

Study on the Effects of a Medicated Oil in the Management of Chronic Wounds

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ABSTRACT :

Chronic wounds are frequently encountered problem in the present era produced due to the complications of trauma or pathological injury and it causes long-term agony to the patients. In the present study *Pachai ennai* was prepared and its wound healing properties were studied on various chronic wounds. *Pachai ennai* was prepared using the standardization procedure the effects were studied on 40 patients with chronic wounds (wounds more than 3 weeks old) selected from Herbal Health Care Centre, Kokuvil. The patients were divided into two groups – Group A (*Pachai ennai* dressing) and Group B (Normal Saline Gauze bandage). The drug was applied topically and patients were studied daily for 30 days and results were analyzed. In Chronic Wound the size was decreased 69.23% which was statistically highly significant. There was considerable improvement (> 80 %) in swelling and unhealthy margin. Pain, tenderness, discharge and unhealthy granulation tissue showed moderate effect (between 60 to 70 percent) in the chronic wounds. From the studies made from clinical cases, it was concluded that, the drug “*Pachai ennai*” possess sufficient efficacy in Pun without producing any adverse effects.

Key words : Pachai ennai , Herbal Health Care Centre, Pun

INTRODUCTION:

Discontinuation of skin & its underlying soft tissue is wound. Long standing and unhealed wound is known as Chronic wound. There are different etiological factors for wound. One of them is venous ulcer. Venous hypertension of varying severity is a common consequence of venous disorder. Raised venous pressure will cause a corresponding increase in capillary pressure and if sustained over long periods with inadequate relief, will cause characteristic changes in the skin and subcutaneous tissues[1]. Wound management is a significant and growing health burden on the community[2]. Healing of diabetic foot ulcers in Larginine- treated patients.

Biomed Pharmacother 58: 588-597. Delayed wound healing and wound infection place a substantial financial burden on health care systems, as a result of increasing dependency and increased hospital admissions. Chronic wounds also have a very large social and quality of life impact on individuals and curers[3]. After injury, healing is a natural phenomenon and continues in sequential manner until the formation as a healthy scar. Usually defense mechanisms of body takes complete care in order to keep the scar clean. But at times, when infection is massive, surface area of wound is very large and slough or necrotic tissue is too much, this auto cleansing mechanism becomes inadequate[4]. The destruction/break/rupture/discontinuity of body tissue/part of body, is called “*Pun*”. It may have features of chronic in nature, foul smell, loss of normal colors, excessive discharge of pus and impure blood, excessive pain, elevated from surface, irregular shape with cavities, everted base and margins of wound [5]. World Health Organization (WHO) as well our country has been promoting traditional medicine because they are less expensive, easily available and comprehensive, especially in developing countries [6]. Traditional forms of medicine practiced for centuries in Africa and Asia are being scientifically investigated for their potential in the treatment of wounds related disorders. According to[7], 70% of the wound healing Ayurvedic drugs are of plant origin. Topical antimicrobial therapy is one of the most important methods of wound care[8]. Some medicinal plants have been employed in folk medicine for wound care [9]. Some of these plants either possess pro-wounding healing activities or exhibit antimicrobial and other related properties which are beneficial in overall wound care[10]. Wound healing processes are well organized biochemical and cellular events leading to the growth and regeneration of wounded tissue in a special manner. Healing of wounds is an important biological process involving tissue repairs and regeneration. It involves the activity of an intricate network of blood cells, cytokines, and growth factors which ultimately leads to the restoration to normal condition of the injured skin or tissue [11]. Therefore researchers are progressively turning their attention to natural products, looking for new leads to develop better drugs against microbial infections and screening of several medicinal plants for their potential antimicrobial activities[12]. The purpose of this study was to investigate the comparative clinical efficacy of the Traditional herbal Medicated oil, in the treatment of wound caused by some bacteria. This may lead to the intervention of an alternative form of treatment other than antibiotics being used at present.

OBJECTIVE

To evaluate the efficacy of a medicated oil in the management of chronic wounds.

MATERIALS & METHODS

The work was carried out in Herbal Health Care Centre, Kokuvil, Jaffna.

Drug Contents:

Pachai ennai contains:-

Datura alpa leaves, Copper, *Curcuma longa*, Neem oil + coconut oil

Method of Preparation:

The *Pachai ennai* was prepared in the Herbal Health Care of Shidda Pharmacy under the guidance of Dr G.Sritharan . In the preparation of medicated oil, following steps were done:-

Procedure:

- a) Wash and grind fresh leaves convert in Juice form. Then, all other drugs were made into powder form.
- b) The juice and powder are mixed and bolus is prepared, then the coconut oil put in the hearth till complete evaporation of moisture content, at this stage temperature gone up to 130° C. The bolus of Kalka were added to the oil After slight cooling, constant stirring is carried.
- c) Then filtered the oil.

Clinical Study:-

Source of data: For the study 40 patients were randomly selected from the Herbal Health Care Centre, Jaffna.

The Ethical clearance

The ethical guidelines of University of Kelaniya. The study protocol, case report forms, regulatory clearance documents , product related information and informed consent form were submitted to the Ethical Review Committee and approved by the same.

Method of collection of data:

Detailed clinical history and clinical examination was carried out by using the special Performa which was prepared before assessing the case and starting the proper treatment with trial drugs.

Grouping: The patients were randomly divided into two groups A&B, each group having 20 patients.

Group A(Pachaiennai Gauze) and Group B (Normal Saline Gauze).

After selection of patients, they were informed about the study and their written consent was obtained. Further, the patients were made to understand that they are able to withdraw from the study any time without prior notice.

Intervention: The Group A patients were asked to apply the Pachaiennai locally on the wounds one time per day for 30 days and compared with the Group B patients.

Duration of study: The duration of study was 30 days.

Follow up: All the patients were asked to follow-up at the interval of every 10 days in 30 days.

Inclusion Criteria:

All types of chronic wounds (wounds more than 3 weeks old) patients including lacerated wound, Post-operative wounds, Fissure, Burn, Pressure Sores, Tropics ulcer, Varicose ulcer were selected. Diabetic ulcers which sugar control.

Exclusion Criteria:

Malignant ulcers, HIV and TB patients, patients suffering from hepatitis and patients with signs of gangrene.

Assessment Criteria: The wounds were assessed using the following parameters.

1. Symptom Rating Scale:

0-No Sign & symptoms

1-Mild Sign & symptoms

2-Moderate Sign & symptoms

3- Severe Sign & symptoms

2. Assessment of Size:

0 - No discontinuity of skin/mucous membrane,

1 - 1/4 of previous area & depth of the wound.

2 - 1/2 of previous area & depth of the wound.

3 - 1/2 of previous area & depth of the wound.

3. Assessment of Pain:

- 0 - No pain,
- 1 - Localized feeling of pain during movement only but no feeling during rest.
- 2 - Localized feeling of pain even during rest but not disturbing the sleep.
- 3 - Localized continuous feeling of pain, radiating & not relieved by rest.

- 0 - Tolerance to pressure,
- 1 - Little response on sudden pressure.
- 2 - Wincing effect on super slight touch.
- 3 - Resists to touch & rigidity.

5. Assessment of Burning:

- 0 – No burning,
- 1 - Little, localized & some time feeling of burning sensation.
- 2 - More localized & often burning sensation which does not disturbed sleep.
- 3 - Continuous burning sensation with disturbed sleep.

6. Assessment of Itching

- 0 - No itching,
- 1 - Slight, Localized itching sensation which is relieved by rest.
- 2 - More, Localized & often itched but not disturbs sleep.
- 3 - Continuous itching with disturbed sleep.

7. Assessment of Color:

- 0 – Normal pigmentation & of skin,
- 1 - Slight red.
- 2 - Reddish black.
- 3 - Pale yellow! Blackish / Bluish

8. Assessment of Margin & Surface:

- 0 – Adheres margin,
- 1 - Smooth, even & regular.
- 2 - Rough, regular & inflamed.
- 3 - Rough, irregular & angry look.

9. Assessment of Base/Floor:

- 0 - Smooth, regular & with healthy granulation tissue,
- 1 - Smooth, irregular, slight discharge, less granulation tissue, needs dressing & soft scar.
- 2 - Rough, regular wet with more discharge, needs dressing & having firm scar.
- 3 - Rough, irregular with profuse discharge, needs frequent dressing & having hard scars.

10. Assessment of Smell:

- 0 - No smell,
- 1 - Bad smell
- 2 - Tolerable unpleasant
- 3 - Foul smell which is intolerable.

11. Assessment of Swelling:

- 0 – Absent,
- 1 - Slight red, tender & hot with painful movement & without indurations.
- 2 - More red, having painful movement, with more local temperature & with indurations.
- 3 – Angry look, hot, resist to touch & with more indurations.

12. Assessment of Discharge:

- 0 - No discharge / dry dressing,
- 1 - Scanty occasional discharge & little wet on dressing.
- 2 - Often discharge & with blood on dressing
- 3 - Profuse, continuous discharge which needs frequent dressing.

13. Assessment of unhealthy Granulation Tissue:

- 0 - Healthy granulation tissue,
- 1 - Smooth less & irregular granulation base covered with slight discharge.
- 2 - Little healthier granulation tissue & discharge which needs dressing.
- 3 - Rich unhealthy granulation tissue with profuse discharge, & needs frequent dressing.

Statistical analysis

All information which are based on various parameter was gathered and statistical was carried out in terms of mean (X), standard deviation (S.D.), standard error (S.E.), paired test (t-value) and finally result were incorporated in term of probability (p) as – $p < 0.05$ - Insignificant $p < 0.01$ - Significant $p < 0.001$ - Highly Significant.

CLINICAL APPLICATION



Fig.I: Pachai oil



Fig.11: before treatment



Fig.11I: Application of Pachai oil

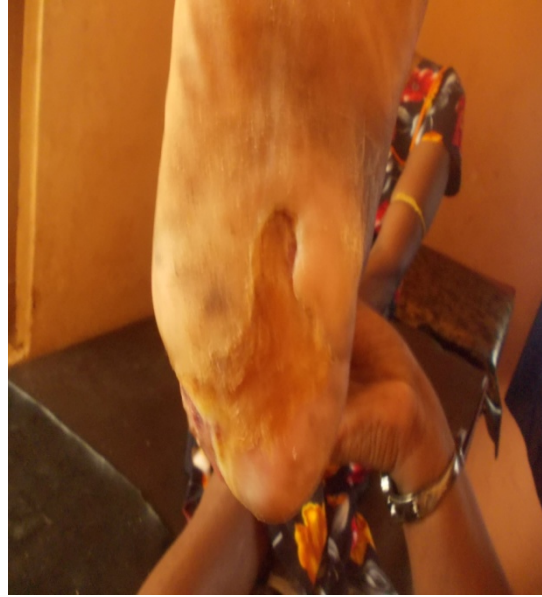


Fig.1V: After treatment

RESULTS :

Based on the statistical analysis, the effects of the drug on various parameters were studied and following results were obtained

Table 1 showing Effect on cardinal sign and symptoms of Group A patients (Pachaiennai):

Cardinal symptoms	Mean Score (BT)	Mean Score (AT)	Percentage Relief	SD	SE	T	P
Size	0.8	0.24	69	0.98	0.21	4.04	<0.001
Pain	1.9	0.74	60	1.18	0.26	7.21	<0.001
Tenderness	1.73	0.61	65	0.99	0.22	7.87	<0.001
Burning Sensation	1.5	0.96	35	0.81	0.18	8.32	<0.001
Swelling	0.33	0.05	84.61	0.57	0.13	2.74	<0.001
Color (Abnormal)	1.1	0.35	67.42	0.77	0.17	6.4	<0.001
Margin (Unhealthy)	0.75	0.3	80	0.62	0.14	5.39	<0.001
Base (Abnormal)	0.8	0.27	66.56	0.6	0.12	5.96	<0.001
Smell	0.45	0.23	50	0.67	0.15	3.01	<0.001
Discharge	1.5	0.47	68.42	0.87	0.19	7.75	<0.001
Unhealthy Granulation tissue	0.1	0.04	64.28	0.44	0.09	1.03	>0.05
Itching	0.85	0.51	40	0.65	0.15	5.81	<0.001

BT = No of Patients before Treatment, AT = No of Patients after Treatment, SD =Standard Deviation, SE = Standard Error of Mean, T = Paired T Test, P = Probability Value

In Chronic Wound the size was decreased 69.23% which was statistically highly significant. There was considerable improvement (> 80 %) in swelling and unhealthy margin. Pain, tenderness, discharge and unhealthy granulation tissue showed moderate effect (between 60 to 70 percent) in the chronic wounds.

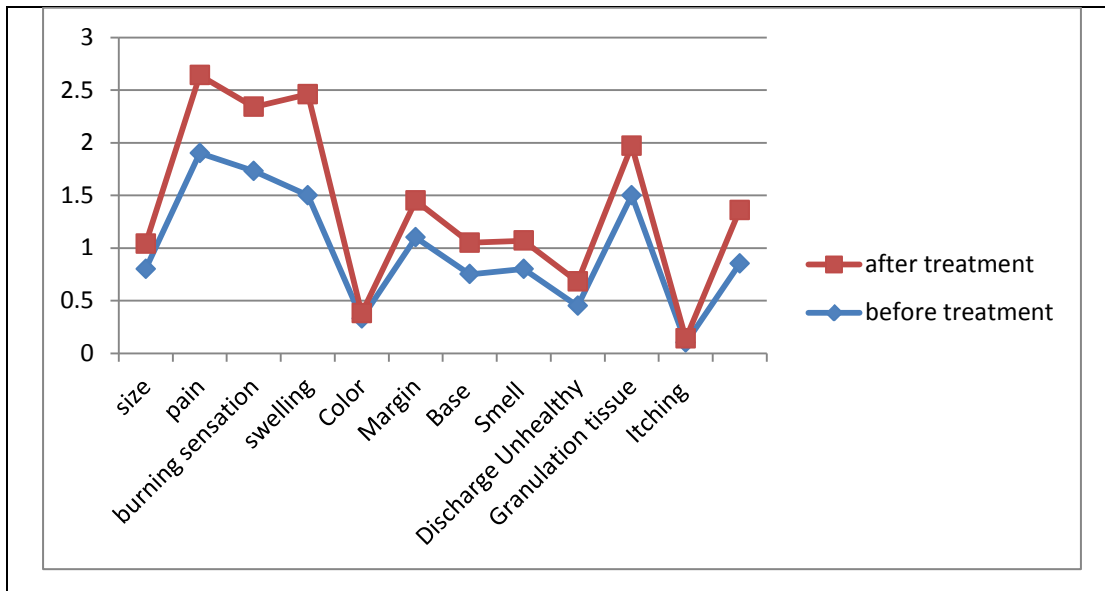


Fig - 1. Effect on cardinal sign and symptoms of Group A patient

Table 2 showing Effect on cardinal sign and symptoms of Control group (Group B)

Cardinal symptoms	Mean Score (BT)	Mean Score (AT)	Percentage Relief	SD	SE	T	P
Size	0.87	0.33	62.31	0.98	0.12	4.06	<0.001
Pain	1.8	0.76	58	1.23	0.28	6.21	<0.001
Tenderness	1.89	0.71	64.1	0.89	0.23	7.84	<0.001
Burning Sensation	1.09	0.78	33.25	0.86	0.17	7.32	<0.001
Swelling	0.45	0.07	82.61	0.77	0.11	2.34	<0.001
Color (Abnormal)	1.2	0.45	66.42	0.97	0.19	6.4	<0.001
Margin (Unhealthy)	0.76	0.17	78.5	0.66	0.14	5.21	<0.001
Base (Abnormal)	0.87	0.37	64.1	0.58	0.12	6.23	<0.001
Smell	0.45	0.23	45.	0.67	0.42	3.01	<0.001
Discharge	1.6	0.67	57.4	0.89	0.16	6.55	<0.001
Unhealthy Granulation tissue	0.1	0.05	53.28	0.54	0.06	1.01	>0.05
Itching	0.81	0.52	36.9	0.65	0.14	5.86	<0.001

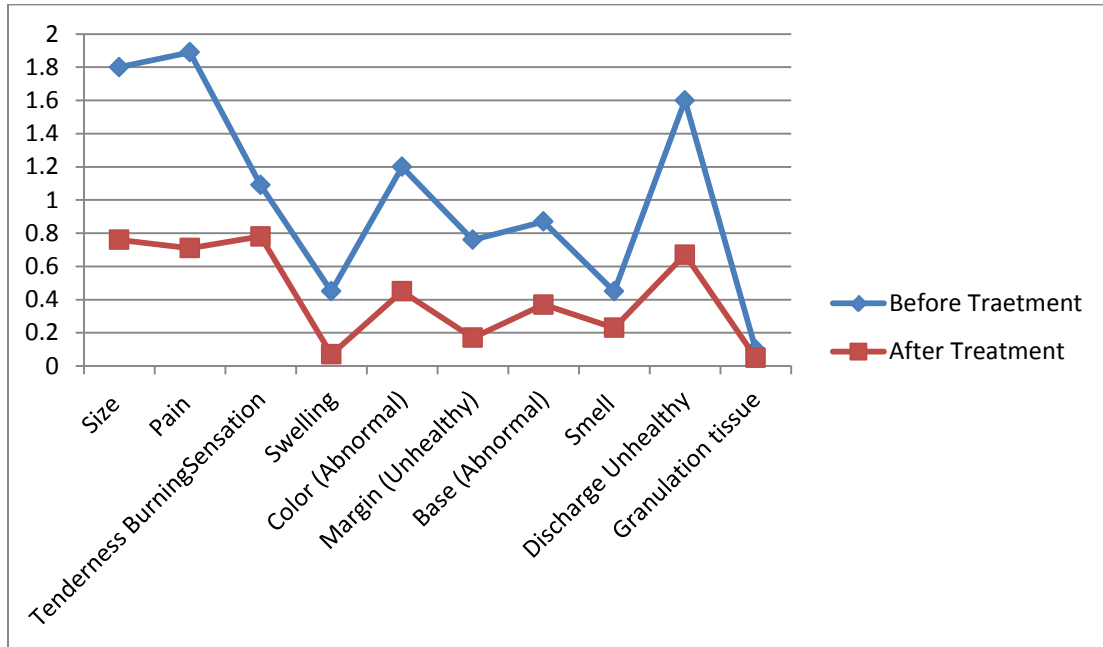


Fig.2: Effect on cardinal sign and symptoms of Group B patients

Table 3: table showing improvement in various types of the wounds

Diagnosis	Cured Patients	Cured %	Markedly improved Patients	Markedly improved %	Improved Patients	Improved %	Unchanged Patients	Unchanged %
Lacerated Wound	-	-	-	-	-	-	-	-
Post-Operative Wounds	2	66.67	1	33.33	-	-	-	-
Fissure	8	72.73	3	27.28	-	-	-	-
Burn	-	-	-	-	-	-	-	-
Pressure sores	1	50	-	-	1	50	-	-
Trophic ulcer	-	-	-	2	100	-	-	-
Varicose ulcer	-	-	-	-	-	-	1	100
Other (wart etc.)	-	-	-	-	1	100	-	-

Overall Result of Therapy in Chronic Wound Group:

It has been concluded that 72.72% of treated cases of fissure were cured, followed by 66.67% of cases of post-operative wound were cured. Similarly some cases (50%) of Pressure sores were also reported as cured; all the patients of varicose wound were unchanged after treatment.

DISCUSSION:

Wound healing is a normal physiological event which outsets immediately after injury till the formation of healthy scar. *Pachai ennai* regenerative properties are also useful for healing wounds and promoting the growth of healthy cells[13]. Analysis of types of wounds showed that 72.72% of treated cases of fissure were cured, followed by 66.67% of cases of post-operative wound were cured. Similarly some cases (50%) of Pressure sores were also reported cured. The size was decreased 69.23% which was statistically highly significant. There was considerable improvement (> 80 %) in swelling and unhealthy margin. Pain, tenderness, discharge and unhealthy granulation tissue showed moderate effect (between 60 to 70 percent) in the chronic wounds. The Karaseelai application expulses the impure debris's and vitiated Doshas (Toxins and unwanted metabolites are removed) [14]. It facilitates fresh blood supply and promotes formation of new tissues. *Pachai ennai* has sohdhona and ropana property[15]. Hence it helps in simultaneous cleansing and healing of infected tissues[16]. This is in accordance with the results of Shanmugapriya et al. which proves that *Datura* has a good wound healing pattern and a marked pro-healing activity[17]. This shows that *Datura* on tropical application produces significant improvement in granulation tissue due to its angiogenic and mitogenic potential, cellular proliferation, increasing collagen synthesis, granulation tissue formation and the ulcer margin reduction[18]. So, this properties are necessary for wound healing. Which enhances the synthesis of collagen and counter balances collagen break down by the action of stabilizing lysosomal enzymes needed to synthesize collagen and it prevents free radical damage[19]. *Datura* produced highly valuable reductions of slough in the margins and surrounding areas [20].

Pachai ennai contains the herb of *Datura* plant. This plant leave juice has chemotactic effect which decreased inflammatory cells towards the wound site and cellular proliferation was observed by hamatoxylin and eosin staining. The formation of peptides which are known to have

angiogenic and chemotactic properties the presence of gelatinase indicates progression of wound healing process.

However further study with large sample size is required to evaluate impact of herbal application on promote the healing efficacy on diabetic ulcer.

CONCLUSION:

The ulcer was completely healed within 4 month with herbal application. Eventhough the diabetic foot is very difficult task to treat. This herbal application of *Patchai ennai* proves to be effective, time saving, affordable and acceptable treatment on diabetic foot ulcer. It can be managed with herbal application.

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