

The Effect Of Kinesio-Taping On Chronic Nonspecific Low Back Pain: A Double Blinded Randomised Clinical Trial.

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Abstract

Objective:

The aim of this study is to assess the effectiveness of Kinesio-Taping in the short and medium term on pain and function in low back pain compared to a placebo.

Methods:

We conducted a double-blind, two-arm randomized clinical trial. The study included a total of 70 patients randomised into 2 groups: Kinesio-Taping (n = 35) and control group (n = 35).

All patients received Kinesio-Tapes with a tension between 25 to 30% in the taping group, and with no tension in the placebo group. Taping was applied at baseline, fourth and eighth day. Patients are assessed at baseline, on day 14 and after 4 weeks by the Oswestry Physical and Functional Disability Index (ODI) Arabic version, which was the primary outcome. The secondary outcomes were the assessment of pain and functional disability according to the visual analog scale (VAS) evaluated on a scale of 0 to 10, as well as Rolland-Morris score.

Results:

Both groups were comparable at baseline concerning the demographical and clinical characteristics ($P > 0.05$). The result of repeated measures ANOVA showed a significant change in ODI score and in pain VAS and functional disability as well as Rolland-Morris score in both groups. A significant improvement of pain and functional scores was noted in Kinesio-Taping group using the ANCOVA.

Conclusion:

Our clinical trial offers evidence on the superiority of Kinesio-Taping in the treatment of chronic back pain.

Keywords: Kinesio-Taping, Low back pain, Randomised controlled trial.

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I. INTRODUCTION

Low back pain is a recurrent symptom that has risen to number one among all chronic conditions in the world [1]. This painful complaint is an extremely frequent reason for consultation.

The disability caused by low back pain seems to increase from decade to decade despite the improvement in physical working conditions. It is therefore necessary to conclude that low back pain is a complex condition in its mechanisms.

The goals of treatment are to relieve pain, improve function, reduce work stoppages and develop coping strategies through therapeutic education. Another approach of treatment is the use of taping techniques.

The concept of Kinesio-Taping (KT) comes from traditional Japanese medicine developed by Kenzo Kase, Japanese chiropractor and kinesiologist, in the 1970s. Therapeutic use of KT in our country is still progressing. Taping aims to return the musculoskeletal system to a state of equilibrium by exteroceptive stimulation. The concept is based on certain principles of human kinetic (study of the movements of the human body) [1].

It is a method of adhesive bandage made from a special waterproof but non-degradable in water material containing no chemicals. Although the physiological mechanism is not fully understood, a number of theories were proposed. The adhesive bandages exert oriented traction on the skin, it would favorably influence the muscular and articular systems by reducing the pressure on the subcutaneous mechanoreceptors. Kinesio-Taping would also improve blood and lymphatic circulation and reduce pain and muscle tension [1].

Therefore, Taping offers the possibility of reducing pain and restoring the ability to perform the movement under almost normal conditions [2,3].

The objective of this study was to assess the effectiveness of Kinesio-Taping in the short and medium term on pain and function in patients with chronic nonspecific low back pain compared to a placebo. The research questions for this study were:

- 1- Does the application of Kinesio-Taping improve the function and pain in patients with chronic nonspecific low back pain?
- 2- Does the beneficial effect last four weeks after the treatment period?

II. MATERIALS AND METHODS

We conducted a double-blind, randomized, two-arm clinical trial with intention-to-treat analysis. Patients with chronic nonspecific low back pain were recruited from rheumatology department. Those patients were followed in consultation and had a medical file with the necessary investigations.

Sample:

To be eligible for inclusion, patients were required to have non-specific chronic low back pain for at least 12 months and to have between 18 and 50 years of age.

We excluded from the study patients with history of intolerance to paracetamol, with a previous spinal surgery, a progressive tumor, inflammatory spinal pathology, a vertebral fracture, radiculopathy, a neuropathy or a spinal compression. We also excluded patients with excessive hair on the lumbar region or patients with a progressive dermatological condition making the application of Kinesio-Taping difficult.

The subjects having had a Taping beforehand or rehabilitation in the 6 months preceding the study were also excluded.

Patients who met the inclusion criteria benefited from a systemic clinical examination including: The measurement of weight and height to calculate the Body Mass Index and to determine the different ranges: underweight (under 18.5 kg/m²), normal weight (18.5 to 25), overweight (25 to 30), and obese (over 30). We also performed spinal examination, Shoerber index, Finger-to-ground distance and neurological evaluation to determine any condition excluding them from the study.

All patients were informed of the purpose and progress of the study, and then they were invited to read and sign a written consent to be able to participate in the clinical trial.

Randomization:

Patients were randomized to the Kinesio-taping group or to the placebo group. Concealed allocation was performed by using a computer generated randomized table by an investigator not involved in the evaluation or the treatment of the patients. Individual cards were numbered with the random assignment and placed in closed envelopes; then an investigator, who has received training from an expert on the application of KT technic, applied the KT for all the patients.

In both groups, an adhesive tape was applied to the most painful region of the lower back. Patients sit in a chair without armrests, positioning their trunk in forward flexion as much as possible, arms crossed on the knees. The goal of this position is to achieve maximum stretching of the lumbar spine, surrounding soft tissue and skin. Four I-shaped adhesive strips arranged in a star were used. Once cut, the angles of the strip were rounded in order to limit the early detachment.

In the Kinesio-Taping group: When the lumbar flexion reached its maximum point, the band was stretched to a maximum tension between 25 and 30% and the middle part of the band was fixed at the site of the pain. The first strip was attached horizontally, the second placed vertically and the other two strips placed diagonally to form a star (**Figure 1**).



Figure 1: Sham Kinesio-Taping in placebo patient (A) and Kinesio-Taping placement in experimental patient (B)

In the Placebo group: The same adhesive tape with four I-shaped strips was applied in the same region but without any tension.

In both groups, each tape application lasted four days before it was replaced; the patients of the two groups had three applications in total: In the beginning, the fourth and the eighth day. The combination of an analgesic treatment based on Paracetamol was authorized in the event of significant pain. All data was collected by an investigator, who ignores the group in which the patient was assigned.

Outcome measures:

The primary outcome was the Arabic version of the Oswestry Physical and Functional Disability Index (ODI). It is a self-assessment questionnaire used to assess physical and functional disability. It includes 10 sections of six propositions, each evaluated on a scale of 0 to 5. The values are calculated using this formula: (total score / total score possible \times 100%). Higher scores indicate more severe disability. The Oswestry Disability Index will be calculated at the baseline, on the 14th day and at four weeks of follow-up.

The secondary outcome was the assessment of pain according to the visual analogue scale (VAS) evaluated from 0 to 10. We also evaluated the function according to the Rolland-Morris Questionnaire scored on a 24-point scale, where 0 represent no disability and 24 severe disability. The assessment was done at the start, on the 14th day and at four weeks.

The study was conducted in compliance with the Helsinki Declaration and approved by ethical committee at each of the collaborating institutions, and it was registered at the Pan African Clinical Trial Registry site (www.pactr.org) under the identification number: **PACTR202008710072142**.

Statistical Analysis:

Many studies considered an improvement of 6 points on the ODI as significant [4]. Therefore, we considered a difference in disability scores between the groups of 10 points significant, assuming a standard deviation of 12 points from the Oswestry handicap index to allow a 10% loss to follow-up.

The study should include a total of 70 patients to provide 95% power to detect a difference between groups of 10 points on the ODI.

Descriptive statistics reported the baseline demographic characteristics of our population. Mixed model analyses of variance (ANOVAs) were used to determine Kinesio-Taping effects (dependent variables) with group (Taping or placebo) as between subject variable and time (baseline, 12 days and 1 month follow up) as within subject variable.

The change in each group at each time point is reported as a mean with standard deviation. The effect of the intervention at each time point is reported as a mean between-group difference in change from baseline, with 95% confidence interval. The hypothesis of interest was the group-by-time interaction at an a priori alpha level of 0.05. Analysis was by intention to treat. All dropouts and their underlying reasons will be reported.

III. RESULTS

During the study period (from July 2019 to July 2020), 70 eligible patients with chronic nonspecific back pain were included in the study to assess the effectiveness of Kinesio-Taping on the pain and function. They were randomized into 2 groups: Kinesio-Taping (n = 35) and control group (n = 35). The selection of the study population and reasons for ineligibility are shown in **Figure 2**.

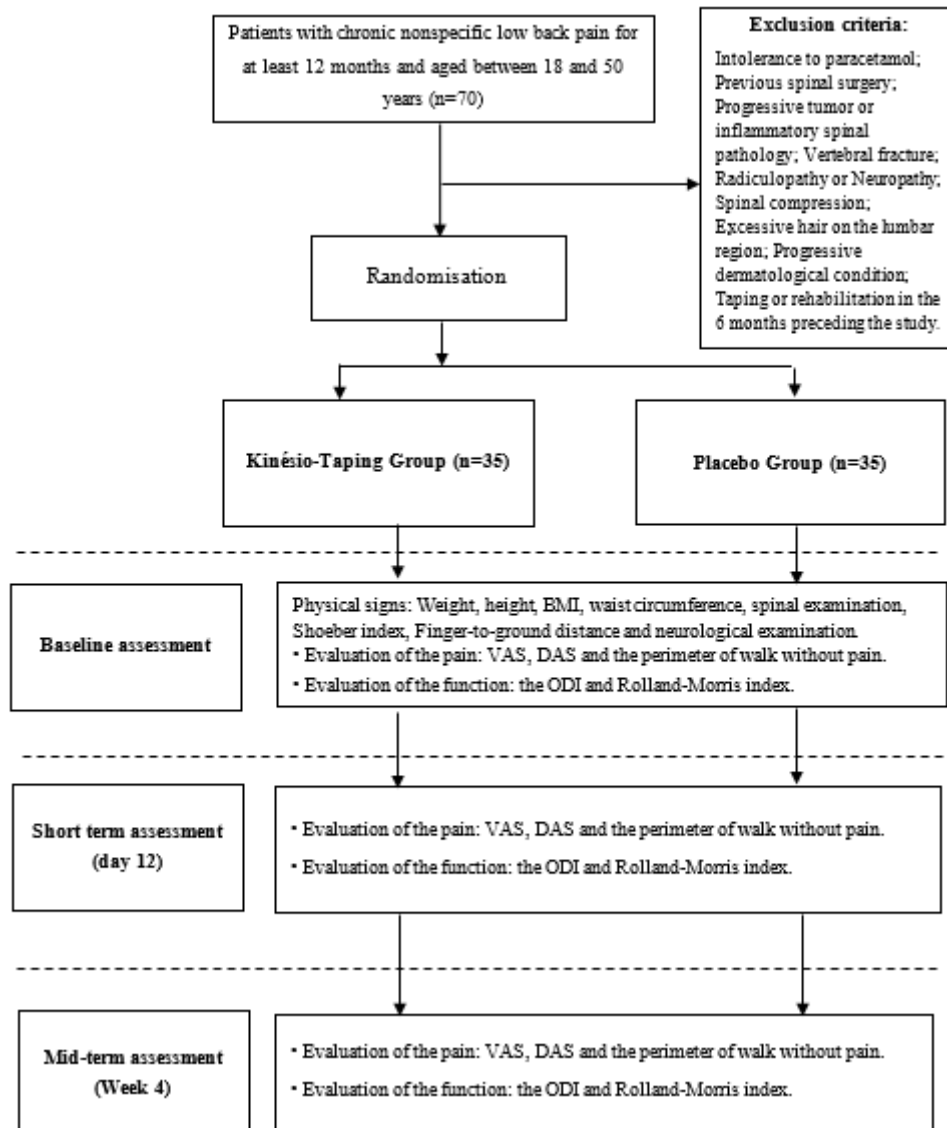


Figure 2: Flow chart of the study population

All patients received the taping to which they had been randomly allocated. No dropouts were noted in our study population. Demographic and clinical characteristics of the two groups are illustrated in **Table 1**.

Table 1: Clinical characteristics of study population.

	Kinesio-Taping group (n=35)	Placebo group (n=35)	p value
Age	40±8,4	40±10	0,768
Female gender	31	24	0,055
Prolonged standing position	26	25	0,788
Heavy load carrying	26	25	0,788
Walking aid	0	2	0,493
Comorbidities	11	8	0,420
Body mass index	28±3,8	28,24±5	0,853
ODI of baseline	26±20,1	23±15,59	0,611

The two groups were comparable in baseline demographic characteristics ($p > 0,05$). In the Kinesio-Taping group thirty-one (88.5%) patients were females, the mean age was 40 ± 8.4 years and 74% (n=26) of them reported prolonged standing position while twenty-six patients (74.2%) carried heavy loads. All patients were

Moroccans, most of whom were overweight (n=40, 57.1%). Among these 40 patients, 20 patients (57.1%) had a BMI between 25 to 30kg/m² and 8 (22.9%) were obese (BMI over 30kg/m²).

The mean body mass index (BMI) was 28±3.8 and comorbidities accounted for a large proportion (n=11, 31.4%). The mean ODI of baseline was 26±20.

The result of repeated measures ANOVA showed a significant change in ODI score (p≤ 0,05) and in VAS for pain and functional disability as well as Rolland-Morris score in both groups (Table 2).

At the 12th day of evaluation, there was a statistically significant improvement on disability and pain. The ODI improved by 9 points compared to baseline in the Kinesio-Taping group and by only 3 points in the control group. Similarly, the VAS of pain and of functional disability was improved by 3 points in the Kinesio-Taping group. The Roland Morris Disability Questionnaire showed a significant benefit after the twelve days of taping (3.2 points improvement). At the end of the four-week period, pain and function improved significantly in the two groups (more in the experimental group than in the control group). Using the ANCOVA, controlling for pre-test scores, a significant difference was found between the two groups (p≤0,05) (Table 2).

Table 2: Primary and secondary outcomes in the Kinesio-Taping and placebo group.

	Taping groupe (n=22)				Placebo groupe (n=24)				ANCOVA
	Baseline	Day 12	4 weeks	p value	Baseline	Day 12	4 weeks	p value	
ODI	36±18,82	24±19,83	24±19,32	<0,001	31±12,65	28±13,32	29±13,24	0,03	<0,001
VAS of pain	7±1,3	3,9±2,2	4,6±2,2	<0,001	6,5±1,2	5,5±2,2	5,7±2,2	0,008	<0,001
VAS of functional disability	6,7±1,5	4±2,8	4,4±2,5	<0,001	5,9±2,3	5,2±2,2	5,3±2,2	0,003	<0,001
Rolland Morris	7,4±4,6	5,2±4,7	5,3±4,6	<0,001	8,4±4,8	7,6±4,2	7,3±4,1	0,05	0,06

ODI: Oswestry Disability Index VAS: visual analog scale

IV. DISCUSSION

According to the results of this double-blind, randomized, controlled study, Kinesio-Taping is effective in the short and medium term in improving pain and disability in chronic low back pain.

Many studies showed an improvement in short-term, but the long term effectiveness was a subject of debate. Castro-Sánchez *et al.* [5] reported the effectiveness of Kinesio taping compared to sham Kinesio taping in chronic low back pain. The study included 60 patients and reported significant short-term improvements in pain intensity in the Kinesio taping group, but there was no significant difference at four weeks. Our study, in the other hand, clearly demonstrated a beneficial effect of KT that lasted 4 weeks after the tape removal.

The Kinesio-Taping is quick to apply, it is maintained in situ for four days and does not require ongoing commitment of time and effort from the patient, which makes it a great addition to the therapeutic arsenal. The protocol that we used is well tolerated by all of our patients, there were no adverse effects noted.

Numerous treatments for low back pain have been studied. A large recent meta-analysis [6], including eight randomized controlled clinical trials, compared the efficacy of Kinesio-Taping on chronic non-specific low back pain with other non-pharmaceutical therapeutic methods (physical therapy, acupuncture, electric therapy). The results showed that KT is superior to other methods (including no Taping) in terms of the reduction of VAS and ODI.

Due to the efficacy of KT on chronic low back pain, it was proposed as an additional method in the therapeutic arsenal of low back pain patients, especially in situations where the practitioner is therapeutically limited, for example in patients with comorbidities (renal failure, diabetes, etc.) and during pregnancy because spinal pain affects 45-56% of pregnant women, it can appear from the 12th week and its severity increase between the 24th and the 30th gestational week [7].

Kalinowski *et al.* [7] reported the use of KT during pregnancy (12% used in the second trimester and 88% in the third trimester), low back pain was evaluated by VAS and Rollad Morris Disability Questionnaire. The pain was reduced significantly compared to placebo. The positive effect started the second day and it was

maintained two days after the removal of KT. There was no adverse reaction reported which supports the security of the use of KT.

We used in our clinical trial a method of application of the KT based on four bands arranged in a star and placed in loco dolenti with a tension between 25 to 30%. Other studies have proposed two I-shaped tapes disposed horizontally over the dimples of the back with natural tension, others proposed more complex applications: I-shaped tape posed in the upper area of the back and an Y-shaped tape along the lumbar muscle to the L1 transverse protrusion [6].

A study comparing the different methods of KT is needed in order to evaluate the difference between the different technics.

Apart from the small sample size, our study investigated the effectiveness of KT in the short and medium term and therefore cannot draw conclusions on the effect in the long term. Another limitation to our study is that in addition to KT with tension arm and KT with no tension arm, a third arm is needed with no Tape (control arm). K nogl  at al. [8] reported a 3 arm clinical trial, the results indicated that a greater improvement was obtained in pain, functionality, lumbar mobility and muscle endurance in KT group in addition to electrotherapy and exercise methods.

V. CONCLUSION

Kinesio-Taping in chronic low back pain is an easy and effective method in the short and medium term, it can be more effective when applied in addition to other therapeutic methods. Further randomized, controlled studies with long-term follow-up should be designed.

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