicine, Angelica aloe vera gel, cancer diseases

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## Introduction

In 2008, the incidence of head and neck cancer in Taiwan was 346.48 cases per 100 000 people. Head and neck cancer was the fifth leading cause of death from cancer in 2010 in Taiwan. Radiotherapy is one treatment modality used in treating patients with cancer. Approximately 25% of head and neck cancer patients receive radiotherapy according to the Department of Health, Republic of China. Radiation dermatitis is a common side effect of radiotherapy treatment, and may interrupt the course of treatment and cause discomfort in the patient. Radiation dermatitis ranging from a mild rash to severe ulceration has been reported in up to 90% of patients treated with radiation<sup>1</sup>. The general principles of skin care include avoiding metallic-based topical products, wearing loose clothing, avoiding friction against the skin and extreme temperatures, and keeping the area of skin that has been irradiated clean and dry<sup>1</sup>. The severity of skin reaction depends on the radiotherapy fraction schedule, the total radiation dose, the area of skin treated, and other variables associated with individual patients.

Generalized erythema may occur hours after radiation exposure. Sustained erythema with a pink, blanchable reaction and other epidermal changes develop 10 to 14 days after a radiation dose. Persistent tender or edematous erythema occurs after 4 to 5 weeks using radiation therapy of approximately 40 Gray or greater. The peak period of acute radiation dermatitis is 1 to 2 weeks after the last treatment. Skin healing begins after 3 to 4 weeks, and complete skin healing is noted within 1 to 3 months after treatment<sup>2</sup>. Skin care during radiotherapy is of major importance for cancer nursing.

Topical steroids can significantly attenuate

irradiation-induced pro-inflammatory cytokine interleukin-6 (IL-6), interleukin-1 (IL-1), tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ) and tissue growth factor-beta (TGF- $\beta$ )<sup>3</sup>, and reduce acute skin toxicity during radiotherapy<sup>3-5</sup>. However, some patients feel uncertain on using topical steroids because of its side effects including skin thinning, striae formation, easy tearing of the skin, telangiectasia, and susceptibility to skin infections and allergies, and these patients look to other alternative topical agents. Aloe vera has been shown to demonstrate anti-inflammatory activity<sup>6-8</sup> by decreasing prostaglandin E2 (PGE<sub>2</sub>), TNF- $\alpha$ , and IL-6 production in burn wounds. Clinical use of aloe gel is commonly used to treat a number of skin complaints, such as atopic dermatitis<sup>9</sup>, irritant contact dermatitis<sup>10</sup>, and for the healing of burn wounds<sup>6,7,11-13</sup>. *Angelica dahurica* (bai-zhi) is used in Chinese medicine to disperse wind and eliminate dampness. According to the Shennongbencaojing, bai-zhi is able to promote tissue regeneration and hydrate the skin. Topical usage of bai-zhi in traditional Chinese medicine has the effect of drying dampness to relieve itching, expel pus, and activate blood to relieve pain. *Angelica dahurica* (bai-zhi) has been reported to demonstrate antimicrobial activity<sup>14,15</sup>, anti-oxidative activity<sup>16</sup>, and possible reduction of skin darkness by inhibiting melanin formation<sup>17</sup>; therefore, it is also commonly used to treat airway inflammation for its anti-inflammatory effect and used as a topical agent for skin whitening or acne treatment.

In this study, we hypothesize that the Chinese medicine *Angelica aloe vera* gel used as a topical agent benefits the treatment of radiation dermatitis. We compare the efficacy between the use of the topical Chinese medicine *Angelica aloe vera* gel and topical steroids to determine whether *Angelica aloe*

vera gel is a potential alternative treatment for radiation dermatitis with fewer side effects.

## Materials and Methods

This study was conducted at Chang Gung Memorial Hospital after approval from the Chang Gung Medical Foundation Institutional Review Board under IRB number 99-2176A3. Patients diagnosed with head and neck cancer and receiving radiotherapy at the Department of Radiation Oncology of Chang Gung Memorial Hospital (including patients undertaking radiation therapy alone and patients undertaking both chemotherapy and radiation therapy) were enrolled for this study. The patients all signed an informed consent before the study. The patients were randomly divided into 2 equal groups: a Western medicine group and a Chinese medicine group. The inclusion criteria and exclusion criteria are shown in Table 1.

### I. Medication

Topical steroid ointment was applied twice a

day to patients in the Western medicine group to treat their radiation dermatitis after radiotherapy and before sleep, whereas Angelica aloe vera gel was used topically twice a day on patients in the Chinese medicine group similarly after radiotherapy and before sleep. The composition of Angelica aloe vera gel is detailed in Table 2. The Chinese medicine for this study was produced under Good Manufacturing Practices within the same batch by Formosa Biomedical Technology Corporation (Changhua, Taiwan), and made specifically for this clinical trial. Formosa Biomedical Technology Corporation held the Republic of China voluntary cosmetic Good Manufacturing Practice Certificate (GMP No: 043774.)

### II. Evaluation

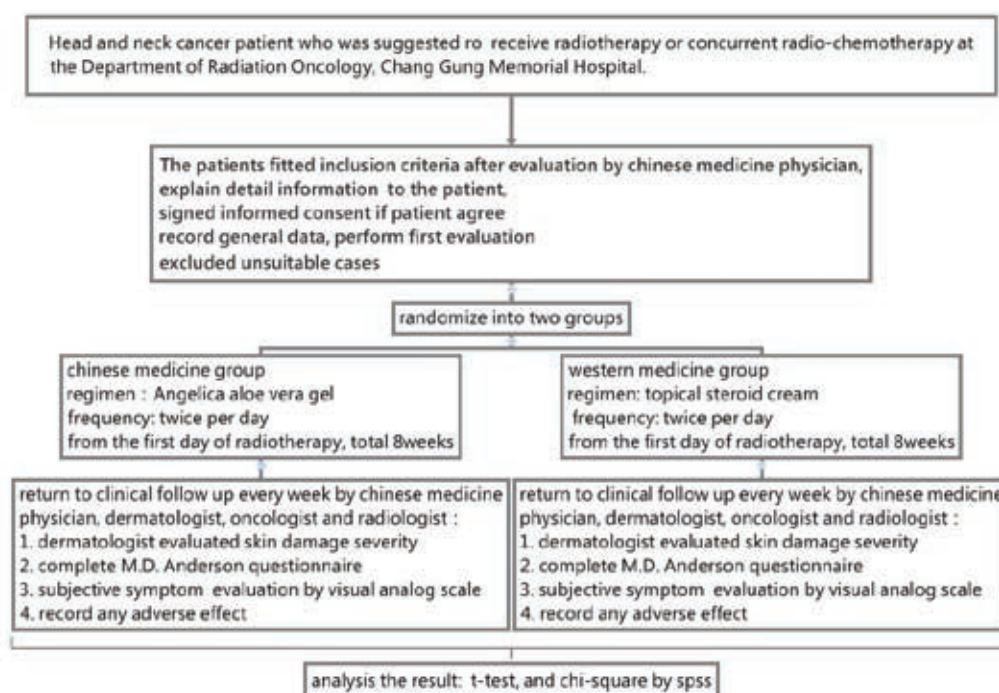
Patient assessment was performed before the clinical trial began and every 2 weeks during the treatment, totaling 4 assessments. Digital photos of the skin injuries were taken, and the degree of the skin injuries was evaluated by a dermatologist according to the Criteria for Adverse Events Version 4.0 (CTCAE v4) of the National Cancer Institute

**Table 1. Inclusion and exclusion criteria.**

Inclusion criteria
1. The patients diagnosed as head and neck malignancy and received radiotherapy at the Department of Radiation Oncology, Chang Gung Memorial Hospital.
2. Evaluated by a Chinese medicine physician to make sure that patients were suitable using external application of Chinese medicine.
3. The patient agreed to join the study and signed informed consent.
Exclusion criteria
1. The patient who was not a malignancy of head and neck or who didn't receive radiation treatment.
2. The Chinese medicine physician identified who was not fitted the syndrome to use the topical Chinese medicine.
3. The patient had allergic history before either topical or oral use of Chinese medicine.

**Table 2. Components of “Angelica aloe vera gel”, every 70 gm contains *Aloe Barbadensis* juice 42 gm, *Angelica Dahurica* extract 0.004 gm.**

Plant name or chemical name	Plant part	Weight(g)	Ratio
<i>Aloe barbadensis</i> Juice	Leaf	42.000	60
<i>Angelica dahurica</i> Extract	Root	0.004	0.005
Disodium EDTA		0.035	0.05
Triethanolamine		0.336	0.48
Iodopropynyl butyl carbamate, DMDM		0.210	
Hydantoin			0.30
Carbomer		0.490	0.70
Xanthan gum		0.070	0.10
Imidazolidinyl urea		0.280	0.40
Scleroglucan, pentylene glycol		1.400	2.00
Aqua		25.179	35.97
Total			100



**Fig. 1. The flow chart of this study.**

Common Terminology. Subjective complaints from the patients, including pain, itching, comfort level, tightness, and severity of desquamation, were evaluated using a visual analog scale. The MD Anderson symptom inventory was used to evaluate the quality of life and systemic symptoms of the patient. The

CTCAE was analyzed using two-way ANOVA statistics. Other results from this study were analyzed using the *t* test and chi-square statistics with SPSS 12.0, and statistical significance was set at a *P* value smaller than 0.05. The flow chart for this study is shown in Fig. 1.

## Results

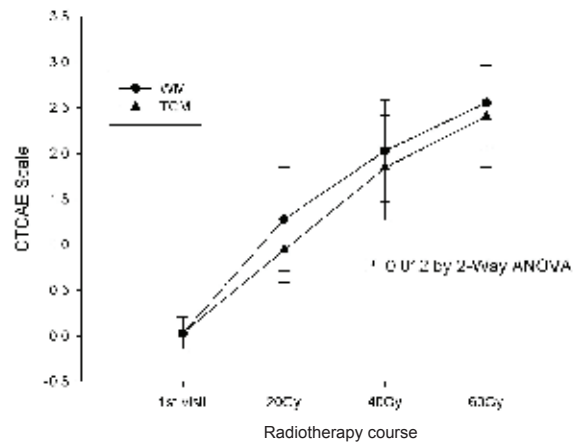
Seventy patients were enrolled in this study, with 35 patients in the Chinese medicine group and 35 in the Western medicine group. Four patients withdrew from the Chinese medicine group for reasons including being transferred to another hospital for treatment, tumor progression, excessive loss of body weight, and being unable to accept the smell of the Chinese medicine. Three patients withdrew from the Western medicine group for reasons including patient transfer to another hospital, tumor progression, and use of topical aloe gel of another brand by the patient's own accord.

There were no differences in the baseline profile, which included age, sex, CTCAE scores, subjective symptoms, and MD Anderson scores, as shown in Table 3, between the 2 groups before

commencement of the study.

The difference in CTCAE scores between the 2 groups had a *P* value of 0.012 (Fig. 2).

The MD Anderson scores showed no differences between the 2 groups, either in symptom severity or



**Fig. 2. Comparisons of side effects (CTCAE score) between WM and TCM groups during radiotherapy course.**

**Table 3. Characteristics of WM and TCM group.**

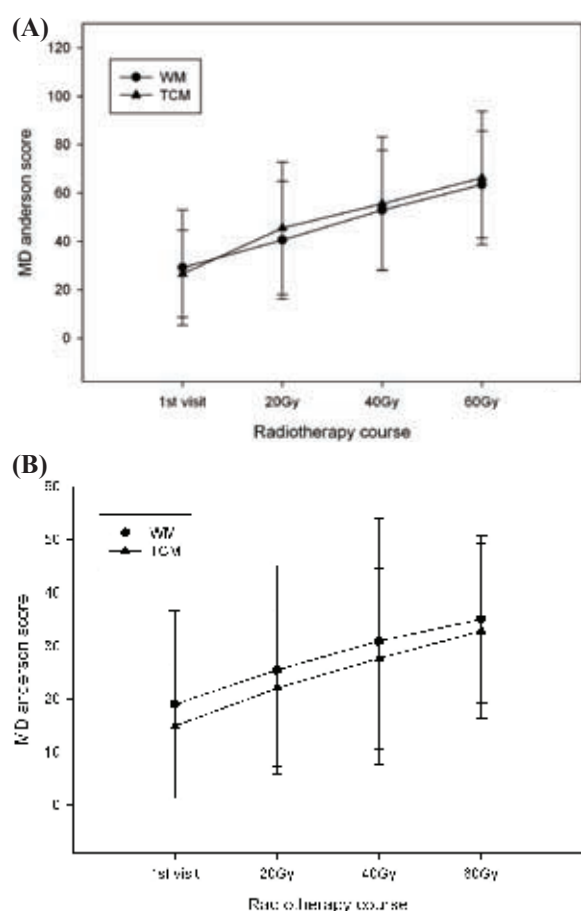
	WM(N=32)	TCM(N=31)	p-value
Sex			
Female	3	6	0.23
Male	29	25	
Age	53.72 ± 11.36	47.03 ± 13.54	0.29
CTCA score	0.03 ± 0.17	0.03 ± 0.17	0.95
Baseline MD Anderson score			
Symptom severity	29.14 ± 23.84	26.58 ± 18.05	0.62
Life quality	19.90 ± 17.60	14.90 ± 11.75	0.27
Initial presentation			
Pain	0.17 ± 0.51	0.45 ± 1.12	0.16
Itching	0.67 ± 2.23	0.82 ± 2.11	0.77
Tightness	2.39 ± 2.82	1.78 ± 2.74	0.37
Comfort	1.08 ± 1.42	1.33 ± 1.67	0.50
Desquamation	0.00 ± 0.000	0.12 ± 0.55	0.18

WM: western medicine (topical steroid)

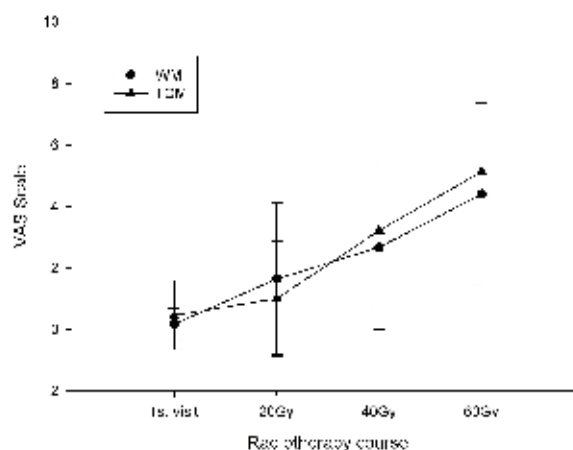
TCM: Traditional Chinese medicine

quality of life (Fig. 3). According to the visual analog scale, there were no differences in itching, pain, tightness, comfort, or desquamation between the 2 groups (Fig. 4-8).

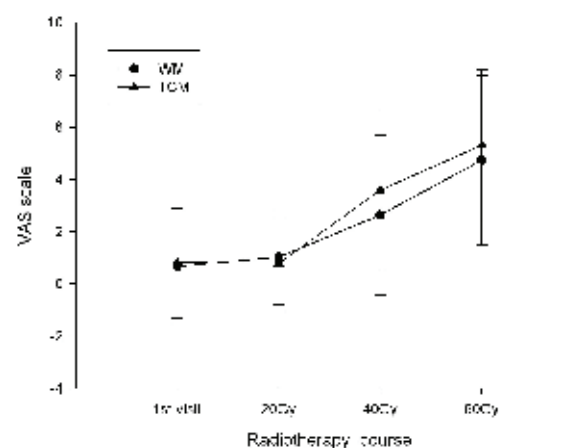
Because radiation treatment area focuses on the tumor field after radiation dosage up to 52 Grays, we compared the changes in severity between cumulative radiation doses of 54-58 Grays and 60-68 Grays (Table 3). The results showed that severity of skin desquamation increased by  $0.25 \pm 1.45$  in the Chinese medicine group compared with  $1.54 \pm 1.93$  in the Western medicine group, with a *P* value of



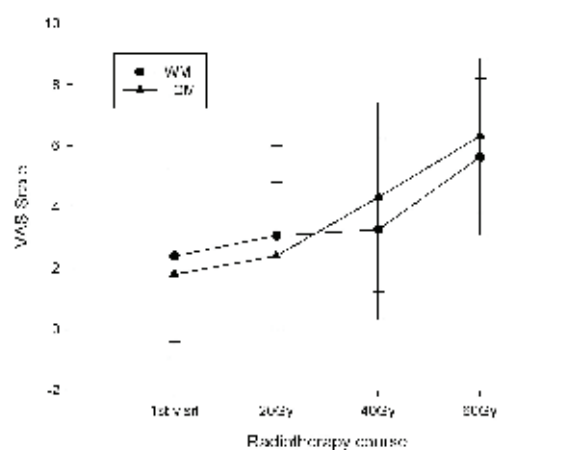
**Fig. 3.** Comparisons of symptoms severities and life quality, among WM and TCM groups on 20Gy, 40Gy, and 60Gy radiotherapy, (Figure A: part 1, the symptom severity, Figure B: part 2 quality of life.)



**Fig. 4.** Comparisons of itching severities between WM and TCM groups.



**Fig. 5.** Comparisons of pain severities between WM and TCM groups.



**Fig. 6.** Comparisons of skin tightness between WM and TCM groups.

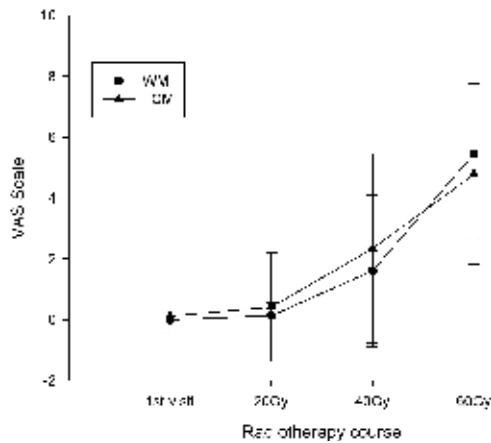


Fig. 7. Comparisons of skin desquamation severities between control and TCM groups.

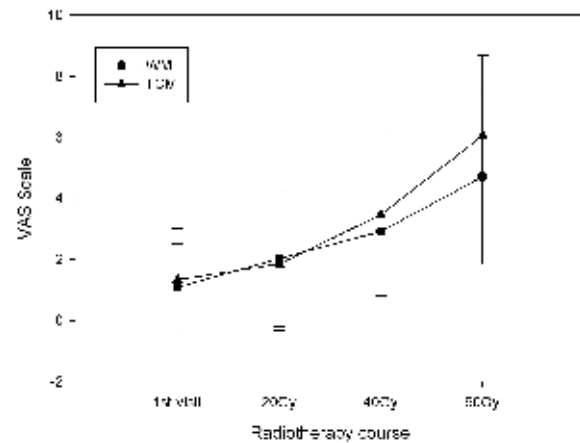


Fig. 8. Comparisons of skin comfort between WM and TCM groups.

Table 4. The gradient between cumulative radiotherapy dosage 54~58 Grays and 60~68 Grays.

	CTCAE	Itch	pain	tightness	comfort	desquamation
Control	$0.32 \pm 0.47$	$0.92 \pm 1.98$	$0.29 \pm 2.20$	$0.63 \pm 1.91$	$-0.04 \pm 2.48$	$1.54 \pm 1.93$
TCM	$0.12 \pm 0.65$	$0.40 \pm 1.54$	$0.40 \pm 0.99$	$0.65 \pm 2.03$	$-0.30 \pm 2.30$	$0.25 \pm 1.45$
<i>p</i> -value	$P=0.14$	$P=0.28$	$P=0.57$	$P=0.56$	$P=0.44$	$P=0.021^*$

\**p*-value < 0.05

0.021, whereas the CTCAE score was  $0.12 \pm 0.65$  in the Chinese medicine group and  $0.32 \pm 0.47$  in the Western medicine group, with a *P* value of .14.

No adverse effects were reported by patients in both groups during the treatment course.

## Discussion

Radiotherapy is one of the major treatment modalities used for head and neck tumors, and radiation dermatitis is of major importance for cancer nursing and treatment adverse side effects resulting from the radiotherapy. The exact mechanisms by which acute radiation acts are unclear, but may act through a cytokine-mediated inflammatory cascade<sup>18</sup>. A cancer care Ontario guideline for the prevention of skin reactions suggests skin washing with mild

soap and water, but there is insufficient evidence to prove the benefits of any topical or oral agent for the prevention or management of acute skin reactions<sup>19</sup>. The severity of radiation dermatitis ranges from mild rashes to severe ulceration of the exposed area of skin. Because of the intolerable side effects, some patients interrupt their radiotherapy course before treatment is complete. Several studies have been conducted to establish treatment guidelines. However, no specific agent has proven superior to others in the prevention and management of acute radiation-induced skin reactions. Hence, future clinical trials on the comparative efficacy of different agents are required, as is the establishment of guidelines for the treatment of radiation dermatitis<sup>19-22</sup>.

Topical corticosteroid agents, which have been shown to decrease the expression of IL-6<sup>23</sup>, IL-1, and

TNF- $\alpha^3$ , affect irradiation-induced pro-inflammatory cytokines and lead to an anti-inflammatory effect. Consequently, topical steroids have been shown to perform as an effective treatment for radiation dermatitis and can reduce acute skin toxicity during radiotherapy<sup>3-5</sup>. Nonetheless, skin thinning, striae formation, easy tearing of the skin, telangiectasia, susceptibility to skin infections, and allergies are reported side effects of using topical steroids, and are the reasons for patients usually feeling uncertain with their use and trying alternative treatments on their own. In this study, we attempted to provide a comparison between the efficacy of using topical steroids and Angelica aloe vera gel.

Although the current study results did not show any differences between the 2 study groups regarding skin itching, pain, tightness, and desquamation (Fig. 4-7), there is an indication that the patients in the Chinese medicine group felt more comfortable during their treatment course (Fig. 8). The results also showed that seems less desquamation occurred in the Western medicine group; however, the changes in desquamation severity decreased after radiotherapy focused on tumor field. The increase in desquamation in the Chinese medicine group may be related to the regeneration of skin tissue after damage, and requires further study for verification. Even the subjective symptoms showed no statistical difference, the Chinese medicine group showed a better CTCAE score than western medicine group with significant difference ( $P=0.012$ ) (Fig 2.) The Chinese medical topical agent, “Angelica aloe vera gel,” may have benefit in radiation dermatitis treatment.

Previous studies have reported the effects of Aloe vera in decreasing PGE<sub>2</sub>, TNF- $\alpha$ , and IL-6 level in burn wounds, and aloe vera has been shown

to demonstrate anti-inflammatory activity<sup>6-8</sup>. Some authors have also demonstrated that aloe vera can increase collagen formation<sup>24</sup>, and increase the rate of re-epithelialization and healing of the partial thickness of burn wounds<sup>12,13,25</sup>. Aloe gel is effective in many skin disorders, such as atopic dermatitis<sup>9</sup> and irritant contact dermatitis<sup>10</sup>, and for the healing of burn wound<sup>6,7,11-13</sup>. Previous studies have shown that topical acid (hyaluronic acid) cream may reduce the toxicity and severity of radiation dermatitis<sup>26</sup>. Radiotherapy may cause dryness of the skin, leading to desquamation and loss of the superficial protective layers of the skin, including lipid barriers. Simple moisturizers, such as hyaluronic acid cream, can hydrate the skin and form a barrier to transcutaneous water loss. Aloe is an effective and commonly used constituent in products used to keep skin moisturized<sup>27</sup>. Previous studies have demonstrated that Aloe gel is able to scavenge free radicals in vitro and has the ability to protect against radiation injury in animal trials<sup>28</sup>. *Angelica dahurica* (bai-zhi) is a Chinese herb used topically for skin whitening and treating airway inflammation. Studies have shown that *Angelica dahurica* (bai-zhi) demonstrates antimicrobial activity<sup>14,15</sup>, anti-oxidative activity<sup>16</sup>, and possibly reduces skin darkness by inhibiting melanin formation<sup>17</sup>. Angelica aloe vera gel can be postulated to act in a similar manner in providing the ability to decrease the severity of or prevent radiation dermatitis.

The results of this study show that the Chinese medicine group achieved a better CTCAE score compared to the Western medicine group. After the radiation field focused on tumor area, the Chinese medicine group showed a better result, with a decreases in the CTCAE score and in skin desquamation. This may be related to the aloe having the

ability to increase collagen synthesis and decrease collagen degradation<sup>24</sup>. In this study, we only used topical agent treatment. Because the MD Anderson Symptom Inventory mainly evaluates systemic symptoms, the inventory showed no significant difference in this study. A visual analog scale was used to evaluate the subjective symptoms, and showed no difference in pain, itching, tightness, or desquamation. The patients in the Chinese medicine group tended to feel more comfortable during their treatment course compared to the Western medicine group. Overall, the results from this study demonstrate that the topical Chinese medicine Angelica aloe vera gel provides effective treatment for radiation dermatitis similar in potency to topical steroids. Data from this study also show that after radiation focused on the tumor, skin toxicity from radiotherapy and the rate of the skin damage decreased, and the patients treated with the Chinese medicine showed a lower rate of desquamation. This may be related to the aloe helping keep the skin moisturized<sup>27</sup>. In addition, because aloe has the ability to increase collagen synthesis and reduce collagen degradation, this may also benefit the treatment of radiation dermatitis. Based on the findings of this study, we conclude that Chinese medicine treatment is not inferior to the use of topical steroids in the treatment of radiation dermatitis.

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# 腫瘤患者放射性皮膚炎中藥治療療效評估

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放射線治療為治療頭頸部腫瘤與鼻咽癌的主要方法，急性放射性皮膚炎仍是放射治療中的重要議題，目前對於放射性皮膚炎的治療和預防並無統一的準則，外用類固醇已被證實對放射性皮膚炎有效，但有許多的副作用被報導。本研究以長庚醫院放射腫瘤科門診，頭頸部腫瘤接受放射線治療的患者為收案對象，總計共中藥組31人及西藥組32人，放射治療期間中藥組使用「白芷蘆薈凝膠」，每日放射線治療後及睡前塗抹中藥白芷蘆薈凝膠，每日兩次，西藥組使用類固醇藥膏，早晚各一次塗抹患處。研究結果發現，以美國國家癌症研究所公布之常見不良事件評價標準來評估皮膚損傷程度，中藥組(N=31)皮膚情況較西藥組(N=32)好，且有統計上顯著差異(P=0.012)。生活品質問卷結果顯示，病人治療中對痛、癢、緊繃、舒適度、脫皮程度主觀症狀的改善程度評分中，兩組並無顯著差異，但是如果比較放射治療54格雷以後的變化，中藥組脫皮程度較緩。研究結論，中藥外用複方「白芷蘆薈凝膠」治療放射線皮膚炎的效果不亞於傳統類固醇。

**關鍵字：**放射性皮膚炎、中藥、白芷蘆薈凝膠、腫瘤疾病

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