Original Research Article

Study on the effect of combined action of topical silicone gel and pressure therapy in hypertrophic scar management

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Received: 26 February 2020

Revised: 28 April 2020

Accepted: 29 April 2020

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ABSTRACT

Background: Widespread hypertrophic scars usually resulting from burn injuries or extensive soft tissue trauma is a common problem presented to plastic OPD. Non-invasive treatment like Pressure/compression therapy and silicone sheets and gels are well-accepted, evidence-based recommendations for a long time. Very few studies are there for their combined effect on hypertrophic widespread scars. Aims and objectives of the study was to see the outcome of hypertrophic scar management following application of combined therapy of silicone gel and pressure garment.

Methods: In the present study we have taken patients, who were randomly allotted in two groups. In one group only silicone gel was used for scar management while other group we applied silicone gel along with customized pressure garment locally for 6 months. Patients are seen in OPD monthly and after 6 months final results were analyzed, to see the effect of combined therapy.

Results: Although silicone gel is alone is effective in widespread post burn scar, pressure garment provides a synergistic effects when used together. There is no significant change in colour and vascularity, but changes in scar thickness and pliability are most significant in combined therapy group.

Conclusions: For small linear scar silicone gel treatment is alone sufficient, but for widespread hypertrophic scar this should always be used along with pressure garment therapy.

Keywords: Hypertrophic scar, Pressure garment, Silicone gel, Vancouver scar scale

INTRODUCTION

Scar formation is a normal physiological response to tissue injury, by burn, trauma and post-surgery, it is the end point of wound healing but has a psychosocial impact on patient health.¹⁻⁴ Despite the wound has healed it keeps the patient restless, they frequently seek medical help for the clinical symptoms it cause as well as the social stigma they perceive because of its appearance. Scars cause significant decrease in patient's quality of social and professional life.

Widespread hypertrophic scars are distressing to the patient as they are excessively raised, wide or erythematous or cause the symptoms of pain, tightness,

itching. Various treatment options are available for improvement of scar.⁵⁻⁷ Non-invasive techniques for scar therapy are topical silicone gel, topical steroid ointment, pressure garment application.⁸ Although there are lots of studies using single agent non-invasive therapy e.g. silicone gel or pressure garment, there are only a few studies with combined effect of silicone gel and pressure garment.⁹

Clinical evaluation of a scar is necessary in determining the best course of treatment and effectiveness of therapy. The ideal scale for scar assessment should demonstrate validity, interobserver reliability and clinically applicability. Though multiple objective and subjective assessment tools have been devised to characterize the

scars, there is as yet no universal consensus on scar grading.

In the present study we have taken 24 patients who were treated to combined therapy of silicone gel and pressure therapy and evaluated the result of combined silicone gel application and pressure garment therapy. Result were compared with another group which only received silicone gel therapy after 6 months. This study was undertaken to verify the efficacy of combined application of topical silicone treatment; and pressure garment in scar management.

METHODS

This was a prospective randomized clinical trial conducted in Plastic surgery Department of N.R S Medical College and Hospital Kolkata, West Bengal, India, during a period of September 2016 to December 2019 (3 years). Study was primarily designed to compare scar quality after primary use of self-drying silicone gel versus use of combined silicone gel and pressure garment therapy in patients with hypertrophic scars. All patients in the study group provided fully informed written consent for inclusion into this study, also prior approval of hospital ethical committee was taken before the study.

Inclusion criteria

Patients of age 15-60 years, hypertrophic scars at least 3 weeks old and patients who are in compliance with treatment procedure and regular follow up visits.

Exclusion criteria

Patients having severe comorbidities, psychiatric illness, children <15 years of age, hypertrophic scar >2 years duration, keloid and scars which have received other treatment earlier.

The study enrolled 48 patients having post burn, or post traumatic hypertrophic scars randomly allotted in age matched two groups. Treatment duration for each group were 6 months. Group one comprising of 24 patients were advised to apply silicone gel ointment as a thin layer, 2-3 times daily, there after rubbed with fingertips for 2 minutes. Another 24 patient of group 2 combined therapy group (CTG) were given combined therapy of silicone gel and pressure garment therapy. They were advised to apply silicone gel and once it get dried to wear customized pressure garment locally, for 23 hours/day. Pressure garments to be changed after 2 months of use or once it get loose, whichever is earlier. Patients were examined by an experienced plastic surgeon, at initial presentation and after 6 month follow up, who was blinded to the treatment. Vancouver scar scale, was used for the assessment of scar and measurements were recorded.¹⁰ The result of each parameter at the beginning of treatment and at completion of 6 months were compared in both groups.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) 16.0 software and $p < 0.05$ was considered statistically significant. They were evaluated monthly for 6 months with the following points in both groups.

RESULTS

A total of 48 subjects were successfully recruited among which 32 were female and 16 were men. Patients in the study were in the age group 15 to 60 years, male to female ratio=1:2. Mean age of study population was 18.7 years. They had developed hypertrophic scar on the upper limbs (60.42%), face, neck and chest (20.83%), lower limb (12.5%) or other areas (6.25%). Most of the scars were caused by thermal burns (47.9%) or scald (33.3%), followed by traumatic injuries (10.4%), chemical burns (8.3%), and other injuries. Out of 48, 12 of patients had scar 3 months to 6 months old, while 16 patients had 6 months to 9 months old scar. 20 patients presented with scar more than 9 months old.

Table 1 shows mean score $\pm$ SD of parameters of Vancouver scale at initial assessment and 6 months follow-up. The measurements of parameters revealed that the treatments improved the scars and accelerated their maturation process with the both groups. When we look at when we compared the Mean scores of pigmentation and vascularity in silicone gel group and combination group at 6 month follow up there were no significant difference between results of both therapy. Meanwhile p-value were significant for pliability and height of hypertrophic scars after 6 month treatment when silicone gel alone compared to combination group, p-value 0.00008 and 0.036 respectively.

Scar thickness

Improvement among the two treatment groups, statistical analysis revealed significant differences (mean value $\pm$ SD in silicone gel alone and combination therapy group 1.38 ± 0.42 , 0.96 ± 0.48 respectively with $p = 0.036204$).

Scar pigmentation and vascularity

All subjects did show improvement of scar pigmentation in terms of lightness across 6 months of treatment. All the scars were lighter than those in the initial assessment, the significant improvements occurred after 6 months of treatment. The scars in the CTG group seemed to have a greater improvement compared with those in the silicone group but no significant difference seen statistically.

Scar pliability

As shown in Table 1, across the 6-month treatment period, all the scars in both groups showed an improvement in pliability.

Table 1: Vancouver scar scale, mean score and standard deviation at initial presentation and over 6 months of treatment follow-up among different groups.

Variables	At initiation of therapy	After 6 month follow up
Pigmentation		
Silicone gel group	3.81±1.68	0.71±0.55
CTG	3.42±1.24	0.62±0.57
Vascularity		
Silicone gel group	2.64±1.75	0.88±0.67
CTG	2.87±0.96	0.75±0.53
Pliability^a		
Silicone gel group	3.28±0.57	2.25±0.72
CTG	4.92±1.89	1.33±0.49
Height^b		
Silicone gel group	4.68±2.25	1.38±0.42
CTG	5.08±1.94	0.96±0.48

^aP=0.00008; ^bP=0.036204.

The scars in the CTG group were found to be significantly softer than those in the silicone group at after post 6 month of initial therapy. For scar pliability: (mean value±SD in silicone gel alone and combination therapy group were respectively 2.25±0.72 and 1.33±0.49 with p-value=0.00008).

DISCUSSION

In present study measurements of various parameters in both groups revealed that the treatments improved the scars and accelerated their maturation process. When mean scores of pigmentation and vascularity in silicone gel group and combination group were compared, difference were not significant. Significant improvement were seen in combination therapy group for pliability and height of hypertrophic scars after 6 months treatment when silicone gel alone compared to combination group.

Mechanism of action of silicone gel: Silicone gel contains long chain silicone polymer (polysiloxanes), silicone dioxide and volatile component. Long chain silicone polymers cross link with silicone dioxide.¹¹⁻¹³ It spreads as an ultra-thin sheet, get dry within 4-5 minutes and works 24 hours per day.^{14,15}

Silicone gel exerts several actions; it increases hydration of stratum corneum and thereby facilitates regulation of fibroblast production and reduction in collagen production, it results in softer and flatter scar, it protects the scar tissue from bacterial invasion and prevents bacteria induced excessive collagen production in scar tissue and it modulates the expression of growth factors, fibroblast growth factor β (FGF β) and tumour growth factor β (TGF β). TGF β stimulates fibroblasts to synthesize collagen and fibronectin, FGF β normalizes the collagen synthesis in an abnormal scar and increases the level of collagenase which breaks down the excess

collagen. Balance of collagen synthesis and collagen lysis is restored.

The mechanism of action of pressure therapy is not fully understood. Pressure therapy has recently been considered as an 'evidence-based' modality for the treatment of scars.¹⁶ Part of the effect of pressure could involve reduction of oxygen tension in scar tissue due to occlusion of small blood vessels, resulting in decrease in fibroblast production and collagen synthesis. Another hypothesis is that pressure therapy stimulates the mechanoreceptors that lead to apoptosis of dermal fibroblasts and diminish the hypertrophic process.¹⁷

Figure 1: (a) Hypertrophic scar over upper limb at initial presentation while; (b) results of combined therapy in the same which demonstrate decrease in thickness and skin colour resembles more to the normal skin after 6 months.

Figure 2: (a and b) 3 months and 6 months follow up of combined therapy in a 15-year-old male child with hypertrophic scar over abdomen and chest.

Finally the pressure therapy may provide symptomatic relief due to alleviation of oedema, itchiness and pain which contribute to patient well-being.¹⁸ In the study by Van den Kerckhove et al, it was shown that preventive 15 mmHg pressure therapy by garment would significantly reduce the scar thickness compared to a 10 mmHg pressure.¹⁹ However, the limitations of pressure therapy include, patient discomfort and difficulty to use in specific anatomical areas. Another annoying problem in burn patients is pruritus.

Though there are not many study in the literature, we have found that combined therapy with silicone gel and pressure garment is effective and can be tried before starting injectable or surgical therapy.

According to study conducted by Seinstraesser et al combined therapy with silicone gel and pressure garment do not provide better result than single agent pressure therapy alone, but other workers are of opinion that combined therapy should be started as early as possible when the wound is closed and patient can tolerate pressure.⁹

Li Tsang et al in their study have shown silicone sheeting can be used in combination with pressure therapy producing better improvement in post-traumatic hypertrophic scars than either therapy alone.²⁰ The two treatments have complementary modes of action with the silicone therapy acting on erythema and pliability of the scar whereas pressure therapy prevents scar thickening.

CONCLUSION

Widespread hypertrophic scar is associated with physical and psychosocial consequences among all age group. Choices regarding appropriate scar therapy should be guided by clinician experience but should be tailored according to individual patient. A combined therapy with both silicone gel and pressure garment should be a rational approach to begin with and should be implemented on HS to enhance the positive treatment effect and reduce treatment duration.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Das D, Yadav N, Arora E. Study on the effect of combined action of topical silicone gel and pressure therapy in hypertrophic scar management. *Int Surg J* 2020;7:1817-20.