Brief Report

An Open-Label Non-Randomized Preliminary Noninferiority Study Comparing Home-Based Handheld Narrow-Band UVB Comb Device with Standard Hospital-Based Whole-Body Narrow-Band UVB Therapy in Localized Vitiligo

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Abstract

Background: Narrow-band ultraviolet B (NB-UVB) is the standard therapy for vitiligo. **Objective:** The objective of this study is to compare the safety and clinical efficacy of a handheld NB-UVB comb device with the standard whole-body NB-UVB therapy in localized stable vitiligo. **Materials and Methods:** Thirty-one vitiligo patients were allocated to either daily therapy with a home-based handheld comb device (group A, n = 17) or thrice-weekly hospital-based whole-body NB-UVB therapy (group B, n = 14) for 4 months, based on their preference. The primary and secondary outcomes were assessed at each follow-up, and appropriate statistical tools were used for analysis. **Results:** Of the 31 patients enrolled, 26 patients (study groups A/B: 15/11) completed the study. Primary outcome: Median percentage repigmentation of the representative patch in groups A and B were 51.35% and 63.85%, respectively (P = 0.64). The median size reduction of the representative patch in both groups was statistically significant ($P < 0.05$). The mean difference between "per protocol analysis" and "intention to treat" showed noninferiority. Secondary outcomes: Both groups were comparable on Lund and Browder score, patient global assessment and investigator global assessment scores, adverse events, color match, and change in the quality of life. The comparison group had a significantly greater number of missed sessions (P = 0.02). The majority of patients had a "good" response in both groups. **Conclusion:** Handheld NB-UVB comb device daily with a fixed dose of fluence was found to be noninferior with better compliance to standard whole-body NB-UVB therapy.

Keywords: *Handheld NB-UVB comb, localized vitiligo, narrow-band ultraviolet B (NB-UVB), whole-body NB-UVB chamber*

Introduction

Narrow-band ultraviolet B (NB-UVB) phototherapy (311 ± 2 nm) is the standard vitiligo treatment administered via whole-body chambers, hand and foot units, and handheld devices. The disadvantage of whole-body NB-UVB chamber is that they are available only in tertiary centers as it is expensive, resulting in long distance travel, multiple sessions, economic loss, poor compliance to treatment, and exposure to hospital-acquired infection. Hence, there is a dire need for home-based phototherapy devices. The NB-UVB comb device, traditionally used for scalp psoriasis, is an inexpensive, lightweight, portable device used on a domiciliary basis. This study aimed to compare the clinical efficacy and safety of the handheld NB-UVB comb device with the standard whole-body NB-UVB therapy in localized vitiligo. We have also formulated new guidelines for handheld NB-UVB comb devices.

Materials and Methods

Study design

An open-label, non-randomized prospective noninferiority study was conducted in the dermatology department of a tertiary care hospital following institution ethics committee approval (IECPG-610/19.12.2018) and clinical trial registration (CTRI/2019/08/020818).

Participants

Participants were all adult patients (≥18 years of age) with localized vitiligo (≤2% body surface area (BSA)

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or ≤10 patches). Patients with no new vitiligo patches or progression in the last month were included in either of the two groups based on their convenience and preference after a washout period of two weeks for topical and four weeks for oral medication. Patients with rapidly spreading disease, recalcitrant forms of vitiligo (lip-tip or segmental vitiligo), concomitant photo-aggravated dermatoses, and inability to maintain the handheld device or come thrice weekly to the hospital for whole-body therapy were excluded. If a patient were found to be using concomitant topical or oral medication, that patient would be withdrawn from the study.

Intervention group

Group A: Handheld NB-UVB comb device (V-Care Meditech Pvt. Ltd.) with two TL-01 lamps and of dimensions 50 × 50 × 270 mm.

Group B: Whole-body NB-UVB chamber (UV-7002 Waldmann) with 42 lamps and closed dimensions of 1266 × 1327 × 2317 mm.

In group A, the vitiligo patches were exposed for 80 s after calculating the mean irradiation of all devices with a fixed dose of energy of 500 mJ/cm^2 (details attached in Supplementary File 1). Initially, the representative patch (the largest patch on the body excluding that on bony prominences, hands, feet or mucosae, with less than 50% leucotrichia) was exposed, followed by sequential exposure of remaining patches, and therapy was administered with the patient wearing UV protective goggles. Patients took the treatment daily at home, for which demonstration of the comb device was done during recruitment and reviewed after two weeks for its proper use.

Group B was treated in the hospital with an initial dose of 350 mJ/cm^2 with increments of 10–20% per session on alternate days (thrice a week), the escalation based on side effects and missed doses as per the Vitiligo Working Group's (2017) phototherapy recommendations.[1]

Outcomes

Patients were followed up biweekly in the first month and then monthly until four months and assessed for primary outcomes (percentage repigmentation of the representative patch using a standard graph). Secondary outcome measures were global repigmentation using the Lund and Browder (L and B) score, investigator global assessment (IGA) based on photographic assessment (score from 1 to 5), patient global assessment (PGA) based on the visual analog scale of 0–10, color match, quality-of-life (QoL) assessment using Vitiligo Impact Scale-22 (VIS-22) (vitiligo-specific QoL instrument at baseline and 16 weeks) and Tjioe M *et al*. questionnaire (at 2 and 16 weeks), adverse events, and missed sessions.[2]

Statistical methods

Sample size calculation

Based on a noninferiority margin of 5%, the observed or expected difference in repigmentation being zero, pooled standard deviation of 0.05, that is, the effect size of 0.14, power of the study 90%, and confidence interval (CI) of 95%, the sample size was calculated to be 34 (17 in each group).

Analysis

All categorical variables in the excel sheet were summarized in frequency percentage, and proportion tests were used to compare two proportions. Quantitative variables at baseline were summarized by mean ± SD or median (range), and Student's *t*-test/Wilcoxon test, as appropriate, was used to compare the values in the two groups for the primary outcome. Effect size (difference in mean percentage of pigmentation in the two groups) and 95% confidence interval were computed as "per protocol" and "intention to treat." A data analysis of every patient's most recent follow-up visit was included in the intention to treat. In case of any imbalance (i.e., confounder), covariance analysis was used to compute the adjusted effect size at a 95% confidence interval. The intervention was declared noninferior to the standard group if the lower limit of 95% CI of the observed effect size was more than the noninferior margin of 5%.

Results

Of 34 patients enrolled, 31 (group A—17 and group B—14) could be inducted due to the COVID-19 pandemic, and 15 and 11 patients in the two groups A and B, respectively, completed the study. The two groups' demographic and clinical profiles were comparable without any statistical difference [Table 1].

Clinical efficacy

The median percentage repigmentation of the representative patch [group A: 51.35%; group B: 63.85% (P = 0.64)] and reduction in its size [group A: 697 mm^2 to 356 mm^2; group B: 984 mm^2 to 469 mm^2 (P = 0.58)] comparison was not statistically significant at each follow-up visit and at 4 months [Figures 1 and 2]. However, median reduction of representative patch size in group A (697 mm^2; interquartile range (IQR): 293–2382 mm^2) and group B (984 mm^2; IQR: 122–1482 mm^2) were statistically significant with P = 0.001 and P = 0.003, respectively. The mean difference in percentage repigmentation of the representative patch as "per protocol analysis" was 1.59 (95% CI: 0.58, 4.39), and intention to treat analysis was 1.39 (95% CI: 0.56, 1.34) which showed superiority, thereby negating the lack of desired sample size calculated due to COVID-19 pandemic.

Secondary efficacy parameters, including global investigator assessment by L and B score, qualitative IGA, PGA scores,

Table 1: Demographic and clinical profile of patients in the two treatment groups

Demographic and clinical profile	Group A: Study group (handheld NB-UVB comb device) *n*=17	Group B: Comparison group (whole-body NB-UVB chamber) *n*=14	*P*
Age (in years) median (range)	28 (18-53)	23 (18-38)	0.25
Male:Female ratio	8:9	4:10	0.25
Marital status			0.49
Married	7 (41.2%)	4 (28.6%)	
Unmarried	9 (52.9%)	10 (71.4%)	
Divorce	1 (5.9%)	0	
Education			0.38
Below 10th class	0%	1 (7.1%)	
10th to 10+2	4 (23.5%)	3 (21.4%)	
Graduation	13 (76.5%)	10 (71.4%)	
Duration of vitiligo in years median (range)	14 (0.3-40)	8 (2-20)	0.83
Family history of vitiligo	3 (17.7%)	4 (28.6%)	0.38
	Grandfather (2)	Mother (2)	
	Grandmother (1)	Grandfather (1)	
		Father (1)	
Type of vitiligo			0.09
Acrofacial	2 (11.8%)	5 (35.7%)	
Vitiligo vulgaris	2 (11.8%)	0	
Acrofacial+vitilgo vulgaris	11 (64.7%)	9 (64.3%)	
Focal	1 (5.9%)	0	
Segmental + vitilgo vulgaris	1 (5.9%)	0	
Skin phototype			
III	2 (11.8%)	0	0.46
IV	12 (70.6%)	13 (85.7%)	
V	3 (17.6%)	1 (14.3%)	
Comorbidities			
Hypothyroidism	3	1	
Fungal infection	2 (Tinea resolved)	0	
Lichen planus	1 (resolved)	0	
Dermatitis	0	1	
Acne vulgaris	0	1	
Hypertension	0	1	
Palmo-plantar hyperhidrosis	1	0	
Gastro intestinal tumor	0	1	
Representative vitiligo patch			0.06
Head and neck	4 (23.5%)	0	
Trunk	9 (52.9%)	7 (50%)	
Upper limb	0	1 (7.1%)	
Lower limb	4 (23.5%)	6 (42.9%)	

and QoL indices, did not show significant differences between the two groups after four months of treatment. In study groups A and B, 57% and 45% of cases attained a "moderate " response (26–50% repigmentation) after four months of therapy (Supplementary Table 1). Group B showed a significantly greater number of missed sessions suggesting better compliance in group A (P = 0.02). The adverse effects were mild, transient, and self-limiting in nature. Phototoxic side effects (erythema, edema, blister, and burning) were noted and were comparable in both groups (P = 0.38) [Table 2].

Discussion

In the present study, the primary efficiency parameter, that is, median percentage repigmentation of the representative patch, was comparable between the two groups at each follow-up visit and at the end of 4 months of therapy (51.35% and

Table 2: Comparison of clinical efficacy between the two treatment groups

	Group A: Study group (handheld NB-UVB comb device) *n*=17	Group B: Comparison group (whole-body NB-UVB chamber) *n*=14	*P*
% repigmentation from baseline of representative vitiligo patch [median (range)]	51.35 (0.46-100)	63.8 (17.40-97.5)	0.64
Mean difference in percentage repigmentation of representative patch			
As "per protocol"	1.59 (95% CI: 0.58, 4.39)		
Intention to treat analysis	1.39 (95% CI: 0.56, 1.34)		
Percentage reduction in Lund and Browder score (BSA) [median (range)] at 16 weeks from baseline	44.6 (1.6-100)	43 (17-97)	0.95
PGA (0-10) [median (range)] at 16 weeks compared to baseline	5 (1-10)	6 (1-9)	0.56
IGA (0-5) [median (range)] at 16 weeks	2 (1-5)	2 (1-5)	0.8
Color match of representative patch (mean±SD) at 16 weeks	2.24±0.46	2.17±0.44	0.67
Missed days of therapy			0
Median (range)	2.5 (0-30)	9 (2-23)	.026
Quality of life assessment (QoL)			
QoL (−28 to+28) Tjioe M at 2 weeks	2.5 (−11 to 12)	6 (−10 to 14)	0.14
QoL (−28 to+28) Tjioe M at 16 weeks	10.5 (−8 to 26)	6 (−8 to 24)	0.49
Median (range) change in QoL score by Tjioe M *et al*. questionnaire	7 (2-29)	5 (−3 to 15)	0.23
Vitiligo impact scale 22(VIS-22) score [median (range)] at 2 weeks	19 (2-40)	21.5 (5-46)	0.36
VIS-22 score [median (range)] at 16 weeks	13 (4-37)	14 (18-38)	0.53
Median (range) change in QoL score by VIS-22	−3 (−13 to 7)	−5 (−18 to 4)	0.3
Adverse events			
Itching	13	10	0.67
Blister formation	3	5	0.41
Erythema	8	7	1
Edema	3	7	0.12
Burning	4	8	0.14
Total adverse events	31	37	0.38

Investigator global assessment (IGA) grading: −1=worsening, 0=no change, 1=1 − 25% repigmentation—minimal improvement, 2=26-50%—moderate improvement, 3=51-75%—good improvement, 4=76-90%—very good improvement, 5=91-100%—complete improvement Patient global assessment (PGA) by visual analogue scale (VAS) from 0 to 10. Color match grading: 1=somewhat lighter, 2=somewhat darker, 3=same

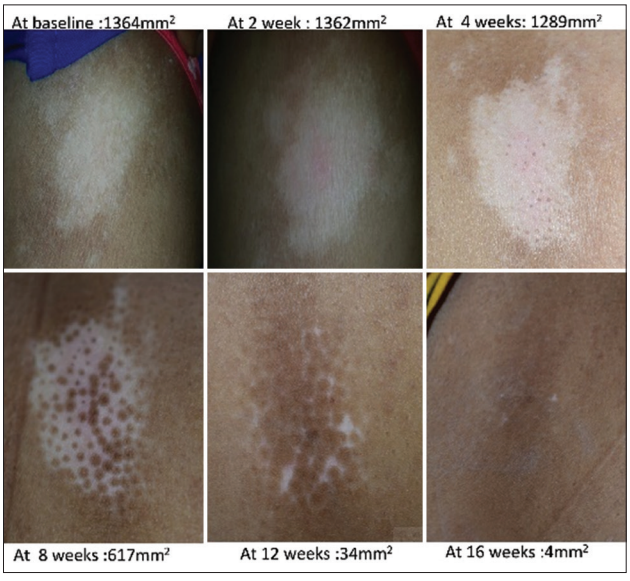

Figure 1: Pre- and post-treatment results with handheld NB-UVB comb device on representative patch over left side of chest

63.8%, respectively, in the study groups A and B). We had achieved 57.8% repigmentation in the representative patch in our previous study with alternate-day nonincremental use of the comb device for six months.[3] A low output from this device and significant decay in irradiance after 5 min of use prevents the use of incremental doses as the exposure time would be very high, making this therapy cumbersome to the patients. We have also observed greater repigmentation with daily use of this device compared to alternate-day sessions (unpublished observation).

According to Zhang *et al*., most patients achieved fair repigmentation (65% with a home lamp and 34% with a whole-body device) followed by a good response (16% with a home lamp and 57% with a whole-body device) after six months of therapy.[4] Liu *et al*. achieved a 49.18% reduction in BSA of vitiligo with home lamp and a 40.66% reduction with a whole-body chamber after five months of therapy.[5] In both studies, including ours, the results were comparable between the two modalities.

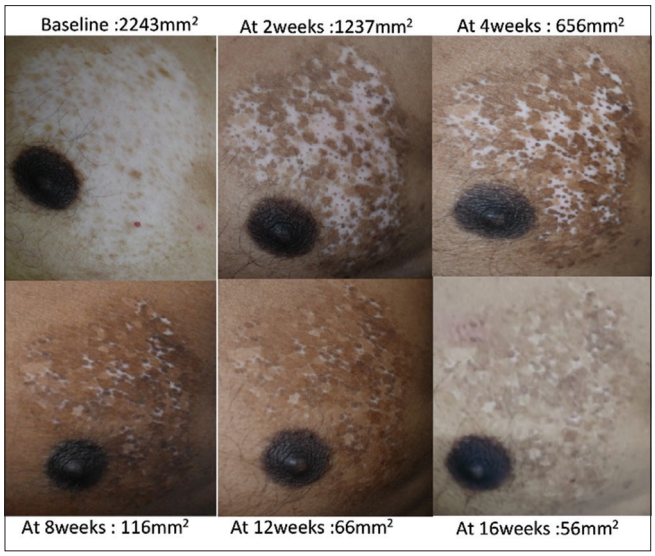

Figure 2: Pre- and post-treatment results with whole-body NB-UVB chamber on representative patch over chest

Goel *et al*. achieved 50–75% repigmentation in 46% of cases and 25–50% repigmentation in 30% of patients after twice weekly use of the handheld device for six months.[6] Khullar *et al*. recorded a mean IGA score of 2.7 ± 0.5 and a mean PGA score of 5.6 after six months of whole-body treatment which were also comparable with our study.[7] Zhang *et al*. using VitiQoL and Khandpur S *et al*. using Tjioe *et al*. questionnaire showed the equivalent result in improvement of QoL like our study.[3,4]

Phototoxic reactions were seen more in group B despite being administered under supervision, probably because of the dose increment of energy. Pruritus and burning were treated with levocetirizine. In group A, two patients had overexposure-induced severe reactions. They were treated with mometasone furoate 0.1% cream with a resolution of symptoms in a week, and treatment restarted as per protocol. Another case with severe reaction was treated with mometasone furoate 0.1% cream until the resolution of symptoms. The initial exposure dose was a half dose (i.e., 40 seconds), and it was increased by 5 seconds every other day until mild erythema appeared.

Our study was unique as we used fixed fluence (500 mJ/cm^2) and daily application of the device at home led to better compliance, minimal side effects, and equal efficacy to the standard whole-body chamber NB-UVB therapy.[8] During the COVID-19 pandemic, lockdown in the state led to more missed sessions in group B (hospital-based) and favored handheld NB-UVB comb device at home. The efficacy of handheld NBUVB device in vitiligo as observed in various studies and its comparison with the whole-body NB-UVB therapy is depicted in Supplementary Tables 2 and 3.

Limitations

It is a nonrandomized design, allocation based on patients' feasibility and preference, small sample size in each group, shorter treatment period, and lack of follow-up after treatment stoppage to compare persistence of repigmentation in the two groups.

Conclusions

Handheld NB-UVB in a nonincremental daily dose was noninferior to the standard whole-body NB-UVB therapy in localized vitiligo, with significantly better compliance and no serious side effects. Hence, it can be used by patients safely at home with fewer hospital visits with the only disadvantage of periodic recalibration, that is, every 3 months due to decay in irradiance because of daily use for good repigmentation.

Acknowledgment

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Nil.

Conflicts of interest

This was an investigator-initiated trial. The handheld NB-UVB comb devices were procured by AIIMS, New Delhi institute and patients had to deposit a security money in AIIMS SBI account on a refundable basis (document attached) while whole-body chamber NB-UVB therapy was free of cost. However, they had no interference in the design, conduct, and analysis of the study.

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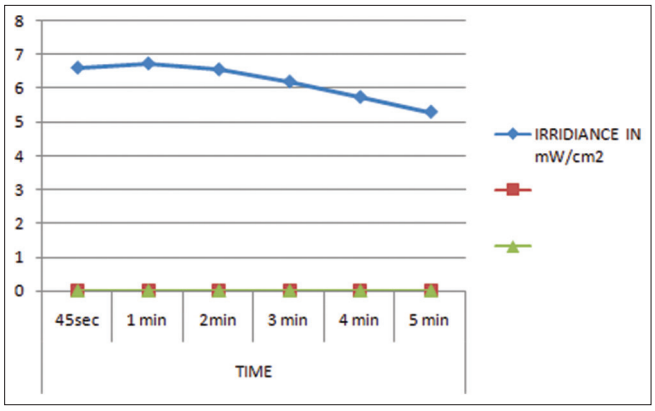
Supplementary file 1

Calculation of irradiance and time of exposure of handheld device.

Each device's mean irradiance was measured at 45 s, 1 min, 2 min, 3 min, 4 min, and 5 min using the UV meter (Herbert Waldmann GmbH and Co. KG Villingen-Schwenningen, Germany). The mean irradiance of the devices was found to be 6.74 mW/cm^2 (at 45 s), 6.61 mW/cm^2 (at 1 min), 6.56 mW/cm^2 (at 2 min), 6.2 mW/cm^2 (at 3 min), 5.74 mW/cm^2 (at 4 min), and 5.3 mW/cm^2 (at 5 min). The exposure time for each vitiligo patch was calculated using the formula:

Exposure time for each patch = 500 mJ/cm^2/Irradiance in mW/cm^2.

We got time of exposure as 74 s (at 45 s), 75 s (at 1 min), 76 s (at 2 min), 81 s (at 3 min), 87 s (at 4 min), and 95 s (at 5 min). However, instead of the exact exposure time calculated above, we used a fixed exposure time of 80 s for patients' convenience and better compliance. The handheld device was kept on for 45 s followed by exposure of each vitiligo patch for 80 s to deliver 500 mJ/cm^2. Since the decay in irradiance was significant after 5 min [Supplementary Figure 1], the equipment was switched off after 5 min and then restarted for exposure to the remaining patches.



Supplementary Figure 1: The decay in irradiance is significant at the end of 5 min; the equipment needs to be switched off at the end of 5 min

Supplementary Table 1: Overall repigmentation in the two treatment groups at the end of 16 weeks

Re-pigmentation, n (%)	Group A (handheld NB-UVB comb device) n=14	Group B (whole body NB-UVB chamber) n=11
Excellent >75%	3(21.42%)	3(27.27%)
Very good (50%-75%)	1(7.14%)	1(9.09%)
Good (25%-50%)	8(57.14%)	5(45.45%)
Fair (1%-25%)	1(7.14%)	2(15.38%)
Poor (<1%)	1(7.14%)	-

Supplementary Table 2: Various studies on handheld NB-UVB device in vitiligo

Authors	Study design	Sample size	Type of vitiligo	Patients' age of inclusion	Intervention	Treatment period	Results
Khandpur *et al*.[3]	Open-label study	10	Nonsegmental localized vitiligo ≤2% BSA or ≤10 patches	≥18 years	Handheld NB-UVB comb device Fixed dose of 0.5 J/cm^2, thrice/week	6 months	At 6 months, median area of representative vitiligo patch decreased by 57.8% from baseline Median PGA score (on VAS of 0-10) of 5.75 (P=0.001) Median global repigmentation of 50% (P=0.03) QOL improved by 6 points (P=0.103).
Goel *et al*.[6]	Open-label study	50	Localized (nonsegmental and segmental) and generalized vitiligo	4-56 years	Handheld NB-UVB: 2 min in first sitting and 20% increment till minimal erythema, twice/week	6 months	12 (24%) had <25% repigmentation, 15 (30%) achieved 25-50% repigmentation and 23 (46%) had 50-75% repigmentation, >75%: no patient
Shan *et al*.[9]	Open-label study	93	Not mentioned	2-65 years	Handheld NB-UVB: 0.3 J/cm^2 and increased by 0.1 J/cm^2 until mild erythema, thrice/week	1 year	After 1 year, no repigmentation in 11 (11.8%) patients, up to 25% repigmentation in 16 (17.2%), 26-50% in 15 (16%), 51-75% in 16 (17.2%), and >75% in 35 (37.6%) patients
Present study	Open-label study	17 patients in handheld group	Nonsegmental vitiligo BSA ≤2% or ≤10 patches	>18 years	Handheld NB-UVB: fixed dose of 500 mJ/cm^2, once daily	4 months	Median % repigmentation in representative patch from baseline was 51.35% Median % global repigmentation 44.95% On IGA, 7.14% had 1-25%, 57.14% had 26-50%, 7.14% had 51-75%, and 21.42% had >75% repigmentation PGA (by VAS from 0 to 10) was 5

Supplementary Table 3: Various studies comparing whole-body NB-UVB therapy (hospital/outpatients) versus handheld NB-UVB device in vitiligo

Author	Study design	Sample size	Type of vitiligo	Patients age	Intervention NB-UVB	Treatment period	Results	Adverse events
Zhang *et al*.[4]	Open-label non-randomized controlled trial (RCT)	94	Nonsegmental vitiligo BSA >2	>16 years	Handheld comb: dose 400 mJ/cm^2 and increased 10-20% till erythema Whole body: based on minimal erythema dose, Thrice/week	6 months	Repigmentation at 6 months: Most patients had very good (42% in home lamp and 37% in outpatient) to good (32% in home lamp and 43% in outpatient) response and few patients had excellent (5% in home lamp and 7% in outpatient) response although no significant difference noted between both arms. No significant difference in VitiQoL score	Erythema: 13% in handheld and 10% in whole-body chamber Pruritus: 21% in handheld and 20% in whole-body chamber Burning: 5% in handheld and 3% in whole-body chamber
Liu *et al*.[5]	RCT	122	Nonsegmental with BSA <5%	>5 years	Handheld comb: dose 400 mJ/cm^2 and increased by 0.1 J/cm^2 versus whole-body chamber thrice/ week	5 months	After 5 months, significant reduction in BSA in handheld (49.18%) and in hospital-based (40.66%) therapy. Marked effective rate (%) as per protocol was 44.20% and 50% in handheld and whole-body NB-UVB chamber therapy, respectively. Marked effective rate (%) as per intention to treat was 37.7% and 39.34% in handheld and whole-body NB-UVB chamber therapy, respectively. Eight patients in whole-body chamber missed more than 10 treatment sessions and hence excluded from study while none in handheld comb group	Whole-body NB-UVB chamber group: Painful erythema: 6 patients Burning: 6 patients Handheld NB-UVB comb group: Painful erythema: 16 patients Burning: 16 patients Blisters: 2 patients Koebner phenomenon and enlarged vitiligo: 1 patient Excessive-hyperpigmentation: 10 patients
Present study	Open-label non-RCT	34	Nonsegmental vitiligo with BSA ≤2%	>18 years	Handheld comb: fixed dose of 500 mJ/cm^2 daily Whole-body chamber: 350 mJ/cm^2 and increased 20% per sessions, thrice weekly	4 months	Median % repigmentation in representative patch was 51.35% and 63.8% in handheld comb and whole-body NB-UVB chamber, respectively. Median % global repigmentation was 44.95% and 43% in handheld comb and whole-body NB-UVB, respectively. No significant difference in PGA scores. Significantly less number of missed sessions with handheld device	Handheld comb: Itching: 13 patients Burning: 4 patients Erythema 8 patients Blister formation: 3 patients Edema: 3 patients Whole-body chamber: Itching: 10 patients Burning: 8 patients Erythema 7 patients Blister formation: 5 patients Edema: 7 patients