International Journal of Dermatology, Venereology and Leprosy Sciences

E-ISSN: 2664-942X
P-ISSN: 2664-9411
www.dermatologypaper.com
Derma 2024; 7(2): 98-102
Received: 25-06-2024
Accepted: 30-08-2024

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Effectiveness of microneedling in the repigmentation process of vitiligo: A randomized controlled trial

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DOI: https://doi.org/10.33545/26649411.2024.v7.i2b.205

Abstract
Background: Vitiligo is considered an acquired autoimmune disorder characterized by depigmentation and white macules in the skin. It causes physical unhealthiness and mental breakdown in patients. Treatment involving oral medication, topical preparations, and phototherapy is available with a little application of microneedling to treat vitiligo.
Objective: The primary objective of this randomization clinical trial is to evaluate the effectiveness of microneedling over standard therapy in vitiligo patients.
Methods: 1.2 yearlong randomization trial conducted with 36 study subjects in the Department of Skin and Venereology, Dhaka National Medical Institute Hospital, Dhaka, Bangladesh. Two groups of patients participated in this trial where the study group of patients received standard therapy with microneedling and the control group of patients received standard treatment without microneedling. The primary outcome measure was the percentage of repigmentation assessed using clinical photographs and validated scoring systems at baseline, 1 week after 1st session, 2 weeks after 3rd session, and 1 month after 6th session. Result: Patients in the trial group showed a significant improvement ($p<0.01$) in pigmentation contrasted to the control group ($p>0.01$). Most of the study subjects were female (69%), and the male-female ratio was determined 1:2.24 in this study. 47.22% of healthy 16-30 years old patients participated in this study with other age groups. 50% of subjects are moderately satisfied with microneedling, where 17% of patients are completely satisfied, and 33% of dissatisfied patients identified by this study.
Conclusion: Microneedling is a painless invasive skin puncture procedure that makes it possible to transport the study drug to the inner binding surface directly. In comparison to the control group, the microneedling group of patients positively showed a notable recovery rate from vitiligo.

Keywords: Vitiligo, microneedling, pigmentation, macule, autoimmune disorder, randomized control trial

Introduction

An autoimmune skin disorder that causes white macules and patches on the body due to the deficiency of pigmentary cells in the epidermis [1]. It is a chronic and psychologically disturbing disorder for both adult and adolescent patients. According to statistical analysis by the Global Vitilogo Foundation, 70 million people worldwide are suffering from vitiligo [2]. A 2023 study in Bangladesh has detected 539 confirmed vitiligo patients over Bangladesh [3]. Vitiligo is considered to a "complex acquired disorder" that was marked as a genetic disorder in the early 1960s [4] where, recent research suggests that vitiligo is highly associated with mental depression [5]. Still, experts believe immunological and genetic factors are primarily responsible for vitiligo in humans [6]. UV radiation is another prime factor to causes vitiligo which is proven by an article where the majority of the study subjects have developed vitiligo after 5.1 months of radiation therapy [7]. Although the accurate etiology is yet to be known, it can be considered that vitiligo can occur due to autoimmunological, genetical, environmental, and psychological factors. A low dose of oral corticosteroid [8], topical calcineurin inhibitors [9], and phototherapies [10, 11] are some medical approaches to treat vitiligo in the current landscape. Phototherapy is taken as the first line of therapy for vitiligo in several cases but it is very uncomfortable. Phototherapy is also an accomplice risk factor to induce cancer in humans [12]. Microneedling is a minimally invasive procedure that involves fine needles to create a tiny puncture in the skin

Researchers claim microneedling is a safe process and has a tremendous benefit in treating vitiligo [13]. On the other hand, pigmentation refers to a process where due to destruction and lack of melanocyte production, an idiopathic disorder like vitiligo can occur [6]. Theoretically, the repigmentation technique can be helpful against vitiligo and recent studies also agree with that point [14]. This clinical trial is designed to find out the effectiveness of microneedling in the repigmentation process of vitiligo in human subjects.

Methodology

A clinical trial involving human subjects was conducted in the department of the Skin and Venereology at Dhaka National Medical Institute, Hospital throughout 1.2-year period on a sum of 36 patients to determine the efficacy of microneedling in the repigmentation technique in vitilago. This clinical trial was divided into two groups: a microneedling repigmentation group and a control group where repigmentation was done without microneedling. The trial group patients received topical 1.5% Ruxolitinib cream branded by "Ruxonib cream" with 6-12 sessions of microneedling with 0.5-1 mm of microneedles within 2 weeks of intervals [15] whereas the control group of patients received Ruxonib cream therapy by applying it to the affected area twice daily. Oral corticosteroids and Calcineurin Inhibitors are non-investigational medicinal products and this drug was administered to patients according to clinical justification. Ruxonib cream was applied to the affected area twice daily. Both groups of patients were advised to avoid sun rays to avoid risk factors. Randomization was done by following the "alternating allocation" procedure. Every patient was well-known about the study before enrollment and written consent was obtained from the patient by following the WMO code of ethics.

Inclusion criteria

a) Patients aged over 16 years with a diagnosis history of vitiligo.
b) Diagnosis based on physical examination and wood's lamp examination.
c) Patient with stable vitiligo.
d) Non-allergic to Investigational Medicinal Products (IMP) and Non-Investigational Medicinal Products (NIMP).
e) No History of contact dermatitis.

Exclusion criteria

a) Children aged patient <16 years
b) Patients who do not require any therapy for vitiligo
c) Self-reported known pregnancy
d) Hypersensitivity to microneedles
e) Lack of informed consent

The data analysis was done by using Microsoft Excel and SPSS version 20.0. Data collection included key analytical factors like improvement rate and timeline with potential adverse events and the degree of patient satisfaction. Some demographical features like age, sex, and the area of residency have also been analyzed in the study to avoid any underline factors to manipulate study results. A p-value less than 0.01 has been considered clinically significant.

Results

The graphical distribution of gender affected by vitiligo in Chart 1 proves the study is female-dominant where the ratio of females and males is 2.27:1.

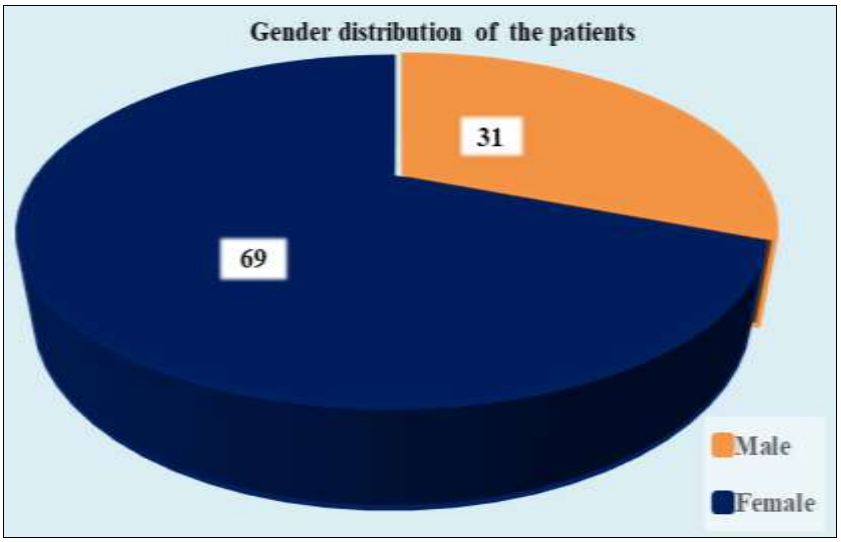

Fig 1: Pie chart showed gender wise patients distribution (N=36)

The area of residency of patients can manipulate the disease severity and treatment results. The distribution of residential areas shows that most of the patients came from urban areas (50%) whereas 31% of semi-urban patients and 19% of rural patients were included in the study.

This study reveals that a bulk amount of patients seeking treatment for vitiligo were healthy young people in the 16-30 age range (47.22%), 36.11% of patients belong to the 31-45 years age group, 13.89% of patients enrolled in this trial were 45-60 years of age group and only 2.78% patient was treated in the age over 60.

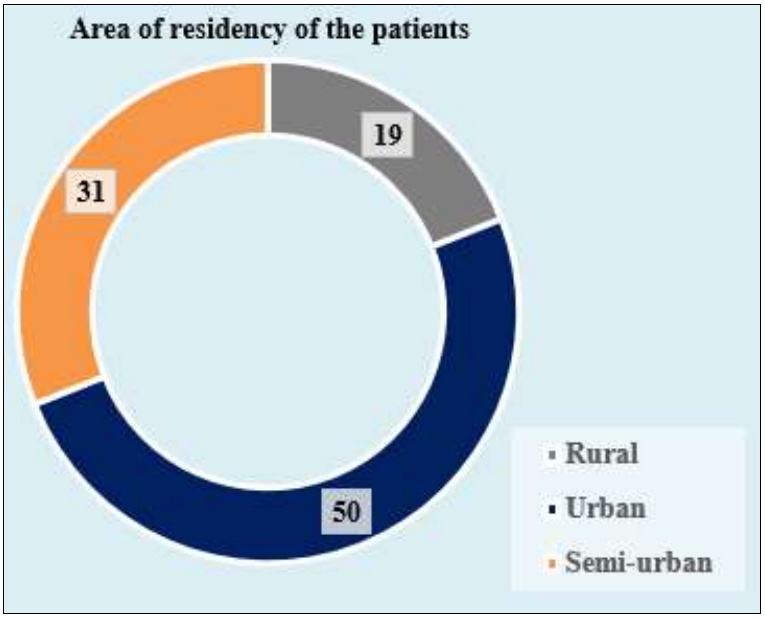

Fig 2: Ring chart showed area of residency among patients (N=36)

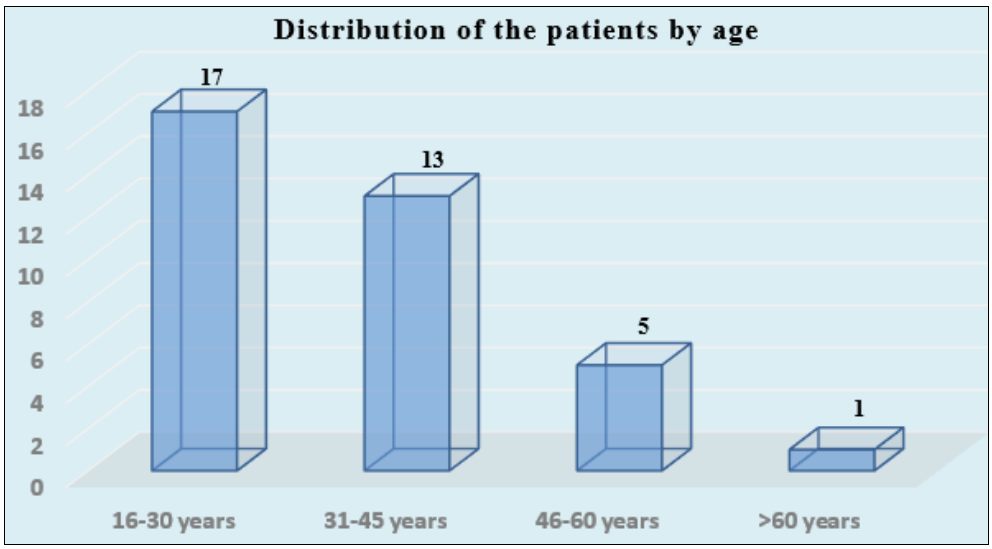

Fig 3: Column chart showed age-wise patients distribution (N=36)

Table 1: Mean of repigmentation grade score by microneedling, and tensity of lesions 1 week after the 1st session, 2 weeks after the 3rd session, and 1 month after the 6th session in the intervention group:

Variables	Mean	SD	*p-Value*
Tensity of lesions at baseline	5.1	1.11	–
Tensity of lesions (%) 1 week after the 1st session	3.5	1.23	0.03*
Tensity of lesions (%) 2 weeks after the 3rd session	2.7	1.25	<0.01
Tensity of lesions (%) 1 month after the 6th session	2.3	0.25	<0.01

A *p-value* less than 0.05 in Table 01 reflects the result of the repigmentation grade suggesting a significant decrease in lesions by microneedling therapy from 1 week after the first session.

Table 2: Mean of repigmentation grade score and tensity of lesions 1 week after the 1st session, 2 weeks after the 3rd session, and 1 month after the 6th session in the control group:

Variables	Mean	SD	*p*-Value
Tensity of lesions at baseline	5	1.22	–
Tensity of lesions (%) 1 week after starting treatment	4.9	1.38	0.15
Tensity of lesions (%) 9 weeks after starting treatment	4.2	1.38	>0.01
Tensity of lesions (%) in the 20th week after starting treatment	3.8	1.20	>0.01

Table 02 portrays a significant decrease in lesions in the control group after the 20th week of starting treatment, with no clinically significant result detected after 1 week and 9 weeks of control therapy with oral and topical medicines.

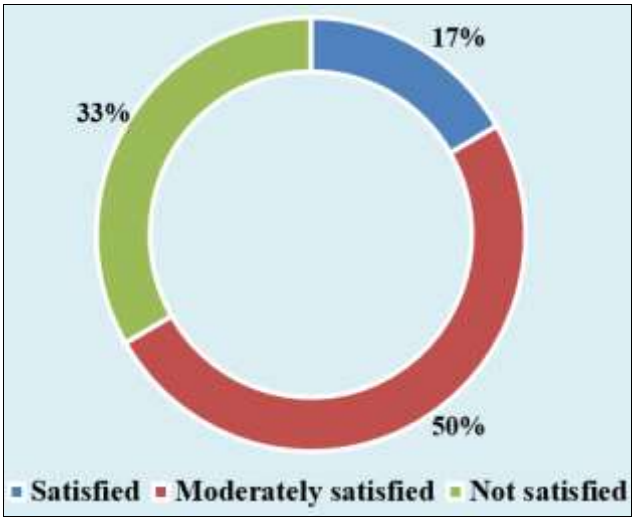

Chart 4: Distribution of patients according to satisfaction level in the intervention group

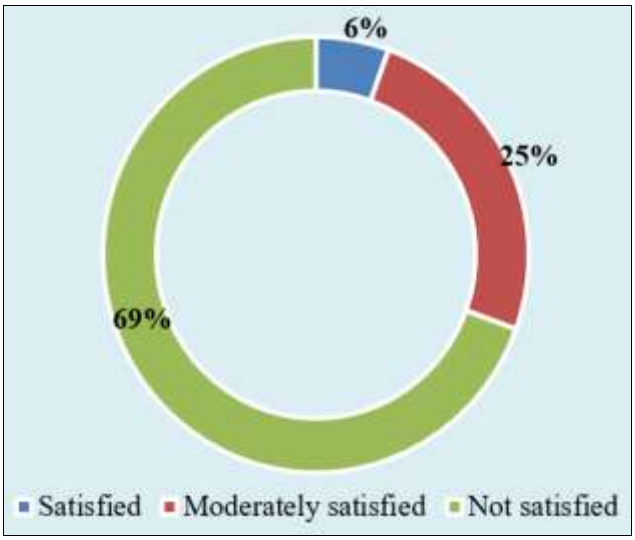

Chart 5: Distribution of patients according to satisfaction level in the control group

Chart 04 and 05 show the degree of satisfaction marked by the patients 1 month after the 6th session or the 20th week of treatment. 17% of intervention group patients were satisfied with microneedling therapy whereas only 6% of control groups of patients were satisfied with standard treatment. The degree of dissatisfaction is two-fold higher (69%) in the control group than in the intervention group (33%).

Discussion

Vitiligo is a familiar dermatological depigmentation that is alarmingly rising in modern days due to excessive sun exposure in childhood when melanin-produced cells are destroyed by sun rays [16]. According to the Vitiligo Global Issues Consensus Conference 2011-12, this autoimmune disorder is classified into three groups; segmental, non-segmental, and mixed/unclassified vitiligo [17]. Some researchers discovered a vital connection in cancer production in vitiligo patients as melanin acts as a defense to cellular DNA; in vitiligo, melanocyte cells are destroyed by the autoimmune response [18]. Phototherapy and immunomodulators are some common treatment approaches for vitiligo in the modern age; although surgical and traditional way of treatments are also popular in some regions [19, 20]. Repigmentation is the widely used vitiligo treatment procedure, it can be done with phototherapy, medications, or microneedling [21]. The current study revolves around the usage of microneedling and topical use of Ruxonib cream in patients with Vitiligo. 69% of clinical trial subjects are female which exhibits a clear relation between female patient's proneness to affected vitiligo. Female gonadotropic hormones and thyroid hormones can play a major role in the development vitiligo in females [22], yet most of the research claims there is no relation between vitiligo and gender [23]. Area of residency can be associated with affected by vitiligo as in rural areas, patients directly work under sun rays. This study was conducted with 19% of rural study subjects. A 2021-22 cross-sectional study in Madinah states that quality of life is highly associated with the production and treatment of vitiligo [24]. Most of the study suggests during puberty, patients are afftects by vitiligo due to hormonal changes and psychological imbalances [25]. This randomization trial relates to these studies as 47.22% patients age were in between 16-30 years. Coming to the treatment, this study shows that the tension of the lesion significantly started decreasing with microneedling depigmentation in comparison to topical medication. Another yearlong randomization trial in India with a 5% 5-Fluorouracil depigmenting agent shares a similar result with our study with p=0.0001 [26]. Patient satisfaction level data shows that the majority (50%) of the patients are moderately satisfied with microneedling repigmentation therapy whereas a mass population (69%) in the control group are dissatisfied. 6% of patients were only satisfied with the topical application of Ruxonib cream and 33% of patients marked their dissatisfaction with microneedling therapy. No significant adverse event has been notified with both microneedling and topical administration therapy by this randomization trial. Likewise, some other studies also reported that microneedling is a safe and effective treatment procedure for vitiligo [27].

Limitation

A limited period and a small study population are the primary drawbacks of this study. Study subjects were divided only into two groups and randomization was done by following alternating methods. There are some future research opportunities to proceed with a blind randomization trial with microneedling depigmentation with an extended study population and time.

Conclusion

This randomization-controlled trial concluded with a demonstration that microneedling can be contemplated as an effective mode of treatment for repigmentation in patients with vitiligo. The result indicates significant successful pigmentation in the patient's skin in the intervention group compared to the control group. Microneedling provides a safe treatment procedure done by clinicians to heal vitiligo contrasted with topical self-administration of depigmentation agents with a high patient satisfaction rate.

Conflict of Interest

Not available

Financial Support

Not available

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How to Cite This Article
Warish N, Hasan MZ, Banik P, Tabassum T, Khan MA, Haque MR *et al.*, Effectiveness of microneedling in the repigmentation process of vitiligo: A randomized controlled trial. International Journal of Dermatology, Venereology and Leprosy Sciences. 2024;7(2):98-102.