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Pilot study of a customized nanotextile wet garment treatment on moderate and severe atopic dermatitis: A randomized clinical trial

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Abstract

Background: Atopic dermatitis (AD) is a common dermatosis. The cornerstone of eczema management is to repair and maintain skin barrier and hydration, as well as to reduce inflammation. Wet wrap therapy (WWT) is a widely used adjunct to achieve this. The conventional material used for WWT is viscose, which presents drawbacks including discomfort, high cost, and poor durability. Here, we explore the possibility of using customized nanotextile (nanopolyester) for WWT, hoping to prove that this material is non-inferior to viscose in clinical effectiveness and patient acceptance.

Methods: Patients aged 0-18 years with moderate to severe eczema were randomized to receive either viscose (Tubifast™) or nanotextile for WWT. Patients were instructed to apply WWT daily overnight for 2 weeks. Patients' disease severity score (IGA, SCORAD) and quality of life (QoL) score (IDQOL/CDLQI) were measured on day 0, 7, and 14 of treatment. Patient survey was conducted to collect patients' feedback about garment use.

Results: Fifty-three children aged 7 months to 17 years were recruited (27 in Tubifast™ and 26 in nanotextile group). Patients in both groups showed significant improvement in disease severity and QoL from baseline ($P < .001$), and such improvement was similar in both groups. However, nanotextile garment was significantly more comfortable (2.73/10 vs 5.12/10, $P = .001$), easier to wear (2.78/10 vs 5.24/10, $P = .003$), and cooler (2.43/10 vs 3.96/10, $P = .033$) from patients' feedback.

Conclusion: This study demonstrates that nanomaterial is as effective as conventional viscose in WWT, while superior in patient acceptability. Nanotextile for WWT has good potential in eczema management, especially in patients with suboptimal response to topicals alone.

KEYWORDS
atopic dermatitis, wet wrap therapy

Trial Registration: ANZCTR Web address: http://www.ANZCTR.org.au/ACTRN12618000864224.aspx; Trial registration number: ACTRN12618000864224

1 | INTRODUCTION

Atopic dermatitis (AD), or atopic eczema, is a common chronic, recurrent, itchy inflammatory skin disease. There is a high prevalence of AD in Singapore, affecting 20.6% of children and 11.1% of adults.[1]

An important role in the pathogenesis of AD is the increased transepidermal water loss from skin barrier impairment. Hence, one of the cornerstones of AD management is to hydrate the skin and restore the skin barrier.[2] Wet wrap therapy (WWT) is a widely used adjunctive modality to achieve this goal.[3]

Wet wrap therapy uses a double layer of bandages—a moist inner layer and a dry outer layer—to wrap around the patient's body.[3] It works in a few ways. Firstly, WWT hastens restoration of the skin barrier by trapping moisture within stratum corneum and decreasing transepidermal water loss. Studies suggest that the hydrating effect increases lamellar body secretion and enhances recovery of the intercellular lipid laminar structure.[4] Secondly, the cooling effect from gradient moisture evaporation causes vasoconstriction, reducing pruritus.[5] It also has an anti-inflammatory effect by reducing inflammatory mediators such as serum chemokines and E-selectin.[6,7] Thirdly, the moist environment enhances uptake of topical medications such as steroids and emollients.[8] Lastly, the wrap creates a mechanical barrier to inhibit scratching and reduce further damage to the skin.

The efficacy of WWT has been proved in several studies. The largest cohort study analyzing the use of WWT on 72 children with moderate to severe AD showed significant improvement in mean SCORAD ($P < .001$) over treatment durations of 2-16 days.[9] Compared to conventional therapy with topical steroids alone, WWT has been shown to be superior when used as an adjunct treatment for moderate to severe AD[10,11]

Cotton is traditionally recommended for use in eczema patients.[12] However, when wet, cotton fibers extend and contract, and can cause abrasive rubbing against skin. This may make it a less acceptable material for WWT.[12,13] Current wet wrap garment products, such as Tubifast™ which is the most commonly used WWT garment in Singapore, are made of viscose rayon. Viscose is a semi-synthetic fiber made from regenerated wood cellulose. Viscose, similar to cotton, has good water retention properties. This material, however, presents a few drawbacks. Firstly, though viscose fiber is smoother than cotton, many eczema patients still complain about its roughness, causing irritation to their sensitive skin.[14] Secondly, viscose fibers lose strength and are easily torn when wet, requiring cautious handling and gentle hand wash.[15] In fact, Tubifast™ garments have poor wash durability and are reported to last for 20 washes by most patients.[16] Thirdly, viscose is a good medium for microorganisms to grow in, which can potentially increase the risk of secondary skin infection.[17] In previous WWT studies using Tubifast™, the secondary skin infection rate was high as 27%.[18] Other materials such as Rediwipe and flannel wrap have also been used uncommonly in WWT, but are not available in garment form. Here, we chose Tubifast™ as the representative material in wet wrap garment.

To date, no other study has investigated the usage of other textile material in WWT. In this study, we explore the possibility of using nanotextile made of 100% nanopolyester in WWT. Polymer nanofibers are unique for their large surface area-to-volume ratio, high porosity, and appreciable durability.[19,20] Textiles made of nanofabrics are durable and breathable and, in recent years, are commonly used in the clothing industry. In contrast to fabrics with natural origins, nanofabric does not provide a good environment for bacterial growth,[21] therefore potentially reducing the risk of secondary skin infection. In addition, nanotextile is reported to have good cooling properties (insulated cool), showing good potential to be used in WWT. Here, we compare the use of nanotextile and Tubifast™ garments for WWT, hoping to prove that nanotextile is non-inferior to viscose in clinical effectiveness and patient acceptance.

2 | MATERIALS AND METHODS

Infants and children below 18 years with moderate to severe AD (SCORAD ≥ 25) were recruited prospectively from the dermatology clinics and inpatient wards at KK Women's and Children's Hospital, during the period of March 4, 2017 to August 8, 2017. Patients with active skin infection, on immunotherapy or on phototherapy, were excluded. Sample size was determined to be 25 in each arm in order to achieve 80% power to detect non-inferiority using a one-sided, two-sample *t* test with alpha value of 2.5%. Patients were randomized to either viscose (Tubifast™) or nanotextile garment for WWT on top of regular eczema treatment with topical emollients and corticosteroids. Randomization was performed by a statistician using statistical software R. Topical steroids applied were with mild to moderate potency (Class 4 and above (USA system)[22]), and there was no change of treatment during the 14-day study period. Patients were instructed to apply WWT daily overnight or 4 hours during the day for 2 weeks. Only the subjects who completed the 2-week study were included in our data analysis.

Disease severity was assessed using the Scoring Atopic Dermatitis (SCORAD) index and the Investigator's Global Assessment (IGA) Scale.[23] Health-related quality of life (QoL) in infants (aged 4 years and below) were measured using the Infant's Dermatitis Quality of Life Index (IDQOL)[24] and QoL in children (aged 5-18 years) were measured using the Children's Dermatitis Life Quality Index (CDLQI).[25] The scoring was done independently by patients' self-reporting.

Patients' disease severity scores (IGA, SCORAD) and QoL score (IDQOL/CDLQI) were measured on day 0, 7, and 14 of treatment. During those visits, total body photographs and close-up views were taken with standard white background and under natural light. The objective part of SCORAD scoring (extent and intensity of lesions) was performed by two blinded assessors (Koh, Lee) using photographs of patient. The subjective score (itchiness and sleeplessness) was recorded from patient's self-reporting. The photograph taking method in SCORAD scoring was also used in previous studies with acceptable interobserver variability.[26,27] IGA measurement was performed by the same investigator (He)

during patient recruitment and follow-up visits. A patient survey was conducted after completing the 2-week treatment to assess patients' feedback about garment use. On a scale of 0-10, patients gave feedback on level of agreement for each of the four comments: the garment is uncomfortable to wear, feels hot/ stuffy when wear it, limits movement, and is difficult to wear. The higher the score, the worse the feedback is, for example, more uncomfortable. Our primary outcome was improvement in eczema scores (SCORAD and IGA) and QoL. Our hypothesis was that the use of nanotextile is non-inferior to Tubifast™. Secondary objectives include patient feedback with regard to comfort and convenience of the material used.

Ethical approval was obtained from the SingHealth Institutional Review Board.

Statistical analysis was performed with SPSS Statistics 24 and R. The correlation of SCORAD measurements by two assessors was analyzed using intraclass correlation. The time trend of disease severity score and QoL score were analyzed using mixed model. The changes in disease severity and QoL score were compared between the two groups using the Student *t* test. The patients' feedback survey scores in two groups were compared using Mann-Whitney U test.

3 | RESULTS

Fifty-three children aged 7 months to 17 years were recruited. The 27 children in Tubifast™ group and the 26 in nanotextile group had mean ages of 6.9 (SD, 4.4) and 9.4 (SD, 4.6) years, respectively (*P* = .10). The demographics of recruited patients are shown in Table 1.

TABLE 1 Demographics of recruited patients

	Tubifast group (N = 27)	Nanotextile group (N = 26)	Total (N = 53)
Sex: female, n (%)	14 (52%)	8 (31%)	22 (41%)
Age (y): mean (SD)	6.9 (4.4)	9.4 (4.6)	8.1 (4.7)
Race: Chinese, n(%)	20 (74%)	16 (62%)	36 (68%)
Race: Malay, n(%)	5 (19%)	7 (27%)	12 (23%)
Race: other, n (%)	2 (7%)	3 (11%)	5 (9%)

In the Tubifast™ group there were 14 women and 13 men, while in the nanotextile group there were eight women and 18 men. One child from nanotextile group and two from Tubifast™ group dropped out due to upper respiratory tract infection, noncompliance, and inability to attend follow-up sessions. Consort chart is shown in Figure 1.

The summary of disease severity score and QoL score change is shown in Table 2.

3.1 | Eczema severity

As the SCORAD assessment scores by the two independent dermatologists were well correlated with intraclass correlation *R* = 0.90, the final SCORAD was calculated as the mean of the two measurements. The mean baseline SCORAD of patients in the Tubifast™ group and the nanotextile groups were 52.3 (SD = 12.8) and 57.0 (SD = 14.4), respectively (*P* = 0.25).

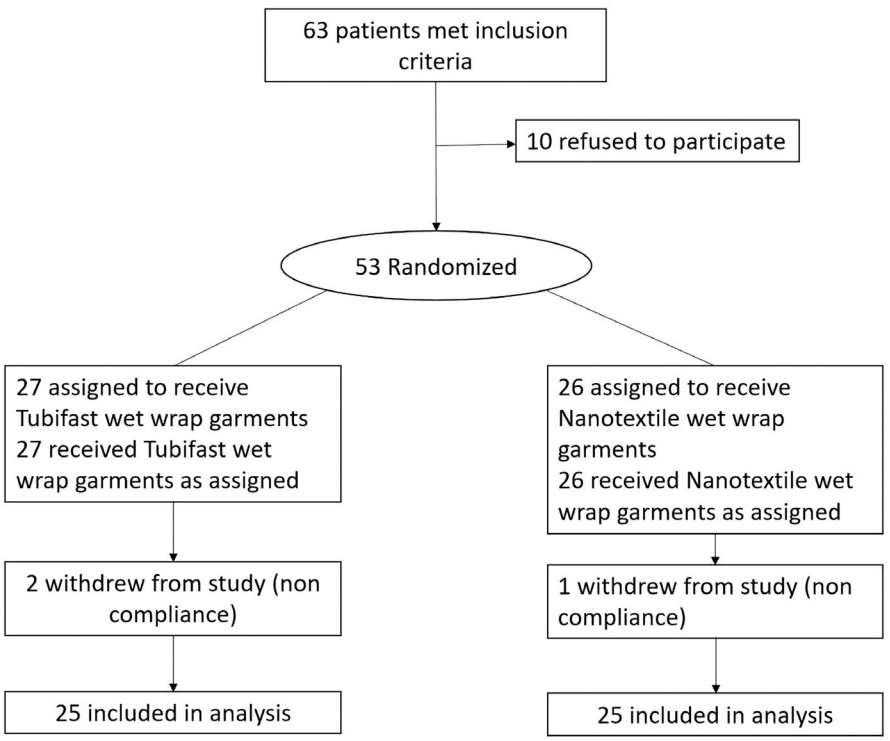

FIGURE 1 Consort chart

TABLE 2 Summary of results

Disease Severity	SCORAD: mean (SD)	Tubifast	52.3 (12.9)	35.3 (15.9)	30.7 (15.1)
		Nanotextile	57 (14.4)	37.3 (15.3)	34.6 (17.6)
	IGA: mean (SD)	Tubifast	3.17 (0.62)	2.13 (0.80)	1.82 (0.89)
		Nanotextile	3.29 (0.68)	2.22 (0.88)	2.1 (0.75)
Quality of Life	IDQOL/	Tubifast	13.6 (6.67)	8.58 (6.05)	8.26 (5.41)
	CDLQI: mean (SD)	Nanotextile	14 (5.85)	9.13 (5.83)	8.29 (5.40)

In the Tubifast™ group, the mean SCORAD decreased from 52.3 on day 0, to 35.3 on day 7 and 30.7 on day 14 (mixed model time effect $P < 0.001$). In the nanotextile group, the mean SCORAD decreased from 57.0 to 37.3 on day 7 and 34.6 on day 14 (mixed model time effect $P < 0.001$). (Figure 2A). The improvement in SCORAD was similar between both groups. In Tubifast™ and nanotextile groups, the mean improvements of SCORAD was 16.1 and 19.3 on day 7 ($P = 0.31$), 21.9 and 23.5 on day 14 ($P = 0.65$).

The mean baseline IGA scores of patients in the Tubifast™ group and nanotextile group were 3.17 (SD, 0.62) and 3.29 (SD, 0.70), respectively ($P = 0.51$). The change in IGA scores showed a similar trend to the change in SCORAD. In the Tubifast™ group, the mean IGA score improved from 3.17 at baseline, to 2.13 on day 7 and 1.82 on day 14 (mixed model time effect $P < 0.001$). In the nanotextile group, the mean IGA score improved from 3.29 at baseline, to 2.22 on day 7 and 2.10 on day 14 (mixed model time effect $P < 0.001$) (Figure 2B). The improvement in IGA score was similar between both groups. On day 7, the mean improvement of IGA was 1 and 1.09 in the Tubifast™ and the nanotextile groups, respectively ($P = 0.66$). On day 14, the mean improvement of IGA was 1.36 and 1.3 in the Tubifast™ and the nanotextile groups, respectively ($P = 0.71$).

3.2 | Quality of life

At baseline, the mean IDQOL/ CDLQI scores of the Tubifast™ group and the nanotextile group were 13.6 (SD, 6.67) and 14 (SD, 5.85), respectively ($P = 0.672$). In the Tubifast™ group, the QoL score decreased from 13.6 at baseline, to 8.58 on day 7 and to 8.26 on day 14 (mixed model time effect $P < 0.001$). In the nanotextile group, QoL score decreased from 14 at baseline, to 9.13 on day 7 and to 8.29 on day 14 (mixed model time effect $P < .001$) (Figure 2C). The improvement in QoL score was similar between both groups. In the Tubifast™ and nanotextile groups, the mean improvement was 5.36 and 4.86 on day 7 ($P > 0.99$), 5.48 and 6.05 on day 14 ($P = 0.57$).

3.3 | Patient feedback

The mean scores for the Tubifast™ and nanotextile groups were 5.12 and 2.73 for the item "discomfort" ($P = 0.001$), 3.36 and 2.56 for the item "movement limitation" ($P = 0.941$), 3.96 and 2.43 for the item "hot/stuffiness" ($P = 0.033$), and 5.24 and 2.78 for the item "difficulty to wear" ($P = 0.003$). (Figure 3).

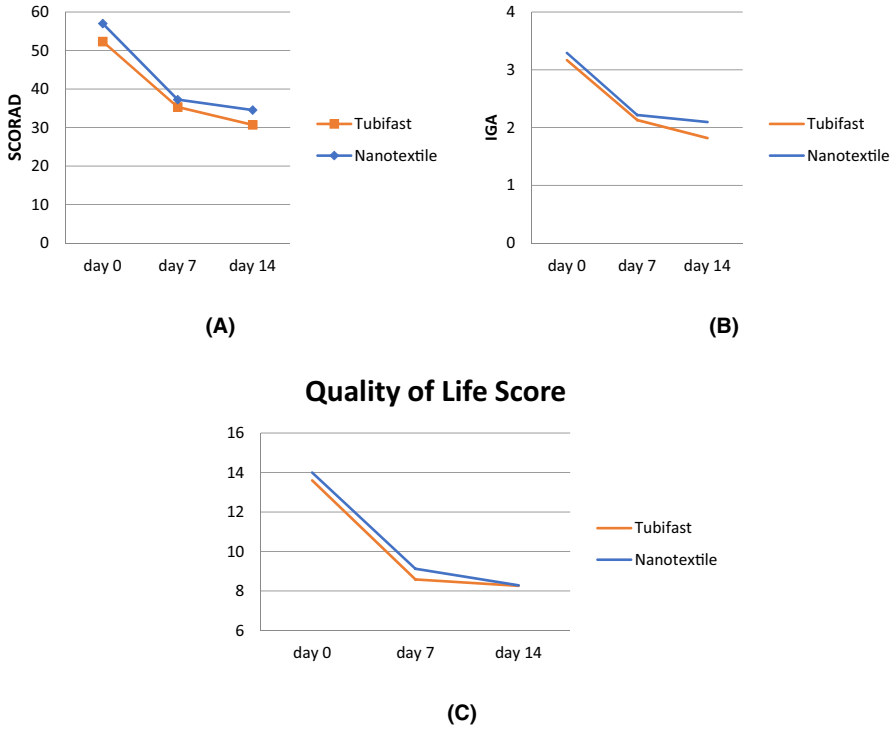

FIGURE 2 Changes of (A) SCORAD (B) IGA and (C) quality of life over time

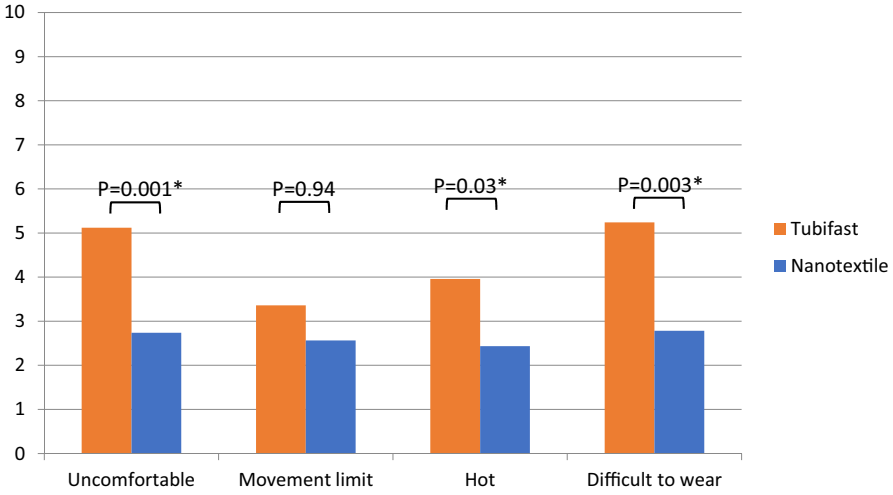

FIGURE 3 Patient feedback toward two wet wrap garments

4 | DISCUSSION

WWT is a widely used adjunct in the treatment of moderate to severe AD.[9] In our study, patients in both the Tubifast™ and nanotextile groups showed significant improvement in disease severity and QoL from baseline. The improvement of SCORAD after 14 days WWT was 41% and 39% in both groups. The result is similar to previous studies on WWT, reporting 14-day disease severity improvement from 27% to 60%.[28,29]

We have also illustrated that the clinic effectiveness of nanotextile wet wrap garment is non-inferior to conventional viscose garment (Tubifast™).

Textile made of nanoscale fibers has been shown to provide good ventilation, insulated cooling effect, and appreciable durability.[19] In our study, the wet wrap garment made of nanotextile was reported by subjects to be more comfortable and breathable ("less stuffy"), easier to wear, and causes less movement limitation compared to viscose. In addition, the insulated cooling effect of nanotextile allows for better temperature control in hot environments like the tropics. The higher comfort level is probably due to nanotextile's smoother surface, causing less irritation to the skin, and cooling effect. Compared to Tubifast™ garment, which has been reported to tear easily and lasts for 20 uses, nanotextile garment has been reported to be stronger and easier to handle. This latter property may explain why patients feel the nanotextile garment is more wearable and cause less movement limitation. In terms of garment care, Tubifast™ garment requires cautions hand washing, while nanotextile garment can be machine washed. This durability makes nanotextile more suitable for use in tropical climates and more cost-effective.

There were several limitations to our study. The appearance of both wet wrap garments is different with regard to color and design. This made it difficult to blind the patients, especially if they have used Tubifast™ products before. Also, the safety of the wet wrap therapies by different garments cannot be fully assessed due to small sample size. The duration of our study was 14 days, comparable to previous studies that have also shown the efficacy of WWT after 2 weeks of treatment is minimal.[30,31] However, there may have been more differences over a longer duration between the two groups. We performed our study from August to March. Being in the tropics, the temperature and humidity level in Singapore is relatively stable throughout the year, and as such there should be minimal changes in climate for the duration of our study.

5 | CONCLUSION

This study has shown that nanotextile (100% nanopolyester) is as effective as conventional viscose in WWT of patients with moderate to severe eczema. It is also superior in patient acceptance. Nanotextile therefore shows good potential in AD management and enables better patient care.

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