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Randomized trial to assess the efficacy of combined *Stichopus horrens* and *Channa striatus* based cleanser and moisturizer compared to Cetrimide Lotion 1% and Petrolatum in treatment of stasis eczema.

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Abstract

Background : *Stichopus horrens* (sea cucumber) and *Channa striatus* (haruan fish) have been shown to effectively expedite wound healing process ^[1-6] and to treat multiple inflammatory disease. We aimed to assess the combination benefits of *Stichopus horrens* (SH) and *Channa striatus* (CS) in the treatment of chronic inflammatory skin disease like stasis eczema.

Methods: This was a single center, randomized prospective, parallel, double-blinded comparative trial in patient with stasis eczema. Subjects were randomized 1:1 to receive either Treatment A (*Stichopus horrens* and *Channa Striatus* based cleanser and moisturizer) or Treatment B (Cetrimide lotion 1% and Petrolatum) which are to be used 3 times a day for 2 weeks. Clinical assessment was done using DASI score and DLQI which was assessed at week 0,1 and 2.

Results: A total of 116 subjects were screened successfully and underwent this trial. From this trial, we found that Treatment A (*Stichopus horrens* and *Channa Striatus* based cleanser and moisturizer) has significant effect on improving sign of skin inflammation in stasis eczema (mean reduction for DASI Total W2 – W0: - 2.19 vs - 1.14, p-value < 0.001) and improves the patient quality of life (mean reduction DLQI W2 – W0 : - 1.00 vs - 0.62, p-value < 0.001) as compared to Treatment B (Cetrimide lotion 1% and Petrolatum). There is no adverse effect observed in both treatment arm

Conclusions: *Stichopus horrens* and *Channa striatus* based cleanser and moisturizer can be used as an adjunct therapy in the treatment of stasis eczema.

Keywords : Stichopus horrens, Channa striatus, eczema.

INTRODUCTION

Stasis eczema (SE) is a common dermatology condition among elderly, affecting 20% of the elderly people aged > 70 years old ^[7]. It is caused by venous hypertension that results from incompetent venous valve, obstruction of the venous flow, failure of the venous pump in lower limb and chronic oedema due to drug or other factor ^[8]. Affected skin are prone to recurrent infection and development of lipodermatosclerosis in later stage.

In diabetic patient, scratching due to itch and dry skin as a results from Diabetic Autonomic Neuropathy (DAN) that lead to impairment of sweat secretion makes the skin prone to recurrent infection and chronic eczema in later stage ^[9]. SE among diabetic patient are usually mixed type that originate from arterial and venous insufficiency^[10] caused by diabetic complication such as kidney and heart failure which lead to chronic oedema of the lower limb.

Stichopus horrens (SH) and *Channa striatus* (CS) are used traditionally in South East Asian population to treat several ailments. SH or better known as "Gamat" which belongs to the Holothurian family had been used as traditional medicine as early as 1368 to 1644 BC during the era of Ming Dynasty. ^[11]. The medicinal properties of SH are attributed to its high content of proteins, essential amino acids and bioactive compound such as triterpene glycoside, chondroitin sulphates, collagen, phenolic and fucoidan^[12, 13]. This unique composition allows SH to exert anti-inflammatory, anti-oxidant, anti-bacterial, anti-viral, anti-fungal, anti-nociceptive, anti-tumour,

anti-angiogenic, and anticoagulant properties that facilitate wound healing process^[14-16]. Multiple clinical trial on human using SH based product has been shown to expedite wound healing and reduce inflammation ^[1-4].

CS or better known as "Haruan fish" are commonly consumed during post-partum period to expedite wound healing in Malaysia. High content of fatty acids such as eicopentaenoic acid (EPA) and decosahexaenoic acid (DHA) and amino acid such as glycine, glutamic acid, aspartic acid, and arginine not only expedite wound healing but also exhibit multiple medicinal properties such as antimicrobial properties, anti-inflammatory, induction of cell proliferation and platelet aggregation, and anti-nociceptive which fasten the wound healing process^[17-22].

Based on the benefit of both SH and CS individually, combination of both should exert more benefit as moisturizer incorporated with anti-inflammatory, anti-microbial and wound healing properties, which will improve SE. Therefore, this pilot trial intended to feasibly compare the efficacy of Treatment A (*Stichopus horrens* and *Channa striatus* based cleanser and moisturizer) versus Treatment B (Cetrimide lotion 1% and Petrolatum) in the treatment of SE.

SUBJECTS AND METHODS

This randomized prospective, parallel, double-blinded trial was done to evaluate the efficacy of Treatment A versus Treatment B as treatment of SE in improving clinical sign and symptoms and quality of life (QOL) of the patient.