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Validation on the Therapeutic Effectiveness of the Siddha Herbo Mineral Preparation of *AgasthiyarKuzhambu* (AGK) Fumigation Therapy for the Clinical Management of *NaalpattaViranam* (Chronic Wound) - A Case Series

Thiruvancheeswaran Soruban[1], Indhu. P. M.[2], Sivakkumar S.[3]

[1]Medical Officer, Siddha Teaching Hospital, Kaithady, Jaffna, Sri Lanka

[2]PG Scholar, Department of Gunapadam, National Institute of Siddha, Chennai, Tamil Nadu, India

[3]Associate Professor, Department of Gunapadam, National Institute of Siddha, Chennai, Tamil Nadu, India

Abstract

Chronic wounds do not proceed through an orderly or timely reparative process, instead having a delayed, arrested, or repetitive cycle of the phases of wound healing, with progress ceasing or slowing. Literature defines chronic wounds in the range of 4 weeks to 3 months. This kind of wound had been explained in Siddha literature under Viranam or Ranam. The Pugai (Fumigation) is one of the external therapies in Siddha medicine. The main purpose of this procedure is to control the infection.

Methods: Seven chronic wound patients were treated by cleaning with normal saline, followed by exposing the wound to Agasthiyar Kuzhambu (AGK) fumigation therapy. Management is done for up to 28 days or until the wound gets healed. The treatment was weekly evaluated by the measurement and pictures of the wounds through the Photographic Wound Assessment Tool (PWAT).

Results: After the fumigation management, all patients showed signs of wound healing with a reduction in the size and depth of the wounds.

[1]Corresponding Author, email: sorruthiru@gmail.com

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[2]Second Author
[3]Third Author

Conclusion: This study results concluded that the Agasthiyar Kuzhambu (AGK) fumigation therapy is effective for the management of chronic wounds.

Keywords.
Naalpatta Viranam, Chronic Wound, Pugai Therapy, Fumigation Therapy, Siddha Medicine.

Introduction

Chronic wounds do not proceed through an orderly or timely reparative process, instead having a delayed, arrested, or repetitive cycle of the phases of wound healing, with progress ceasing or slowing. Literature defines chronic wounds in the range of 4 weeks to 3 months (1,2). Wound Healing Society classifies chronic wounds into 4 major categories: pressure ulcers, diabetic foot ulcers, venous ulcers, and arterial insufficiency ulcers (3,4). The incidence of chronic wounds has been growing like a "silent epidemic (5)." Approximately 2% of all hospitalized patients worldwide have a chronic wound, and elder patients are at the highest risk because aging impairs the healing process (6,7).

A chronic wound is known as *Nalpatta viranam* and has been explained in the Siddha classical text book *Sarabendhirar Vaidhya Muraigal Virana Karappan Roga Sigitchai* and classified into *Sutha viranam* (Simple wound) and *Thusta viranam* (chronic wound) as another category. (8)

In Siddha Medicine, there are 32 internal and external medicines are explained in the Siddha Literature. *Pugai* (Fumigation) is one of the external therapies. The main purpose of this procedure is infection control. Fumigation is done to the affected part particularly, chronic ulcers, fistula, and anorectal diseases (9).

Agathiyar kuzhambu (AGK) is one of the herbo-mineral siddha formulas, Mentioned in the Siddha textbook, *Siddha Vaithiya Thirattu* (10). According to the literature, *Agathiyar kuzhambu* is a form of internal medicine that is commonly used in purgation therapy and used in some external therapies such as *Pugai* (fumigation), *Nasiyam* (nasal drops), *Kalikkam* (eye drops), and *kudori marunthu* (directly applied in cut vessels) (10).

This preparation contains eleven ingredients that are mentioned in the classical Siddha text *Siddha Vaithya Therattu*. The ingredients are *Induppu* (Sodium chloride impure), *Rasam* (Mercury quicksilver), *Manosilai* (Red orpiment), *Aritharam* (Yellow orpiment), *Vengaram* (Sodium biborate), *Naabi* (*Aconitum ferox*), *Perungayam* (*Ferula asafoetida*), *Kadugu* (*Brassica nigra*), *Omam* (*Trachyspermum ammi*), *Karunjeerakam* (*Nigella sativa*) and

Nervalam (Croton tiglium) (10).

A scientific study was published in the journal about the effectiveness of AGK fumigation therapy for *Silaipun* (Non-healing varicose ulcer) as a case report (11). This study had to be selected for the confirmation of the therapeutic effectiveness of fumigation therapy with trial drug AGK for scientific validation. This study may help to propagate our external fumigation therapy for Chronic wounds.

Objective

To assess the clinical effectiveness of *Agasthiyar Kuzhambu* (AGK) fumigation in the management of *Nalpatta Viranam* (Chronic Wound) through the case series.

Case Series

Patients with chronic wounds were undertaken in this study through nonrandomized sample methods.

In this study the patients enrolled based on the following inclusion criteria, Age: 20 - 65 years; Both sexes; non-healing ulcer more than 4 weeks including diabetic ulcer, venous ulcer with or without clinical symptoms of pain, itching, edema, fibrinous exudates in the lesions, patients who are willing to undergo *Pugai* (fumigation) application, willing for blood investigation before and after treatment, willing to attend out-patient department (OPD) or admission in in-patient department (IPD) for 28 days and willing to take photograph before and after treatment.

In this study, the patients enrolled based on the following Exclusion criteria, Extensive and localized gangrene require amputation**,** osteomyelitis**,** deep ulceration with bone, joint involvement**,** known history of venereal ulcer**,** known history of Hansen's disease**,** known history of tuberculosis, known history of malignancy ulcer**,** any other systemic illness**,** pregnancy and lactation, bronchial asthma and allergic to fumes.

Ethical approval

All potential subjects were informed of their rights to discontinue their participation in the study at any time without affecting their usual and outlined wound treatment protocols. Study subjects signed a written consent form explaining these rights. Ethical approval for this study was given by the National Institute of Siddha. The study was registered under the Clinical Trials Registry, India (CTRI/2022/02/040140). Number of IEC: NIS/IEC/2021/PS – I.

Case No 1

The 60-year-old male patient was admitted to the IPD, Department of Gunapadam, National Institute of Siddha, from Kanchipuram district, Tamil Nadu, working as a Tea seller. The patient has had a Diabetic wound located in the first metatarsal bone region, plantar surface of the right foot for two months with few watery discharges and without pain. He had a history of Diabetic mellitus for 10 years and managed with modern medicine. (Figures no 6 and 7)

Case No 2

A fifty-six-year-old male was admitted to the IPD, Department of Gunapadam, National Institute of Siddha, from Chitlapakam, Chennai district, Tamil Nadu, working as a laborer. The patient had complaints of a coin-sized wound in the lateral side of the right lower leg due to a road traffic accident in November 2021 gradually increased in size to a large wound in six months. He suffered from pain, burning sensation, hyperpigmentation in his right lower leg, and swelling. He had a history of Diabetic mellitus for 2 years and he followed the allopathy medicine. According to the results of a venous Doppler study dated 29th December 2021 which is revealed that incompetent perforators are seen in both lower legs along the greater saphenous veins. (Figure. no 8 and 9)

Case No 3

A 21-year-old male student was admitted to the IPD, Department of Gunapadam, National Institute of Siddha, from Kanchipuram District, Tamil Nadu. He is a student and was admitted with complaints of ischemic, multiple pitting types, an irregularly shaped ulcer in the left sole, and a single pitting ulcer in the right sole for one month with pain, pustular discharge, the floor of the ulcer is filled with slough, swelling of both feet and hyperpigmentation in the surrounding area. (Figures no 10, 11, 12 and 13)

Case No 4

A Fifty-three-year-old male was admitted to the IPD, Department of Gunapadam, National Institute of Siddha, from Thiruvanamalai District, Tamil Nadu, working as a Security Guard. He had complaints of the gradual onset of a small papule-like lesion that occurred in the dorsal aspect of the right foot followed by pus collection and discharge. Then became ulcerated and suffered from a burning sensation and pedal edema for 6 months. He has a newly diagnosed Diabetic mellitus history also. (Figures no 14 and 15)

Case No 5

A 61-year-old male was admitted to the IPD, Department of Gunapadam, National Institute of Siddha, from Kanchipuram District, Tamil Nadu. His complaints were an oval-shaped wound due to Diabetic mellitus located in the anterior and middle part of his left lower leg for one month with pain, pustular discharge, swelling, and erythematous in the surrounding area. He had a history of Diabetic mellitus for 10 years and was under the control of blood glucose level with the support of modern medicine. (Figure. no 16 and 17)

Case No 6

A Forty-year-old female visited the OPD, Department of Gunapadam, National Institute of Siddha, from Kanchipuram District, Tamil Nadu working as a Software engineer. She had an oval-shaped wound due to a burn located in the anterior part of the left ankle of her foot for one month with mild pain, watery discharge, mild swelling, and hyperpigmentation in the surrounding area. (Figure.no 18 and 19)

Case No 7

A 58-year-old male was admitted to the IPD, Department of Gunapadam, National Institute of Siddha, Kanchipuram District, Tamil Nadu. He had complaints of a non-healing amputated wound due to Diabetic mellitus, located in his left foot for six months with pain, pustular discharge, swelling, bad odour, and erythematous in the surrounding area. He had a history of Diabetic mellitus for 10 years and was under the control of blood glucose level with the support of modern medicine. (Figure. no 20 and 21)

Preparation method of *Agathiyar Kuzhambu* (AGK) *Thiri* and fumigation

3 grams of *Agasthiyar kuzhambu* was applied on sterile cotton cloth (Figure no 1) and rolled. This medicated cotton cloth was burnt in a specially designed fumigation therapy box (Figure. no 2 and 3). The fume was allowed to expose the ulcerated area (Figure. no 4 and 5).

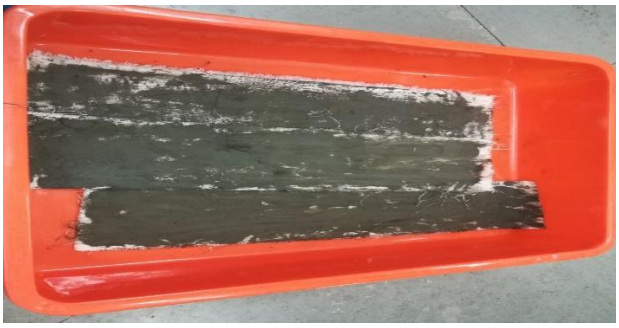

Figure 1: Prepared *Agathiyar Kuzhambu* (AGK) *Thiri*

Treatment Protocol

The patient was treated according to the Siddha line of treatment. On the first day, the patient underwent an oil bath with 30 ml of *Arakku thylam* (14). On the second day, *Agathiyar kuzhambu* with a dosage of 200mg along with 10ml ginger juice was administrated on an empty stomach for purgation (15). From the third day onwards, the wound was cleaned with normal saline after that the *Agathiyar kuzhambu Pugai* (fumigation therapy) was administrated for 20 minutes, for 28 days. Every day after this therapy, the patient was observed for 30 minutes, and vital signs were checked and recorded. The outcome was assessed by reduction of clinical symptoms, routine blood investigation, and by using the PWAT Scale (Photographic Wound Assessment Tool).

Figure : Front view of Fumigation Therapy Box

Figure 3: Upper view of Fumigation Therapy box

Figure 4: Upper view at the time of Fumigation Therapy

Figure 5: Front view at the time of Fumigation Therapy

Result and Discussion

According to this study, 7 patients were selected randomly and among these 57.14% of patients were diagnosed with diabetic wounds, 14.28% of patients were diagnosed as wounds due to varicose vein, 14.28% of patients were diagnosed as wounds due to ischemic and 14.28% of patients were diagnosed as wound due to burn.

The score of PWAT is mentioned in Table no 1, the measurement of the wound is reported in Table no 2, and the blood investigation of all the cases is mentioned in Table no 3.

Table No 1: The score of the Photographic Wound Assessment Tool (PWAT) before and after treatment

PARAMETERS	ASSESSMENT BEFORE TREATMENT							ASSESSMENT AFTER TREATMENT						
	Case No 01	**Case No 02**	**Case No 03**	**Case No 04**	**Case No 05**	**Case No 06**	**Case No 07**	**Case No 01**	**Case No 02**	**Case No 03**	**Case No 04**	**Case No 05**	**Case No 06**	**Case No 07**
Size (cm)	2	4	4	3	2	2	4	1	4	2	2	0	2	2
Depth	2	3	2	1	3	2	3	1	2	1	1	0	1	3
Necrotic tissue type	2	2	2	1	2	2	3	0	1	0	1	0	0	1
The total amount of necrotic tissue	2	2	4	2	4	3	4	0	1	0	2	0	0	1
Granulation tissue type	3	2	4	3	4	2	4	1	1	0	1	0	0	2
The total amount of granulation tissue	4	3	4	2	4	4	3	1	2	0	1	0	0	4
Edges	2	2	3	1	3	3	3	1	1	0	0	0	0	3
Periulcer skin viability	3	3	4	2	3	3	3	2	2	2	2	1	1	3
Total Score	**20**	**21**	**27**	**15**	**25**	**21**	**27**	**7**	**14**	**5**	**10**	**1**	**4**	**19**

Table No 2: Comparison of the wound measurement

Case Numbers	Wound measurement before the management (Cm)			Wound measurement after the management (Cm)		
	Length	Width	Depth	Length	Width	Depth
Case No 01	1	1.5	0.5	0.5	0.5	0.1
Case No 02	8	6	0.3	7	5	0.1
Case No 03 Right Leg	2	2.5	0.2	0.5	1	0.1
Case No 03 Left Leg	2	1.5	0.1	0	0	0
	1.5	1	0.1	1	0.5	0
	3	2	0.1	1.5	0.5	0
Case No 04	3	4	0.1	2	2	0
Case No 05	2	1.5	0.5	0.5	0.5	0.1
Case No 06	4	3	0.2	1	2	0
Case No 07	2.5	2	1.5	1.3	1	0.5
	3	1.5	2.8	2	1	1.7

Table No 3: The blood investigation parameters before treatment

Blood Investigation Parameters	Case No 01	Case No 02	Case No 03	Case No 04	Case No 05	Case No 06	Case No 07
Hb (gm/dl)	14.6	10.8	12.8	14.7	9.8	8.0	10.8
Tot WBC (Cells/µl)	6700	5000	11200	8000	8500	4170	9400
RBC (Millions/µl)	5.1	4.4	4.7	4.8	3.4	3.77	4.4
ESR (mm/Hr) ½ hr	18	20	42	13	34	11	21
Neutrophils (%)	61	58	65	53	50	63.7	64
Lymphocytes (%)	30	36	27	39	46	27.9	30
Monocytes (%)	09	05	06	02	04	6.6	05
Basophils (%)	00	01	02	06	00	0.47	00
Eosinophils (%)	00	01	00	00	00	1.4	02
FBS (mg/dl)	193	95	104.5	268	267.5	81.8	66
PPBS (mg/dl)	298	186	96	394	475	126	169
HbA_1C (gm/dl)	11.0	6.0	4.7	11.7	13.6	5.5	4.8

Table No 4: The blood investigation parameters after treatment

Blood Investigation Parameters	Case No 01	Case No 02	Case No 03	Case No 04	Case No 05	Case No 06	Case No 07
Hb (gm/dl)	14.5	10.8	12.5	14.1	10.1	8.8	10.4
Tot WBC (Cells/µl)	6550	5000	11200	7800	7900	5400	9500
RBC (Millions/µl)	5.1	4.4	4.7	4.9	3.4	3.76	4.3
ESR (mm/Hr) ½ hr	14	15	18	12	18	9	16
Neutrophils (%)	69	58	60	66	59	69.0	67
Lymphocytes (%)	31	36	25	33	38	28.1	32
Monocytes (%)	06	05	03	02	03	04	02
Basophils (%)	00	01	01	02	00	00	01
Eosinophils (%)	00	01	00	00	00	01	00
FBS (mg/dl)	159	95	100.5	205	189	92.0	94.9
PPBS (mg/dl)	198	186	90	280	255	129.0	158
HbA_1C (gm/dl)	10.7	5.6	5.1	7.2	11.2	5.1	5.21

Case No 1

Figure 6: Before the treatment of a diabetic wound	**Figure 7: After the treatment of diabetic wound**

He presented with a diabetic wound, and its size was 2cm x1.5cm, depth 0.5cm, painless, few water discharges, and the surrounding area was covered by a slough and necrotic tissues (PWAT score was 20). The size of the wound was reduced to 0.5cm x 0.5cm depth of 0.1cm and the healthy granulation tissues developed after the fumigation therapy (PWAT score was 7). 65% of wounds were cured according to the Photographic Wound Assessment Tool.

Case no 2

Figure 8: Before treatment wound due to varicose vein	**Figure no 9: After treatment-wound due to varicose vein**

Initially, the patient's wound size was 8cm x 6cm, depth 0.3cm, pain with burning sensation, and water discharge, based on the wound being covered by slough and induration of the surrounding tissues (PWAT score was 21). The wound size was reduced to 7cm x 5cm depth of 0.1cm and the granulation tissues and induration of the surrounding tissues were reduced at the end of treatment (PWAT score was 14). 33% of the wound was cured and it was assessed by the Photographic Wound Assessment Tool.

Case No 3

Figure 10: Before the treatment wound due to ischemic - Rt Leg

Figure 11: After the treatment wound due to ischemic - Rt Leg

Figure 12: Before the treatment wound due to ischemic - Lt Leg

Figure 13: After the treatment wound due to ischemic - Lt Leg

He presented with an irregularly shaped ulcer, its size was 2cm x 2.5cm, depth 0.2cm, in the right sole with pain, and purulent discharge, the base of the wound was covered by slough and erythematous, and the surrounding area was swelling and hyperpigmented. The left leg wound size was 2cm x 1.5cm, 1.5cm x 1cm, and 3cm x 2cm, depth 0.1cm, with purulent discharge, the base of the wound was covered by slough and the surrounding area was swelling and hyperpigmented (PWAT score of wounds was 27).

Case No 4

Figure 14: Before the treatmentof a diabetic wound

Figure 15: After the treatmentof diabetic wound

After treatment, the right sole wound size was reduced to 0.5cm x 1cm depth of 0.1cm and the granulation tissues also developed. the size of the wound in the left sole was reduced to 0cm x 0cm, 1cm x 0.5cm, and 1.5cm x 0.5cm depth 0 cm, decreasing the percentage of discharge and slough and also increasing granulation tissue (PWAT score of wounds was 5). According to the Photographic Wound Assessment Tool, 82% of wounds were cured in both soles of the feet.

He had a multiple pitting wound, and its size was 3cm x 4cm, depth 0.1cm, with purulent discharge, the base of the wound was covered by a slough, and the surrounding area was swelling and hyperpigmented (PWAT score was 15). After treatment, the wound size was reduced to 2 cm x 2 cm depth of 0 cm as well the therapy increased the granulation tissues in the wound (PWAT score was 10). 33% of the wound was healed up.

Case No 5

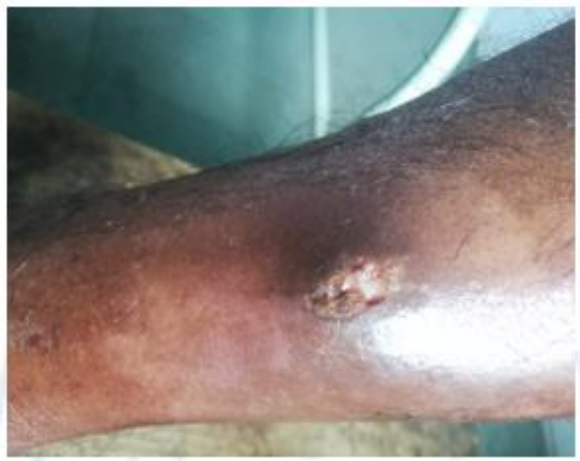

Figure no 16: Before the treatment of a diabetic wound

Figure 17: After the treatment of diabetic wound

On examination, the wound size was 2cm x1.5cm, depth 0.5cm, with pain, and purulent discharge, the base of the wound was covered by slough and erythematous, surrounding area was swelling and hyperpigmented (PWAT score was 25). At the end of therapy, the wound area was 0.5cm x 0.5cm depth 0.1cm, and the healthy granulation tissues also developed (PWAT score was 1). 96% of the wound was healed up.

Case No 6

Figure 18: Before the treatment wound due to burn	**Figure 19: After the treatment wound due to burn**

She had an oval-shaped wound with a size of 4cm x 3cm, a depth of 0.2cm, with erythematous, serous discharge, burning sensation, and surroundings area were hyperpigmented, mild swelling, covered by slough and few amounts of necrotic tissues (PWAT score was 21). At the end of the management, the wound size was reduced to 1cm x 2cm with a depth of 0 cm and epithelialization (PWAT score was 4). 81% of the wound was cured.

Case No 7

Figure 20: Before the treatment of a diabetic wound

Figure 21: After the treatment of diabetic wound

He presented with non-healing wounds due to amputation, the size of the wounds was 2.5cm x 2cm, depth 1.5cm, and 3cm x 1.5m, depth 2.8cm. The symptoms were pain, bleeding, erythematous, unpleasant odor, the surrounding area covered by slough and necrotic tissues, undermining, and rolled edge (PWAT score was 27). The wound's size was reduced to 1.3cm x 1cm, depth 0.5cm, and 2cm x 1cm, depth 1.7cm, and the development of healthy granulation

tissues and epithelialization of the surrounding area was seen after fumigation therapy (PWAT score was 19). 30 % of the wound was cured and it was assessed based on the Photographic Wound Assessment Tool.

Conclusion

This Study revealed that the *Agasthiyar Kuzhambu* (AGK) fumigation promotes the process of wound healing by improving the blood circulation of the wound. The warming effect of the fumigation also enhances the blood and lymph circulation in the wound which results in wound healing. This study results concluded that the *Agasthiyar Kuzhambu* (AGK) fumigation therapy is effective for the management of chronic wounds.

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