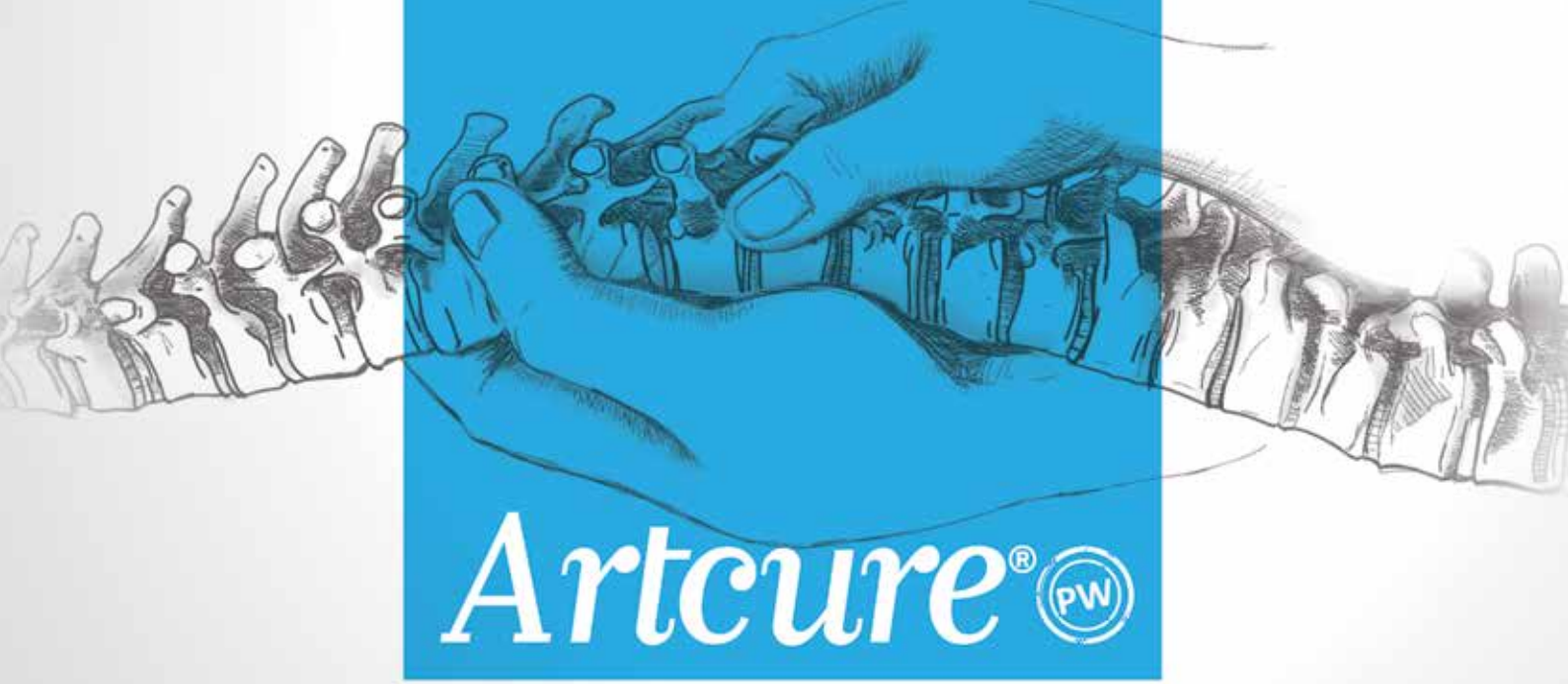


Artcure® PW

CLINICAL STUDY SUMMARIES

CE 1783

Diffusional
Patch & Gel

PROVIDING SUPPORT FOR THE EXISTING TREATMENTS WITH MAGNETIC DIFFUSIONAL PATCHES AT DISC HERNIAS

CLINICAL STUDY CENTRE
DIŞKAPI TRAINING AND RESEARCH HOSPITAL
HEAD OF THE CLINICAL RESEARCH
ASSOC. PROF. DR. MEHMET SORAR

TOTAL NUMBER OF VOLUNTEERS SCREENED
AT THE BEGINNING OF THE STUDY 80
NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 40
PLACEBO APPLICATION DURING THE STUDY 40

Average age of the patients who took part in the study was 41.90±8.52, BMI was 25.26±4.08, number of the disc hernia patients was 15, number of the extrude disc hernia patients was 25. All of the patients were the ones who were previously administered medicine as well as rest treatment and physiotherapy.

SYMPTOMS

Average VAS scores of the 40 patients intotal who were included in the study, before the treatment was 7.85 ± 1.39. At the end of 24 hours, second VAS was reported as 3.15±2.11 ($P<0.001$, Anova) with significant decrease and at the end of 48 hours, the third VAS was reported as 1.86±1.65 ($P<0.001$ Anova) with significant decrease and the correlation between the second and the rhird VAS was reported as $P<0.01$ with significant decrease (Diagram 1). Such decrease does not show correlation with age and BMI ($p>0.05$, Pearson).

CLINICAL STUDY CENTRE

DIŞKAPI TRAINING AND RESEARCH HOSPITAL

HEAD OF THE CLINICAL RESEARCH

ASSOC. PROF. DR. MEHMET SORAR

TOTAL NUMBER OF VOLUNTEERS SCREENED
AT THE BEGINNING OF THE STUDY 80
NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 40
YEAR OF THE STUDY 2012

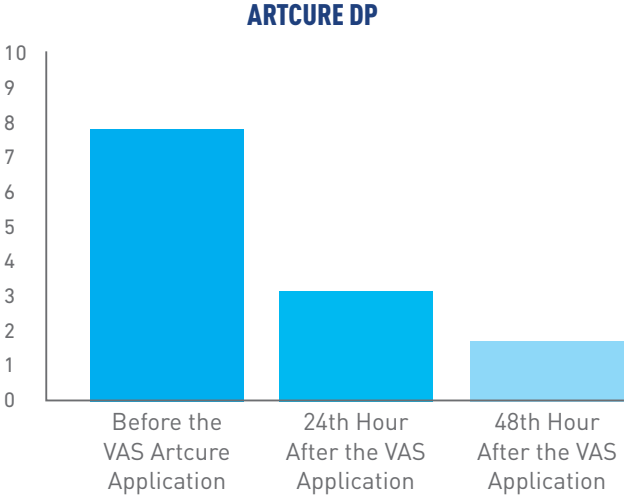
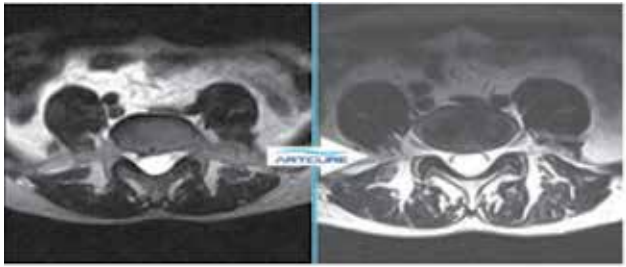


Diagram 1. Values of VAS Pain scores of the disc hernia patients at the end of 0, 24 and 48 hours.

At the result of MRI imaging after 4 weeks, massive contraction is observed on the patients' herniated areas (Patient 1, 2, 3, 4, 5,6).

PATIENT 1



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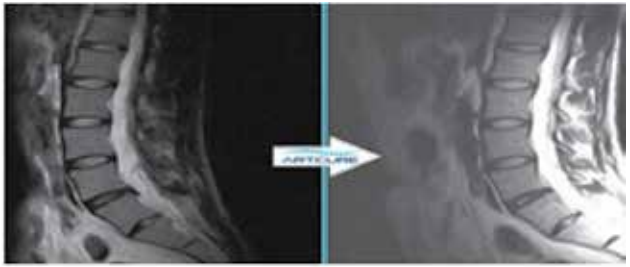

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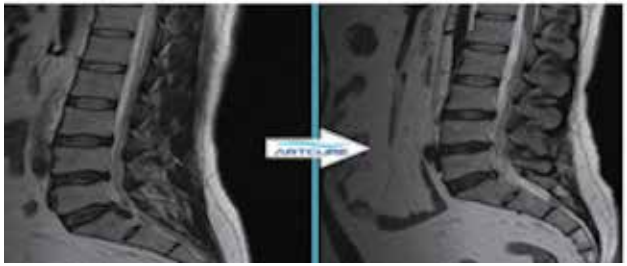

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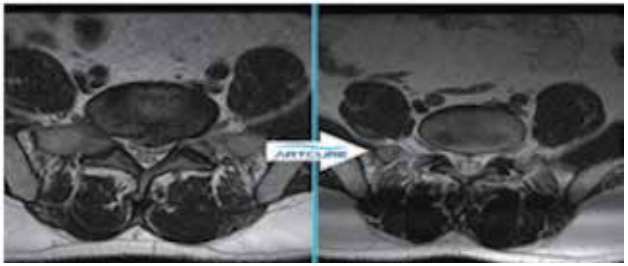

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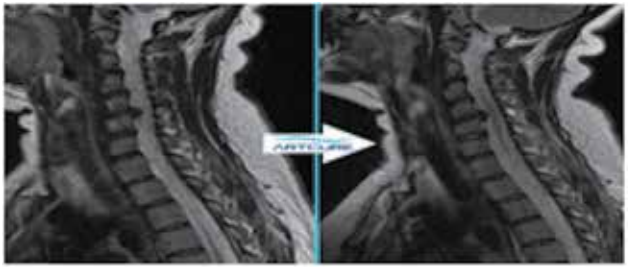

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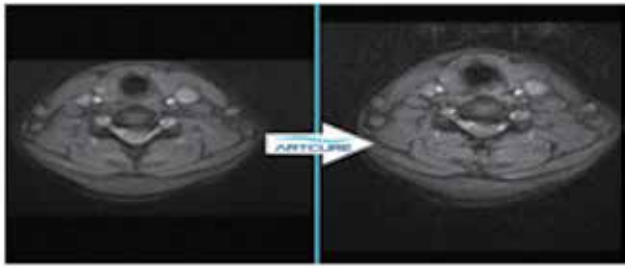

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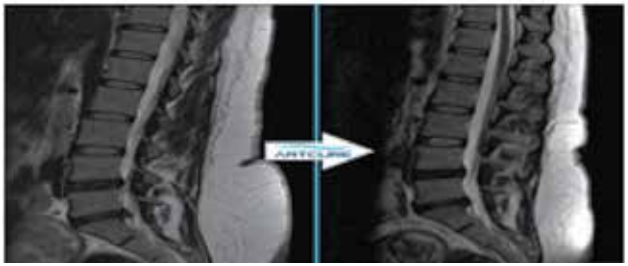

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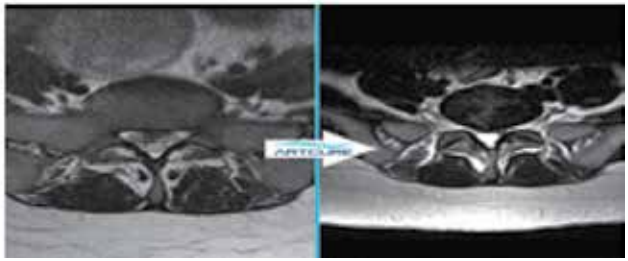

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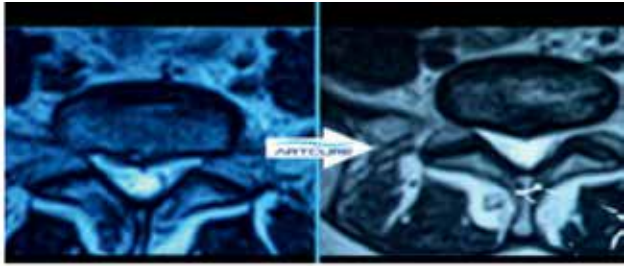
PATIENT 5

BEFORE AFTER



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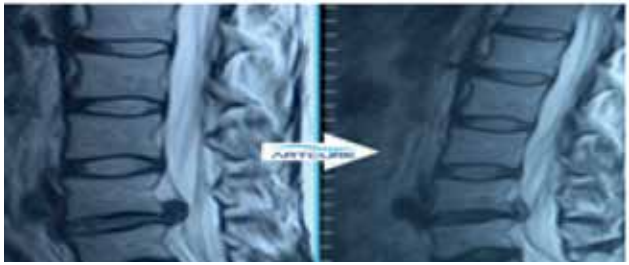
PATIENT 6



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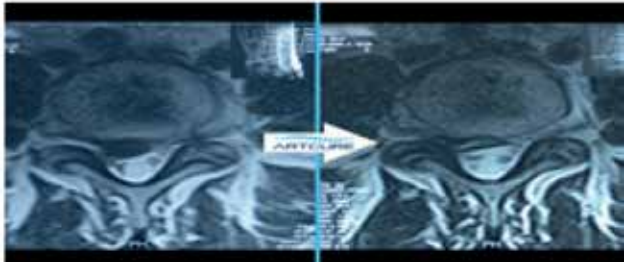


BEFORE AFTER

APPLYING PLACEBO

For ARTCURE ® diffusional patch which had been applied on 40 healthy individuals in the age range of 45.40±5.20 (20-54) , VAS scores before applying placebo was declared as follows: 0 for VAS1, 0 for VAS2 and 0 for VAS3. No difference was observed during the neurological evaluations before and 48 hours after the study.

DETERMINING SHORT AND LONG TERM EFFECTS OF DIFFUSIONAL PATCH APPLICATION ON PAIN AND FUNCTIONAL CONSTELLATION ON THE PATIENTS WITH LUMBER DISC HERNIA

CLINICAL STUDY CENTRE

YILDIRIM BEYAZIT UNIVERSITY
ANKARA ATATÜRK TRAINING AND RESEARCH HOSPITAL

HEAD OF THE CLINICAL RESEARCH

ASSOC. PROF. DR. ATIF AKSEKİLİ

This study,was presented at the 26th TOTBID Congress held on 25-30 October 2016

Our main purpose in this study is to show the effectiveness of Artcure Diffusional Patch, which is in the structure of “hypoosmolar lipid” and consists of a mixture of 6 types of vegetable oil, in the treatment of patients with Lumbar Disc Hernia and to discuss the advantages and disadvantages of this treatment over surgical treatment.

METHOD

This study included 79 of 120 patients who were clinically diagnosed with lumbar disc prolapse. The clinical measurements were made according to the degrees of protrusion and extrusion in the MRI images examined of the patients and to the dermatomal distribution of their pain. “Artcure Diffusional Patch (ADP)” was applied to the treatment group and “Transdermal Diffusional Patch (TDP)” was applied to the placebo group. The functional capacities of the patients were measured with the “Oswestry Disability Index (ODI) scale” and the changes in pain intensity were measured with the “Visual Analog Scale (VAS) scale”. In addition, criteria such as degree of limitation in movement, Lasegue Test, Femoral Stretch Test and Paravertebral Muscle Spasm were used for these. Statistical analyzes also include Oswestry Disability Index, Visual Analogue Scale, patient satisfaction and time to return to work.

SYMPTOMS

In the first month after the treatment, a significant improvement and positive improvement was observed in the pain levels felt by the treatment group, Oswestry Disability Index values and Visual Analog Scales. In the evaluations made 3 days after the admission, it was determined that the improvement in the physical examination findings and scoring of the treatment group was statistically many times higher than that of the control group.

INFERENCES

Artcure Diffusional Patch treatment compared to placebo treatment; in patients with Lumbar Disc Herniation with radiculopathy, clinical scores, patient satisfaction, physical examination findings, and patients' return to work were significantly superior. According to these findings, Artcure Diffusional Patch therapy may be a good alternative for conservative treatment in patients with Lumbar Disc Herniation and Radiculopathy.

Table 1: The datas before and after application in the experiment group General Linear Model Repeated Anova (Wilks' Lambda) Post Hoc Test: LSD - Cochrans's Q Test - Post Hoc Test: nonparametrik posthoc test (Miller(1966) Average Values±Ss(standard deviation), Median Range(Maximum-Minimum) ve n(%)

		Preoperative=I N=40	3rd Day=II N=40	1st Month=III N=40	P Value I-II	I-III	II-III	General
ODI		59,2±13,37	44,8±15,61	33,4±10,13	<0,001	<0,001	<0,001	<0,001
VAS		9(10-3)	7(10-2)	5(10-2)	<0,001	0,042	0,016	<0,001
SLR	Positive	32(80,0)	16(40,0)	4(10,0)	0,001	<0,001		<0,001
	Negative	8(20,0)	24(60,0)	36(90,0)			0,016	
K-SLR	Positive	32(80,0)	16(40,0)	4(10,0)	<0,001	0,001		<0,001
	Negative	8(20,0)	24(60,0)	36(90,0)				
Flexion	Normal	15(37,5)	25(62,5)	33(82,5)	0,019	<0,001	0,085	<0,001
	Disabled	25(62,5)	15(37,5)	7(17,5)				

		Preoperative=I N=40	3rd Day=II N=40	1st Month=III N=40	P Value I-II	I-III	II-III	General
Extansion	Normal	14(35,0)	25(62,5)	2(80,0)	0,006	<0,001	0,148	<0,001
	Disabled	26(65,0)	15(37,5)	8(20,0)				
Right Lateral Flexion	Normal	17(42,5)	28(70,0)	32(80,0)	0,003	<0,001	0,704	<0,001
	Disabled	23(57,5)	12(30,0)	8(20,0)				
Left Lateral Flexion	Normal	17(42,5)	28(70,0)	32(80,0)	0,003	<0,001	0,704	<0,001
	Disabled	23(57,5)	12(30,0)	8(20,0)				
Paravertebral muscle spasm	Disabled	40(100,0)	12(30,0)	8(20,0)	<0,001	<0,001	1	<0,001
	Yes	0(0,0)	28(70,0)	32(80,0)				
Femoral Streching Test	Positive	31(77,5)	15(37,5)	6(15,0)	<0,001	<0,001	0,082	<0,001
	Negative	9(22,5)	25(62,5)	34(85,0)				

Table 2: The data before application and 3rd day after application in placebo group Independent T Test(Bootsrap) - Mann Whitney U Test(Monte Carlo) - Fisher Exact Test (Exact)
Average Values±Ss(standard deviation), Median Range(Maximum-Minimum) ve n(%)

		Placebo Preop	3rd Day	P Value
ODI		61,8±11,42	52,2±12,5	<0,001
VAS		8(10-3)	7 (10-2)	<0,001
SLR	Positive	29 (74,4)	25 (64,1)	0,219
	Negative	10 (25,6)	14 (35,9)	
K-SLR	Positive	29 (74,4)	24 (61,5)	0,063
	Negative	10 (25,6)	15 (38,5)	
Flexion	Normal	17 (43,6)	18 (46,2)	1
	Disabled	22 (56,4)	21 (53,8)	

Table 2: The data before application and 3rd day after application in placebo group Independent T Test(Bootsrap) - Mann Whitney U Test(Monte Carlo) - Fisher Exact Test (Exact)
Average Values±Ss(standard deviation), Median Range(Maximum-Minimum) ve n(%)

		Placebo Preop	3rd Day	P Value
Extansion	Normal	17 (43,6)	18 (46,2)	1
	Disabled	22 (56,4)	21 (53,8)	
Right L Flexion	Normal	16 (41,0)	18 (46,2)	0,500
	Disabled	23 (59,0)	21 (53,8)	
Left L Flexion	Normal	17 (43,6)	19 (48,7)	0,500
	Disabled	22 (56,4)	20 (51,3)	
Paravertebral muscle spasm	Yes	30 (76,9)	21 (53,8)	0,004
	No	9 (23,1)	18 (46,2)	
Femoral Strecthing Test	Positive	27 (69,2)	20 (51,3)	0,016
	Negative	12 (30,8)	19 (48,7)	

Table 3: The difference between groups before application and the third day after application .
General Linear Model Repeated Anova (Wilks' Lambda) - Independent T Test(Bootsrap) - Mann Whitney U Test(Monte Carlo) - Fisher Exact Test (Exact)
Average Values±Ss(standard deviation), Median Range(Maximum-Minimum) ve n(%)
[a] :Odds Ratio (95% Confidence interval for Odds Ratio)

		Placebo	Experiment	P Value
ODI	Preoperative	61,8±11,42	60,9±13,15	0,724
	3rd Day	61,8±11,42	46,0±15,4	
	Difference(Pre 3rd Day)	8,2±7,7	14,2±12,9	0,010
VAS	Preoperative	8(10-3)	10(10-3)	<0,001
	3rd Day	7 (10-2)	7 (10-2)	
	Difference(Pre 3rd Day)	1 (4- -2)	2 (8- -1)	0,003

CLINICAL STUDY CENTRE

YILDIRIM BEYAZIT UNIVERSITY ATATURK TRAINING AND RESEARCH HOSPITAL ORTHOPEDICS, BRAIN AND NERVE SURGERY, PHYSIOTHERAPY AND REHABILITATION DEPARTMENTS

HEAD OF THE CLINICAL RESEARCH

ASSOC. PROF. DR. ATIF AKSEKİLİ

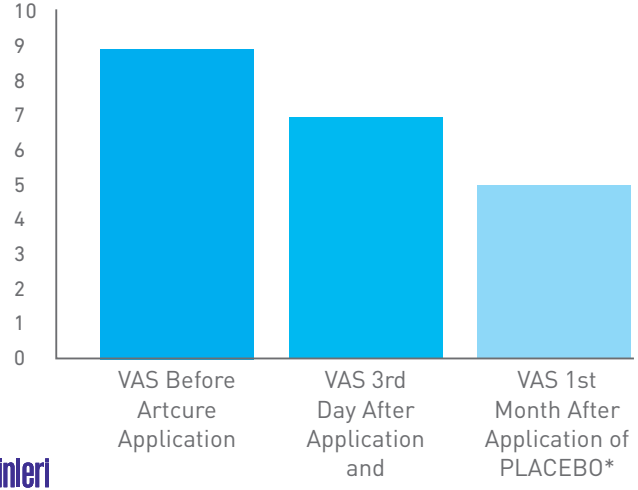
TOTAL NUMBER OF VOLUNTEERS SCREENED AT THE BEGINNING OF THE STUDY 129

NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 40

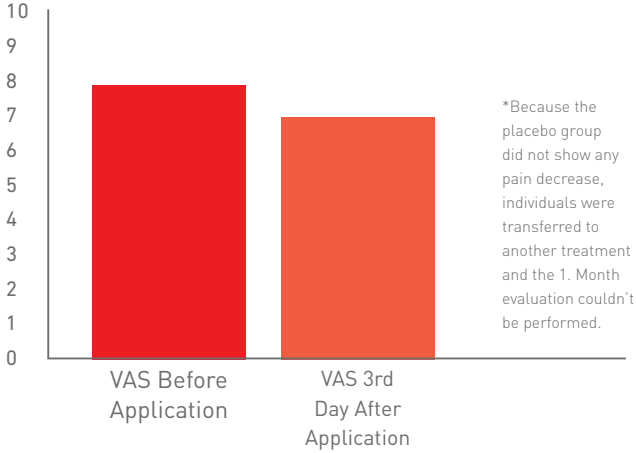
PLACEBO APPLICATION DURING THE STUDY 40

YEAR OF THE STUDY 2015

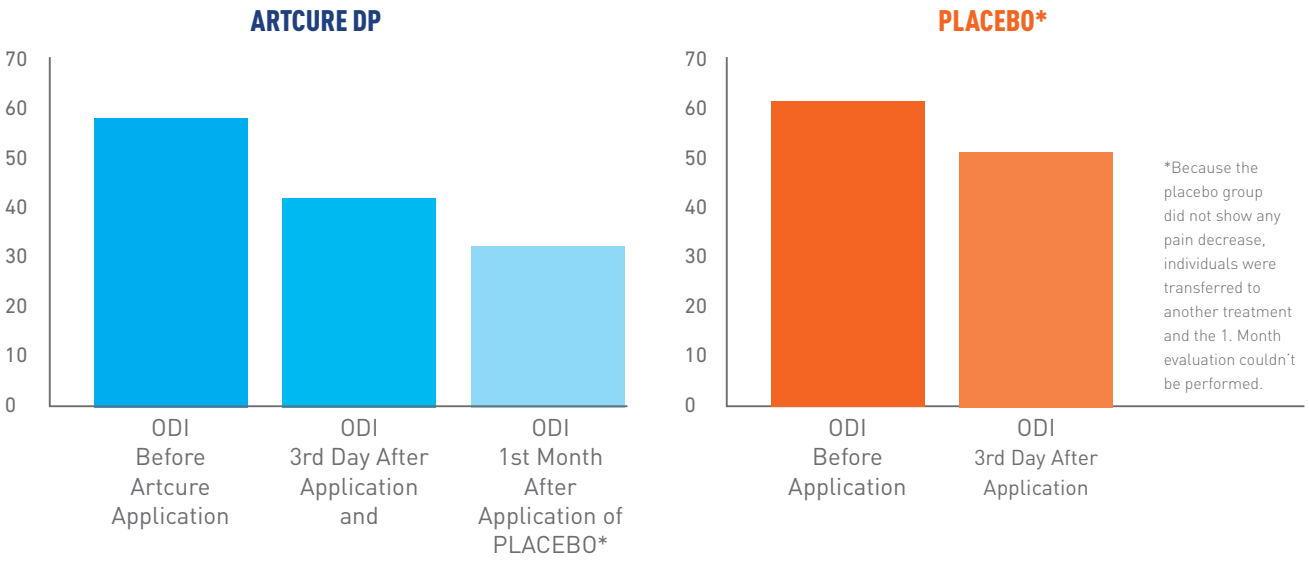
ARTCURE DP



PLACEBO*



*Because the placebo group did not show any pain decrease, individuals were transferred to another treatment and the 1. Month evaluation couldn't be performed.


ARTCURE DP
70
60
50
40
30
20
10
0
ODI Before Artcure Application
ODI 3rd Day After Application and
ODI 1st Month After Application of PLACEBO*
PLACEBO*
70
60
50
40
30
20
10
0
ODI Before Application
ODI 3rd Day After Application
*Because the placebo group did not show any pain decrease, individuals were transferred to another treatment and the 1. Month evaluation couldn't be performed.

CLINICAL STUDY 3

DIFFUSIONAL PATCH'S EFFECT ON PAIN AND FUNCTIONAL CONSTELLATION DURING LUMBAR DISCOPATHY TREATMENT.

CLINICAL STUDY CENTRE

EGE UNIVERSITY MEDICAL FACULTY
DEPARTMENT OF NEUROSURGERY

HEAD OF THE CLINICAL RESEARCH

PROF. DR. MEHMET SEDAT ÇAĞLI

AIM

The transdermal diffusional patch (ArtcureDP) is a novel transdermal patch of plant origin, based on essential oils, that works through diffusion. The purpose of this prospective, open label study was to examine the effect of the 'diffusional patch' on pain and functional status in the treatment of lumbar discopathy.

METHODS

This study was designed to include 60 patients, aged 24-80, with lumbar disc herniation. The Artcure patch was attached to the lumbar region with a hypoallergenuic plaster, and 24-h bed rest was advised. Patients received no other treatments for 24 h. The clinical researchers removed the patch the following day. The neurological examinations were performed before treatment; 24thhour, 48th hour and first month after treatment including straight leg raise test, muscle strength, sensorial status, reflexes, range of motion at flexion, extension, lateral bending and rotation. Paravertebral spasm was also recorded if presented.

Severity of pain was assessed using a visual analogue scale (VAS) and functional status using the Oswestry disability index (ODI).

RESULTS

After the patch application the mean VAS scores were decreased statistically significantly. The range of motion in flexion was statistically significantly increased in all three assessments after treatment. Straight leg raise test was positive in 26 patients before treatment, after treatment at the first month only 14 patients were positive for straight leg raise test; this change was statistically significant. The patch treatment resolved paravertebral spasm statistically significantly. Also, decrease in ODI scores following patch application was statistically significant. Control MRI at the first month revealed disc shrinkage in 10 patients (16.7%), and the degree of shrinkage observed was statistically significant.

CONCLUSIONS

The results of this study revealed that the transdermal diffusional patch (ArtcureDP) application caused statistically significant amelioration in pain scores and clinical conditionof the patients. Furthermore, this treatment caused astatistically significant shrinkage of disc. In conclusion, the hypo-osmolar diffusional transdermal patch (Artcure) can be used in the treatment of patients with protruded, extruded and fragmented disc hernias.

Table 1: The results of the clinical assessments.

Variable	Pretreatment	24th hour	48th hour	1st month	p-value
VAS	8 (3-10)a,b,c	6 (1-9)a,d,e	3 (0-9)b,d,f	1.5 (0-5)c,e,f	<0.001†
ROM-Flexion	49 (81.7%)b,c	54 (90.0%)	58 (96.7%)b	58 (96.7%)c	<0.001‡
ROM-Extention	54 (90.0%)	58 (96.7%)	58 (96.7%)	56 (93.3%)	0.062‡
ROM-Rotation	58 (96.7%)	58 (96.7%)	58 (96.7%)	60 (100.0%)	0.112‡
ROM-Lateral Bending	57 (95.0%)	57 (95.0%)	57 (95.0%)	57 (95.0%)	1.000‡
SLR – positivity	26 (43.3%)a,b,c	14 (23.3%)a	10 (16.7%)b	14 (23.3%)c	<0.001‡
PVS - positivity	39 (65.0%)a,b,c	47 (78.3%)a,e	47 (78.3%)b,f	22 (36.7%)c,e,f	<0.001‡
Muscle strength	5 (4-5)	5 (4-5)	5 (4-5)	5 (4-5)	0.074†
Sensorial evaluation	5 (8.3%)	2 (3.3%)	5 (8.3%)	2 (3.3%)	0.083‡
ODI	54 (32-74)a,b,c	50 (20-61)a,d,e	42 (20-60)b,d,f	36 (18-54)c,e,f	<0.001†

† Friedman test, ‡ Cochran's Q test, a: The change between pretreatment and 24th hour is statistically significant (p<0,0083),
b: The change between pretreatment and 48th hour is statistically significant, c: The change between pretreatment and 1st month is statistically significant (p<0,0083),
d: The change between 24th hour and 48th hour is statistically significant (p<0,001),
e: The change between 24th hour and 1st month is statistically significant (p<0,001),
f: The change between 48th hour and 1st month is statistically significant (p<0,001).
VAS: visual analogue scale, ROM: range of motion, SLR: straight leg raise, PVS: paravertebral spasm, ODI: Oswestry disability index.

CLINICAL STUDY CENTRE

EGE UNIVERSITY MEDICAL FACULTY
DEPARTMENT OF NEUROSURGERY

HEAD OF THE CLINICAL RESEARCH

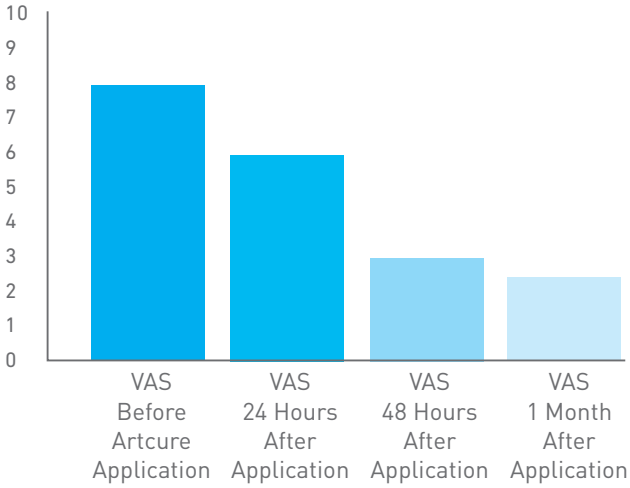
PROF. DR. MEHMET SEDAT ÇAĞLI

TOTAL NUMBER OF VOLUNTEERS SCREENED AT THE BEGINNING OF THE STUDY 60

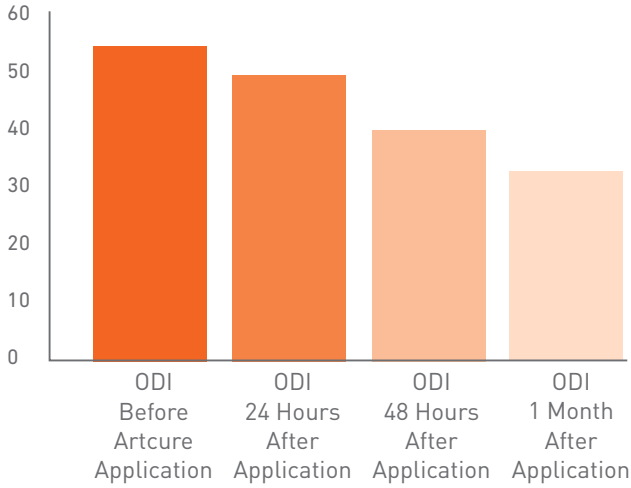
NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 60

YEAR OF THE STUDY 2015

ARTCURE DP



ARTCURE DP



CLINICAL STUDY 2018/5: THE RETROSPECTIVE ANALYSIS OF THE PATIENTS TREATED WITH DIFFUSIONAL PATCH (ARTCURE)

CLINICAL STUDY CENTRE

BURSA HIGHLY SPECIALIZED TRAINING AND RESEARCH HOSPITAL

HEAD OF THE CLINICAL RESEARCH

OP. DR. ADNAN YALÇIN DEMİRCİ

DETAILS OF STUDY

On 250 patients;

VAS score;

- Before the transaction: 8.41
- 10th day after the transaction: 3.77
- The application was terminated in 2 patients as the allergy developed in the application area.

CONCLUSION

These findings suggest that there may be an alternative treatment for protruded or extruded lumbar disc hernias that do not require surgery and coexist with radiculopathy. In this sense, larger prospective randomized controlled studies are required.

CLINICAL STUDY 5

ARTCURE DIFFUSIONAL PATCH APPLICATION FOR LUMBAR DISC HERNIATION IN PATIENTS WITH TYPE 1 AND 2 DIABETES MELLITUS: STUDY PROTOCOL FOR A RANDOMIZED PLACEBO-CONTROLLED, DOUBLE BLIND STUDY

CLINICAL STUDY CENTRE

ANKARA BASKENT HOSPITAL

HEAD OF THE CLINICAL RESEARCH

PROF. DR. NURİ ÇETİN

BACKGROUND AND AIMS

Lumbar disc herniations are common musculoskeletal problems in general population. Many treatment methods are available . In refractory cases, interventional procedures or surgery should be considered (1). However, interventional procedures are avoided in diabetic patients due to delayed wound healing or susceptibility to infection. Artcure patch contains low molecular weight lipid formation and is a treatment method that aims to decrease the volume of herniated disc following the absorption of this gel-like substance through the skin (2,3). The aim of our study is to demonstrate the effectiveness of artcure diffusional patch application in the treatment of lumbar disc herniation in diabetic patients.

METHODS

Forty-seven patients aged between 25-60 years with Type 1 and 2 diabetes mellitus and with lumbar disc herniation protruded or extruded disc herniation were included in the study. Patients were received real artcure or placebo in a 3 to 1 ratio (34 patients real artcure, 13 placebo). Patients were evaluated with Oswestry disability index (ODI), Visual analog scale (VAS) and changes in measurement of disc diameter before and 3th month follow-up.

RESULTS

There were not any significant difference between in terms of sociodemographic and clinical features of the patients before the application. Within group comparisons, VAS, ODI and changes in disc diameter parameters improved significantly in artcure group according to the baseline. The rate of changes in ODI, VAS and disc diameter were significantly higher in artcure group.

CONCLUSION

Artcure seems to be effective and safe in lumbar disc herniated diabetes mellitus patients. Disability decreased and pain scores were improved.

REFERENCES

1. Gadjradj PS, Smeele NVR, de Jong M, Depauw PRAM, van Tulder MW, de Bekker-Grob EW, Harhangi BS. Patient preferences for treatment of lumbar disc herniation: a discrete choice experiment. J Neurosurg Spine. 2021:1-9.

2. Uğurlu M, Aksekili MAE, Alkan BM, Kara H, Çağlar C. Effects of Artcure Diffusional Patch application on pain and functional status in lumbar disc herniation patients: a prospective randomized controlled study. Turk J Med Sci. 2017 ;47(3):874-882.

3. Colak, H., Akturk, S., Buyukavci, R., & Ersoy, Y. Investigating the effectiveness of artcure transdermal diffusional patch in patients with cervical disc herniation: A randomized placebo-controlled study. Medicine,2022;11(2), 502-6.

SHORT AND LONG TERM EFFECTS ON PAIN AND FUNCTIONAL CONSTELLATION OF ARTCURE DIFFUSIONAL PATCH APPLICATION ON PATIENTS WITH LUMBER DISCOPATHY.

CLINICAL STUDY CENTRE

HACETTEPE UNIVERSITY FACULTY OF MEDICINE - PHYSICAL MEDICINE AND REHABILITATION DEPARTMENT, ANKARA TRAINING AND RESEARCH HOSPITAL - PHYSICAL MEDICINE AND REHABILITATION CLINIC, YILDIRIM BEYAZIT UNIVERSITY FACULTY OF MEDICINE - PHYSICAL MEDICINE AND REHABILITATION DEPARTMENT, NUMUNE TRAINING AND RESEARCH HOSPITAL - RADIOLOGY CLINIC, ANKARA / TURKEY.

HEAD OF THE CLINICAL RESEARCH

PROF. DR. PINAR BORMAN

The effectiveness of Transdermal Herbal Patch (Artcure®) in the treatment of Low back Pain due to Lumbar Disc Herniation: A Randomized Placebo-controlled Clinical and MR imaging-based Study

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BACKGROUND / AIM

Low back pain due to lumbar disc herniation (LDH) is common in our routine practice. Artcure® is a recently developed transdermal patch comprising a mixture of 6 herbal oils, which has been shown to reach to the bulged out herniated disc and decrease the volume of HNP, reduce the nerve root irritation and relieve the pain (1). After wrapping the Artcure® patch to the LDH area, absolute bed rest is necessary for 24 hours. Then the patient take off the patch and turn back to routine daily activities. The product has been on the market and used among LDH patients since a few years. The aim of this randomized placebo controlled study was to investigate the effects of Artcure® patch in the treatment of LDH, with regard to pain, functional status and magnetic resonance imaging (MRI) findings.

METHODS

We conducted a randomized placebo-controlled double-blind trial to evaluate the effectiveness of Artcure patch application for patients with low back pain due to LDH. The diagnoses were based on clinical symptoms (24) and consistent images by MRI (25). Patients were recruited from outpatient clinics of Physical Medicine and Rehabilitation, Ankara Training and Research Hospital between August 2019 and March 2020. Written informed consent was obtained from all participants. The study was conducted in accordance with the Helsinki Declaration and was approved by local ethics committee of the Yıldırım Beyazıt University (2019-).

The inclusion criteria were; aging 20-60 years; having low back pain and radicular pain due to LDH confirmed clinically (limited range of motion of the lumbar spinal columna, sensory or

motor disturbance, positive results from straight leg raising test -for L5-S1 disc herniation, or femoral nerve stretch test-for L3-4 disc herniation) and by MRI findings (protrusion or extrusion of lumbar disc); BMI <30 kg/m^2 ; ruling out other comorbid pathologies (fracture, spondylolisthesis, malignancy, ostoporosis, infection); willing to participate in this study and signing the informed consent. In addition, this had to be the first onset or presentation in the acute or subacute stages of a repeated attack. Individuals having a history of any spinal surgery; having other pain syndromes like neuropathic pain; having neurological diseases; diabetes mellitus, asthma, cardiovascular disease, chronic rheumatic conditions; who are pregnant; having skin problems in the lumbar region; having indications for immediate surgery (myelopathy or cauda equina syndrome); having muscular strength of muscles innervated by lumbar roots <3; having severe muscle spasm in the lumbar region; presence of disc herniation at more than 2 disc levels; lumbar canal stenosis and having bilateral symptoms (median disc herniation), were excluded.

At enrollment a baseline evaluation of all subjects was completed then the patients were recruited according to the inclusion and exclusion criteria. Demographic and clinical properties; comprising age, sex, body mass index (BMI), duration of pain, range of lumbar motion and MRI findings were determined. The lumbar/radicular pain were assessed by visual analog scale (VAS), and functional disability was assessed by Turkish version of Oswestry Disability Index (ODI) (26). A 100- mm VAS with vertical lines intersecting multiples of 10 was used to measure the intensity of pain. The ODI calculation formula is actual cumulative score/45

x 100% with higher percentage indicating more severe functional disability. Previous studies have shown good reliability and validity in Turkish patients (26).

All individuals underwent MRI evaluation of their lumbar spines before and 2 months after the study. The same MRI technique and the same 1.5 Tesla MRI scanner (Magnetom Avanto, Siemens Healthineers, USA) were used for both groups. Subjects were scanned in the supine

position using a spine matrix coil. MRI images as a focal displacement of the disc fragment beyond the intervertebral space was determined (25). Disc herniations are classified as protrusion and extrusion, using T2 weighted sagittal MRI. The size of the herniated mass was determined from the ratio of the antero-posterior diameter of the spinal canal (C- value) to the maximum antero-posterior diameter of the herniated disc (H-value) on T2 weighted axial MRI scans (27,28). All MRI studies were evaluated by an experienced radiologist, in a blinded fashion.

Patients were randomly assigned to Artcure Diffusional Patch group (Group 1) and placebo patch group (Group 2) by the ratio of 2:1 using computer-generated numbers. The randomized treatment assignments were sealed in opaque envelopes and opened individually for each patient who agreed to participate in the study. The therapeutic and placebo patches were obtained from the manufacturer (Metuas Medical Limited Cooperation, Turkey).

The patients in Group 1 applied Artcure patch and the subjects in Group 2 applied placebo patches. The Artcure Diffusional Patch is a mixture of different herbal oils combined together in a gel form with dextrine palmitate in which liquid paraffin is used as a solving agent. The product is formulated as an oleogel. The oleogel form is selected in order to transfer the hydrophobic basic materials to the affected area without any corruption regarding physicochemical structures (22,23).

This patch penetrates the skin and distribute towards to target herniated nucleus pulposus area beneath the application area and acts with diffusion and volume effects (23). The gel contains no color additives or preservation products. The main ingredients are oleum thymi (CAS No: 8007-46-3), oleum chamomillae (CAS No: 8015-92-7), oleum rosmarini (CAS No:8000-25-7), oleum black cummin seed (CAS No:8014-13-9), oleum lauris nobilis (CAS No:8002-41-3) and oleum limonis (CAS No:8008-56-8).

In the development phases of formulation 11 single formulation were composed. These formulations were examined regarding incompatability, physicochemical and microbiological features, density, absorption by skin in 37

degrees, osmolarity and viscosity values. The ratio of oils in this formulated gel is shown in Table 1. It is suggested that these oil ingredients of the patch increases the membrane permeability of anulus fibrosis, decreases the intra-osmotic pressure and causes water loss by diffusion. By means of this and by the anti-inflammatory and anti-edema effects of the ingredients of Artcure patch, the mass of nucleus pulposus decreases in the herniated disc area (22,23).

The placebo patch was identical to Artcure Patch in color, stiffness, and smell but lacking of the active 6 herbal oils. The identical smell and color were formulated by essences of Daphne-30161, peppermint-0701544 and eucaliptus-0701603 according to the same production method, along with dextrine palmitate and liquid paraffine. A gel without 'mixture of different herbal oils' yet with a very similar herbal odour was placed into patch instead of the active gel and patch was closed by the same production method. The superior border of the iliac crest was palpated while the patients are lying in prone position and the L4 – 5 level was determined. The level of disc pathology was identified by drawing a line with a dermal pen. The center of the patch is placed on the signed area. The patches in which herbal oils were placed at the midmost region, were fixed with flaster given in the box, to the lumbar affected area (Figures 2-5). After wrapping the Artcure® patch to the area of herniated nucleus pulposus, the hospitalized patients were given a bed rest in supine position for 24 hours except imperative daily activities like eating and toilette activities. It was taken off 24 hours later and patients went back to their routine daily activities.

All subjects received information about disc disease and instruction about daily living activities. All were given isometric lumbar exercises based on home exercise program. They were not allowed to take any pain medication during the study.

The primary outcome measures were; the intensity of low back/radicular pain and functional disability assessed by ODI, which were determined at baseline, immediately after the interventions (24-48 h later) and 2 months later; and the changes in the size of herniated nucleus pulposus assessed by axial MR images, which were determined at baseline and at the end of two months. The secondary outcome measure was the improvement in lumbar ROM. All questionnaires were administered by a blinded study coordinator at each follow-up. All patients, clinicians, radiologist, post-procedure evaluator remained blinded to treatments until after database lock, except those persons responsible for the distribution of the patches and the biostatistician preparing the random code.

RESULTS

Between August 2019 and March 2020 a total of 258 patients with low back pain due to LDH were recruited. 178 were rejected according to inclusion and exclusion criteria and 14 patients did not give informed consent. Therefore 66 patients were randomly assigned in accordance with the ratio of 2:1 to the therapeutic patch and placebo patch group. There were 4 dropouts in

Artcure Diffusional Patch and 2 dropouts in the placebo groups due to nonpermitted medication or loss of 2 month follow-up. Figure 1 indicates the flow chart.

Table 2 shows the demographic and clinical properties of the subjects in both groups. No statistical difference was observed between the groups in regard to baseline demographic and clinical characteristics. The majority of the subjects were women. The locations of symptomatic nerves in the patient and placebo groups were mostly at L4-L5 and L5-S1 nerve roots. The most common anatomical herniation profile was protrusion in both groups.

The mean values for outcome measures are reported in Table 3 for treatment and placebo groups across time points. Both groups improved with treatments immediately after (24-48 h) the interventions in regard to pain and functional disability, assesed by VAS and ODI. At 2 month follow-up, compared with baseline, the improvements in pain and disability scores remained significant only in the Artcure Diffusional Patch group but not in the placebo group.

Accordingly, the change in the size of the herniated mass (C/H) was statististically significant only in the therapeutic group (Table 3). The mean resorption ratios were 12.53 and 2.86 in the patch and placebo groups respectively. Figures 6 and 7 show the MRI images of 2 patients before and after the Artcure diffusional patch treatment. In addition mean extension and rotation ranges of the lumbar spine were improved in the Artcure Patch group, not in the placebo group, at the end of 2 months.

Clinically significant improvements in pain and disability have been defined previously as 3 point decrease in VAS and 10-point decresae in ODI (29,30). We have further performed subgroup analyses. The number of patients improved in regard to pain and disability was similiar between the groups, immediately after the interventions ($p>0.05$, data not shown). 18 (52.9%) patients in therapeutic group and 3 patients (17.6%) in placebo group had an improvement in pain scores (change score >2) from baseline to 2 month follow-up and the difference between

the groups was statistically significant (p=0.016). 28 patients (82.4%) in group 1 and 9 (53%) patients in group 2 reported better outcomes in physical disability (>30% change from baseline) assessed by ODI at the second month follow-up, and the difference between the groups was statistically significant (p<0.05).

Adverse events: 2 patient in Artcure and 1 patient in placebo group experienced mild itching and irritation during the intervention. After taking off, no local symptoms rash, blister or redness of skin was observed. No other adverse events were encountered in either therapeutic patch or placebo group. No patients developed neurological deterioration during the study period.

CONCLUSION

The results of this randomized controlled trial support the notion that the treatment effects provided by Artcure Diffusional herbal patch are non-placebo effects as shown in outcome measures and MRI imaging at 2 month follow-up in patients with LDH. Therefore this alternative intervention offers as a non-invasive simple, time saving and safe option for these carefully selected patients. The positive effect of Artcure may delay or prevent the need for extensive or time consuming conservative or minimal invasive interventional approaches which are costly and needing human resources. The potency and longer relief of pain and requirement of only one day bed rest may make it a practical alternative choice in selected patients suffering from LDH. A lengthier follow-up period with a large sample may be beneficial in determining the longer term benefits of Artcure transdermal patch.

Table 2: The demographic and clinical properties of the patients in both groups.

	Group 1 n=40		Group2 n=20		
	Mean	SD	Mean	SD	P
Age (years)	45.6	10,05	43.7	10,06	0,283
BMI (kg/m²)	28,52	4,22	28.86	3,47	0,827
Duration of pain (weeks)	22,67	25,88	18,29	24,9	0,313
Gender (male/female)	18/22	-	8/12	-	0,512
MRI pathology n (%)					
L3-4 protrusion	33(8,8)		21(5,9)(10		
L4-5 protrusion	12- (30)		5-(25)		
L5-S1 Protrusion	2610(29,4)(65		153(17,6)(75		
L5-S1 extrusion	2-(5,9)		2-(10)		
	25(73,5)		13(76,47)		
	2(5,9)		1(5,9)		

Table 3: The outcome measures of Artcure and placebo patch groups before and after the therapies

	Group 1 n=40		Group2 n=20		
Outcome Measure	Mean	SD	Mean	SD	P
VAS-pain					
Baseline	6,15	1,5	5,88	1,76	0,806
After therapy	4,73	1,5	4,47	2,29	0,976
2 month	3,35	1,8	5,23	2,43	0,003[a]
ODI score					
Baseline	51,11	15,42	55,17	14,45	0,362
After therapy	44,11	14,24	49,41	14,97	0,269
2 month	33,68	15,36	48,23	13,39	0,002[b]
MRI-C/H (%)					
Baseline	39,94	1,83	38,74	1,87	0,145
2 month	34,89	1,91	37,63	1,95	0,001[b]
Lumbar flexion (°)					
Baseline	54,41	9,75	55,88	9,87	0,674
2 month	59,88	5,81	60,88	7,12	0,641
Lumbar extension (°)					
Baseline	8,08	7,58	7,94	5,32	0,749
2 month	14,23	5,84	10,29	4,49	0,023[b]
Lumbar rotation (°)					
Baseline	23,55	8,56	31,52	7,81	0,004[b]
2 month	30,73	4,7	35,05	6,62	0,007[b]
Lumbarlateral flexion(°)					
Baseline	29,55	7,42	31,94	7,18	0,368
2 month	35,2	5,15	34,47	7,81	0,758

VAS: visual analog scale, **ODI:** Oswestry Disability Index, **MRI:** Magnetic resonance imaging [a]Student t Test
[b]Mann Whitney U Test

Table 4: Comparison of the improvement in the outcome measures between the Artcure and placebo patch groups

	Group 1 n=40		Group2 n=20		
Outcome Measure	Mean	SD	Mean	SD	P
VAS-pain					
Baseline	6,15	1,5	5,88	1,76	0,806
After therapy	-1,41	0,89	-1,41	1,12	0,966
2 month	-2,79	1,66	-0,64	1,45	0,000[a]
ODI score					
Baseline	51,11	15,42	55,17	14,45	0,362
After therapy	-7,0	4,29	-5,76	6,36	0,441
2 month	-17,23	10,86	-6,94	11,53	0,006[b]
MRI-C/H (%)					
Baseline	39,94	1,23	38,74	1,87	0,959
2 month	-12.53	0,8	-2,86	0,4	0,001 [a]
Lumbar flexion (°)					
Baseline	54,41	9,75	55,88	9,87	0,674
2 month	5,47	7,7	5,0	10,15	0,408
Lumbar extension (°)					
Baseline	8,08	7,58	7,94	5,32	0,749
2 month	6,14	5,49	2,35	5,33	0,032[b]
Lumbar rotation (°)					
Baseline	23,55	8,56	31,52	7,81	0,004
2 month	7,17	6,9	3,52	5,91	0,094
Lumbarlateral flexion(°)					
Baseline	29,55	7,42	31,94	7,18	0,368
2 month	5,64	6,94	2,52	8,05	0,162

VAS: visual analog scale, **ODI:** Oswestry Disability Index, **MRI:** Magnetic resonance imaging [a]Student t Test
[b]Mann Whitney U Test

CLINICAL STUDY CENTRE

ANKARA TRAINING AND RESEARCH HOSPITAL AND HACETTEPE UNIVERSITY DEPARTMENT OF PHYSIOTHERAPY

HEAD OF THE CLINICAL RESEARCH

PROF.DR. PINAR BORMAN

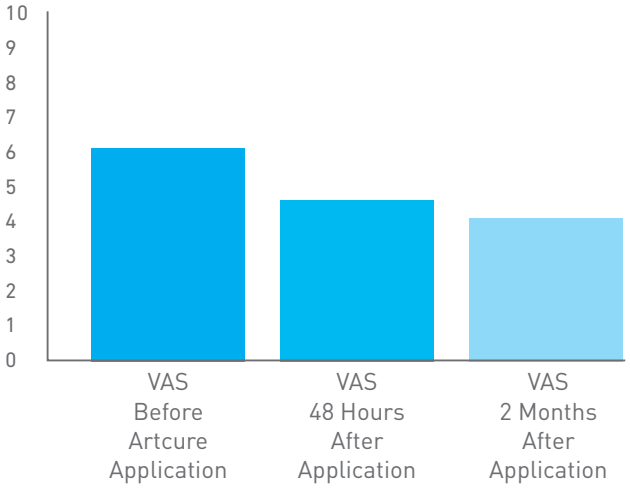
TOTAL NUMBER OF VOLUNTEERS SCREENED AT THE BEGINNING OF THE STUDY 80

NUMBER OF VOLUNTEERS PATCHED DURING THE STUDY 34

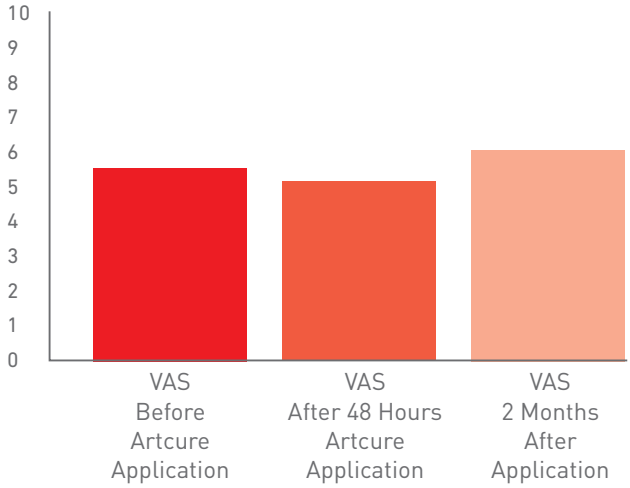
PLACEBO APPLICATION DURING THE STUDY 17

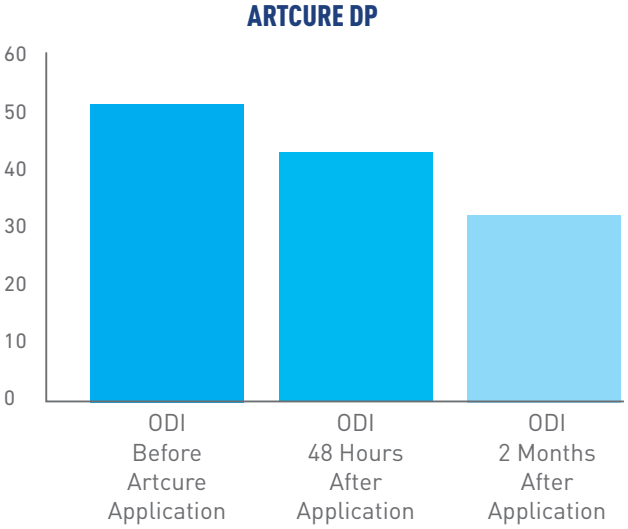
YEAR OF THE STUDY 2019

ARTCURE DP



PLACEBO




ARTCURE DP
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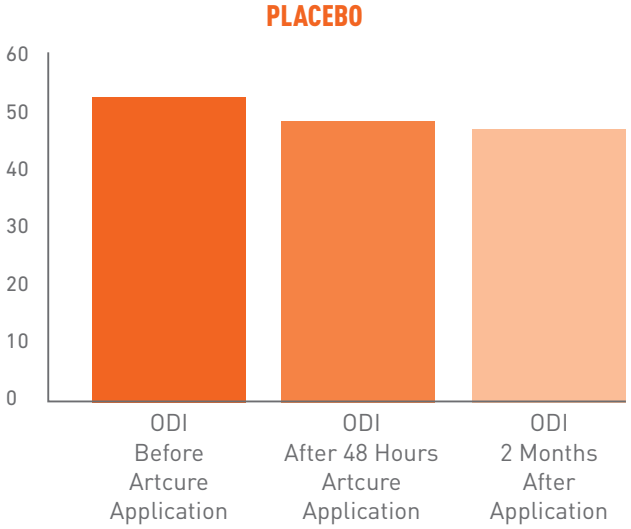
ODI Before Artcure Application
ODI 48 Hours After Application
ODI 2 Months After Application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ODI Before Artcure Application
ODI After 48 Hours Artcure Application
ODI 2 Months After Application

SPECIALTY IN MEDICINE THESIS / 2020: RESEARCH OF THE EFFECTIVENESS OF ARTCURE TRANSDERMAL DIFFUSIONAL PATCHING ON PAIN AND FUNCTIONAL CONDITION IN PATIENTS WITH CERVICAL DISC HERNIA

CLINICAL STUDY CENTRE

INONU UNIVERSITY FACULTY OF MEDICINE - DEPARTMENT OF PHYSICAL MEDICINE AND REHABILITATION

HEAD OF THE CLINICAL RESEARCH

DR. HÜSEYİN ÇOLAK

MATERIAL/METHOD

48 patients aged 21-59 years and diagnosed with cervical disc herniation were included in our study. Individuals were randomly divided into two groups as the diffusional patch group and the placebo patch group. After obtaining the demographic information of all individuals, Visual Analog Scale (VAS) was used to evaluate pain, Leeds Assessment of Neuropathic Symptoms and Signs Scales (LANSS) was used to evaluate neuropathic pain, and Neck Disability Survey (NDS) was used to determine functional level. The evaluations of all individuals at baseline, at week 4, and at week 12 were obtained. The diffusional transdermal patch and the placebo patch were applied once to each patient group for 24 hours as recommended.

FINDINGS

A total of 48 patients, 33 women and 15 men, with a mean age of 48.33±8.99 years, were included in the study. When compared with the initial parameters in the Diffusional Transdermal Patch applied group; It was determined that pain decreased, neuropathic symptoms regressed and functional level improved. When the groups were compared among themselves, it was determined that there was a significant difference between the groups in terms of pain, neuropathic symptoms and functional status at the 4th and 12th weeks, and this difference was more distinct in the transdermal diffusional patch group ($p<0.05$).

CONCLUSION

48 patients (24 patients in each group) aged 20-60 years were included in the study. The average age of all patients participating in the study was 48.33±8.99 years, 68.75 % (n=33) of whom were female and 31.25 % (n=15) were male (Table 1).
Radiologically, 81.25% (n=39) of the participant patients had protruded disc herniation and 18.75% (n=15) had extruded disc herniation (Table 1). Groups of patients with apparent cervical spondylosis or spinal stenosis were not included in the treatment. Of the patients, 47.9% (n=23) were treated for one herniated disc, 37.5% (n=18) for two herniated discs, 12.5% (n=6) for three, and 2.08% (n=1) for four discs. Radiologically, 27.08% (n=13) of the participant patients with cervical disc herniation had central disc herniation, and 72.91% (n=35) had posterolateral disc herniation.
Both groups were similar concerning age, gender, type of cervical disc herniation, and localization ($P>0.05$) (Table 1).

Table 1: Demographic data and baseline values of outcomes

		Artcure	Placebo	P
		n=24(50)	n=24(50)	
Age		46.75±8.09	49.91±9.72	0.794[a]
Gender	Female	15(62.5)	18(75)	0.350[b]
	Male	9(37.5)	6(25)	
Type of Herniation	Protrusion	18(75)	21(87.5)	0.267[b]
	Extrusion	6(25)	3(12.5)	
Herniation Localization	Central	8(33.3)	5(20.8)	0,330[b]
	Posterolateral	16(66.6)	19(79.16)	
Number of Herniation	Single	13(54.16)	10(41.66)	0,055[b]
	Multiple	11(45.83)	14(58.33)	

a: Independent t test

b : Pearson Chi-Square test

Intra-group and inter-group average VAS values for pre-treatment, 4th and 12th post-treatment weeks are given in Table 2. It was determined that there was a significant decrease in the VAS values at the 4th and 12th weeks in the 1st group of Artcure patients compared to the 2nd group of placebo patients ($p<0.05$). In the placebo group, the VAS values at the 4th and 12th weeks were similar ($p>0.05$).

Although there was a significant difference concerning the NPDS values between the pre-treatment and 4th and 12th post-treatment weeks in the Artcure group, there were no significant changes in patients in the placebo group concerning the values of pre- treatment and 4th and 12th post-treatment weeks ($p>0.05$) (Table 3).

Intra-group and inter-group averages of the LANSS values for pre-treatment, 4th, and 12th post-treatment weeks are given in Table 4. Evaluating the VAS values at the 4th and 12th post-treatment weeks between the groups, it was determined that there was a significant difference in favor of the Artcure group ($p<0.05$). However, it was determined that there was no significant change between the pre-treatment and post-treatment values in the placebo group ($p>0.05$) (Table 4).

Table 3: Comparison of intra and inter-group NPDS parameters

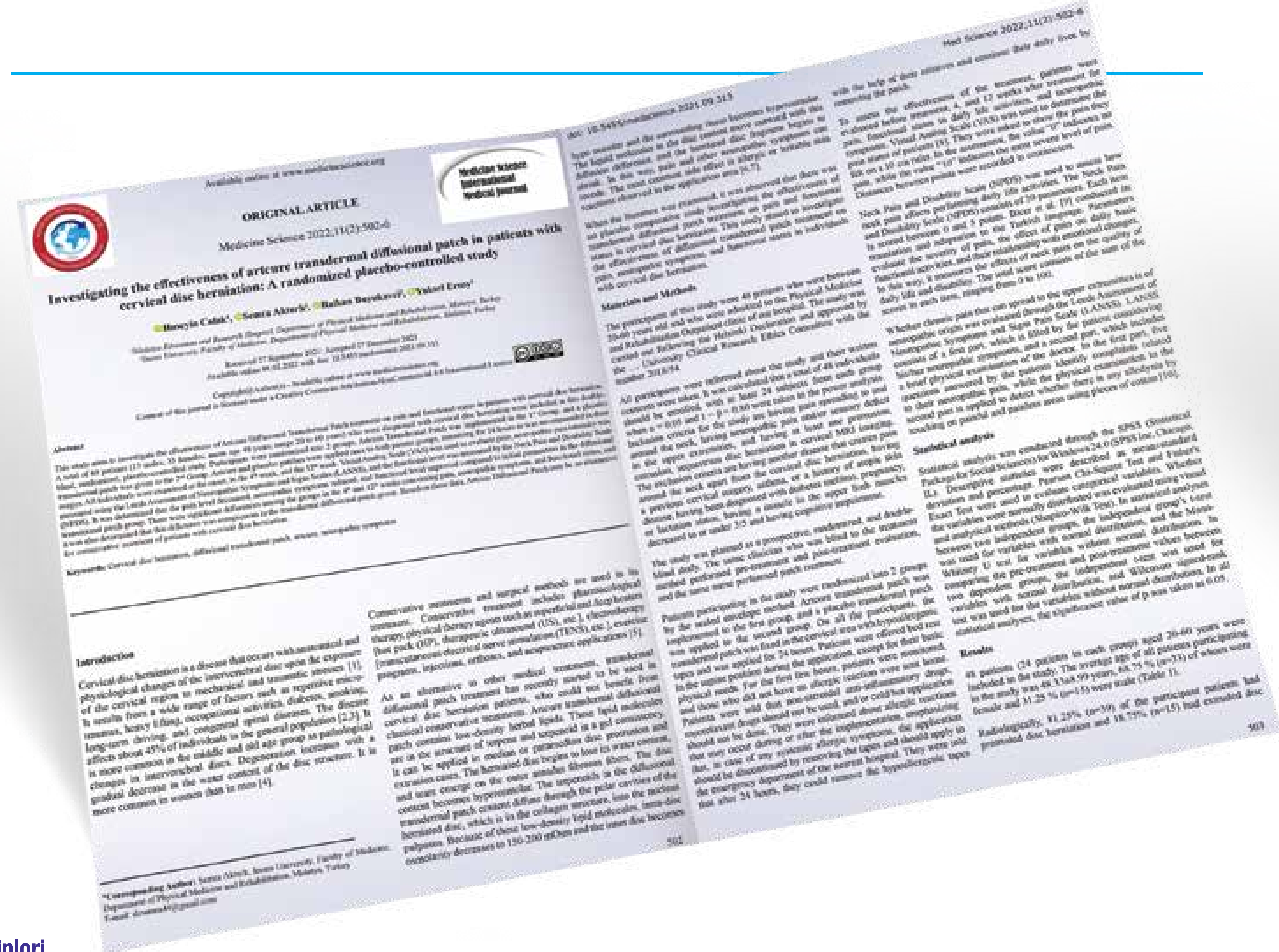
		Artcure (n=24)	Placebo (n=24)	P
NPDS	Pretreatment	31.45±9.72	28.41±0,83	0.37[a]
	4th week	17.08±1.93	29.16±1.01	<0.001[a]
	12th week	21.20±1.84	29.91±0,97	0,006[b]
	P	P1:<0.001[d]	P1:0.09[d]	
		P2:<0.001[e]	P2:0.1[e]	
		P3:<0.001[e]	P3:0.68[e]	

NPDS: Neck Pain and Disebility Scale **a:** Independent T test **b:** Mann-Whitney U test **c:** Wilcoxon signed rank test **d:** Paired Sample T test
P1: Comparison of pretreatment and 4th week **P2:** Comparison of pretreatment 12th week **P3:** Comparison of 4th week and 12th week

Table 4: Comparison of intra and inter-group LANSS parameters

		Artcure (n=24)	Placebo (n=24)	P
LANSS	Pretreatment	16,54±0,66	14,58±0,75	0.113[a]
	4th week	8,54±0,97	15,37±0,83	<0.001[a]
	12th week	11,08±1.05	15,41±0,82	<0.001[b]
	P	P1:<0.001[d]	P1:0.114[d]	
		P2:<0.001[e]	P2:<0.084[e]	
		P3:<0.001[e]	P3:0.739[e]	

LANSS: Leeds Assesment of Neuropathic Symptoms and Signs Pain Scale **a:** Independent T test **b:** Mann-Whitney U test **c:** Wilcoxon signed rank test
d: Paired Sample T test **P1:** Comparison of pretreatment and 4th week **P2:** Comparison of pretreatment 12th week **P3:** Comparison of 4th week and 12th week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ORIGINAL ARTICLE

Medicine Science 2022;11(2):502-6

Medicine Science International Medical Journal

Investigating the effectiveness of artcure transdermal diffusional patch in patients with cervical disc herniation: A randomized placebo-controlled study

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doi: 10.5455/medscience.2021.09.315

Med Science 2022;11(2):502-6

Abstract

Keywords: Cervical disc herniation, diffusional transdermal patch, artcure, neuropathic symptoms

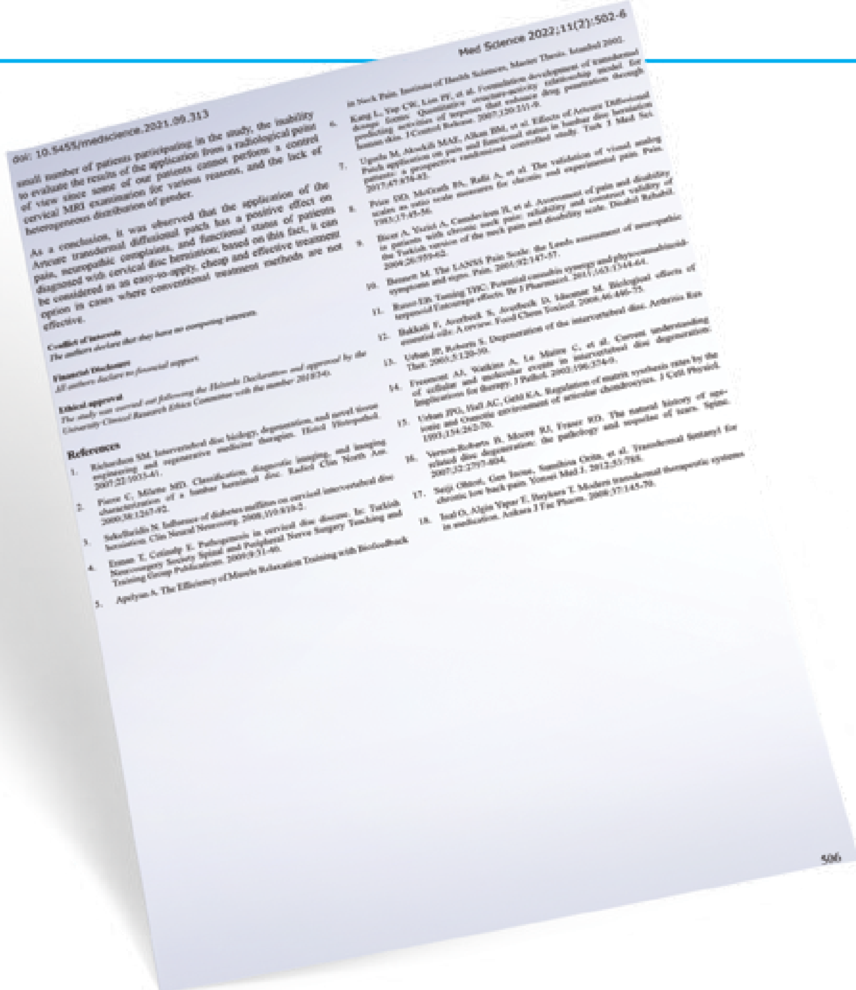
Introduction

Cervical disc herniation is a disease that occurs with anatomical and physiological changes of the intervertebral disc upon the exposure of the cervical region to mechanical and traumatic stresses [1].

Materials and Methods

Statistical analysis

Results



doi: 10.5455/medscience.2021.09.313

Med Science 2022;11(2):502-6

small number of patients participating in the study, the inability to evaluate the results of the application from a radiological point of view since some of our patients cannot perform a control cervical MRI examination for various reasons, and the lack of heterogeneous distribution of gender.

As a conclusion, it was observed that the application of the Arcuate transdermal diffusional patch has a positive effect on pain, neuropathic complaints, and functional status of patients diagnosed with cervical disc herniation; based on this fact, it can be considered as an easy-to-apply, cheap and effective treatment option in cases where conventional treatment methods are not effective.

Conflict of interests

The authors declare that they have no competing interests.

Financial Disclosure

All authors declare no financial support.

Ethical approval

The study was carried out following the Helsinki Declaration and approved by the University Clinical Research Ethics Committee with the number 2019/34.

PROVIDING HYPO-OSMOLAR CONDITION WITH DIFFUSIONAL TRANSDERMAL PATCH SUPPRESS DEGENERATED INTERVERTEBRAL DISC-INDUCED PAIN POSSIBLY VIA TRANSIENT RECEPTOR POTENTIAL VANILLOID IN RABBITS

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AIM

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Materials-Methods: Rabbits underwent IVD degeneration with an annular stab surgical technique and were randomly assigned to sham (n=25), sham +transdermal patch (n=20), IVD degeneration (n=25), IVD degeneration +transdermal patch (n=27), and IVD degeneration +transdermal patch +ruthenium red, a transient receptor potential vanilloid (TRPV) antagonist (n=20), groups. The patch was taped on the animal's back for 24 hours at 4 weeks post-surgery. Ruthenium red was injected intraperitoneally at 1 hour before the patch was applied. Pain was assessed by the grimace scale, and IVDs were harvested at 5 weeks post-surgery, being analyzed by the measurements of density and viscosity and immunohistochemical staining.

Results: Pain score was significantly worse in the IVD degeneration group, and was significantly improved by the patch, which significantly decreased density, viscosity and cellularity associated with proapoptotic cleaved-caspase-3 activation in the degenerated IVD. Ruthenium red abolished the patch's effects.

CONCLUSION

Providing hypo-osmolar condition with diffusional transdermal patch may be a new non-surgical treatment against IVD degeneration-induced pain by decreasing viscosity, density and increasing proapoptotic effect possibly via TRPV.

KEYWORDS

Intervertebral disc, Pain, Rabbit, Transdermal patch

This study was presented Fifth Medical Rehabilitation Congress.(3-6 November 2016)

INTRODUCTION

Upper extremity lymphedema is a concerning complication after treatment for breast cancer. If left untreated, functional disability, psychosocial problems, and impaired quality-of-life (QoL) can be seen in patients with breast-cancer-related-lymphedema (BCRL).

AIM

The aim of this study was to evaluate the effects of complex-decongestive-therapy(CDT) in patients with BCRL, in regard to volume reduction, functional status and QoL and to investigate the effect of obesity on recovery.

METHOD

Eighty one patients with unilateral BCRL were included. All patients received combined phase1 CDT including skin care, manual lymphatic drainage, multilayer bandaging and supervised exercises five times a week for three weeks, as a total of 15 sessions. Patients were assessed by limb volumes and excess volumes according to geometric approximation derived from serial circumference-measurements of the limb, prior to treatment and at the end of third week. The functional disability was evaluated by quick disability of arm, shoulder and hand questionnaire (Q-DASH). QoL was assessed by the European Organization for Research and Treatment of Cancer Core Cancer Quality of Life Questionnaire (EORTC-QLQ-C30), its breast cancer module (EORTC-QLQ-BR23) and Lymphedema Quality-of-Life Questionnaire-Arm (LYMQOL-Arm).

RESULTS

This retrospective study included a total of 81 BCRL patients (81 females; mean age 53.64±10.43 years; range, 28 to 87 years). Half of the patients were obese and the mean BMI was 30.32 kg/m^2. The median duration of lymphedema was 12 months. There were 28 patients in stage1, 52 in stage2 and one patient in stage3. The mean baseline limb and excess volumes were significantly decreased at the end of therapies (3183±681cm^3 vs 2912±599cm^3 and 30.1% vs 19.3%, p=0.000,respectively).

Q-DASH, physical functioning, pain, global health status scores in EORTC-QLQ-C30 instrument, arm symptoms in BR23, as well as all subscores of LYMQOL-Arm questionnaires were significantly improved after 3 weeks-CDT therapy ($p<0.05$). When the patients with a body mass index below and above 25 were compared, the improvement in function, appearance, symptom and emotion scores of LYMQOLARM was significantly different between the two groups. We determined a significant negative correlation between the improvement of function and appearance subscores of LYMQOL-Arm and body mass index (p=0.005, r=-0.486 and p=0.042, r=-0.361), as well as a significant negative relationship between the improvement of excess volumes and stemmer sign positivity (p=0.012, r= -0.279).

CONCLUSIONS

In conclusion, phase 1 CDT performed daily for 3 weeks, greatly reduces the volumes and obesity affects the improvement in quality of life obtained as a result of CDT. included in the study. Patients will be given placebo and real artcure in a 3 to 1 ratio (30 patients for real artcure, 10 patients for placebo application). Patients will be evaluated by the same physician 2 times before the application and at 3rd month after the application with Visual Analog Scale, Oswestry and Neck Disability Index and the volume of herniated nucleus pulposus of the patients.

RESULTS

The duration of the study was determined as 6 months. The findings will be reported 6 months after the initiation of the study.

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STUDIES TO BE PRESENTED AT ISPRM 16th WORLD CONGRESS

THE EFFECTS OF OBESITY ON COMPLEX DECONGESTIVE THERAPY OUTCOMES IN PATIENTS WITH BREAST CANCER RELATED LYMPHEDEMA

Ayşegül Yaman[1], Pınar Borman[2], Funda Koç[3], Ruveyda Sarpat[1]

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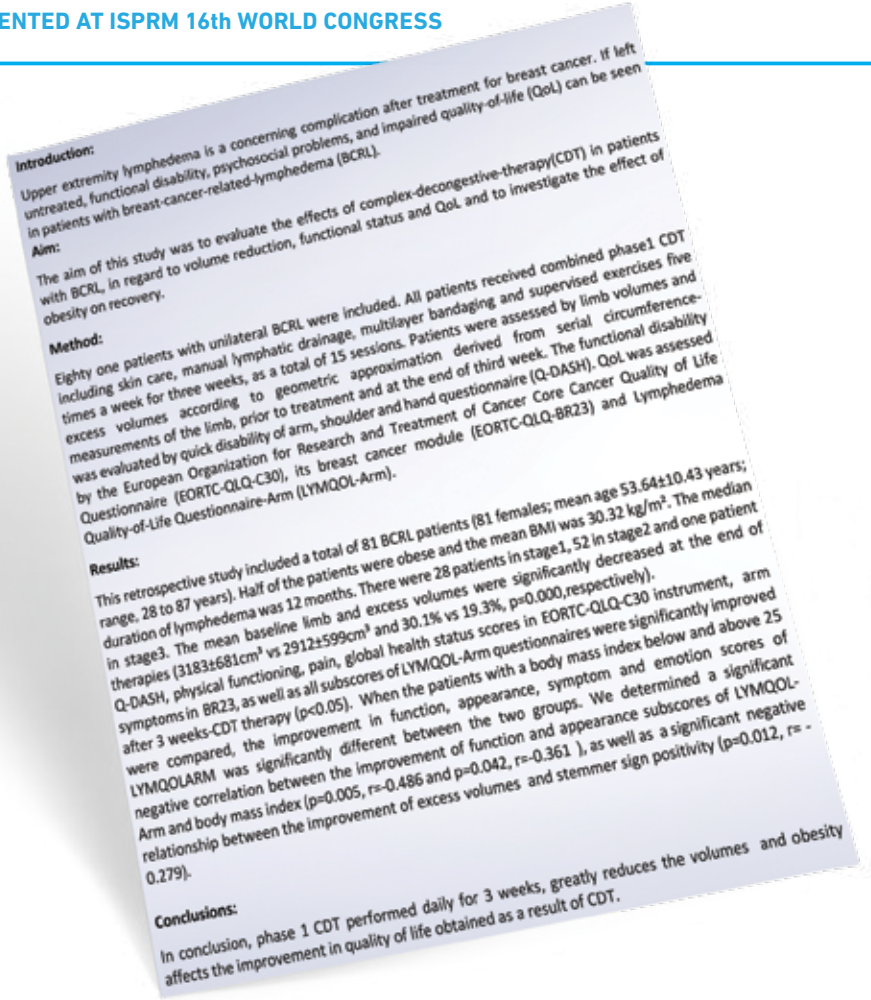
[3]Department of Physical and Rehabilitation Medicine, Hacettepe University Medical School, Ankara, Turkey



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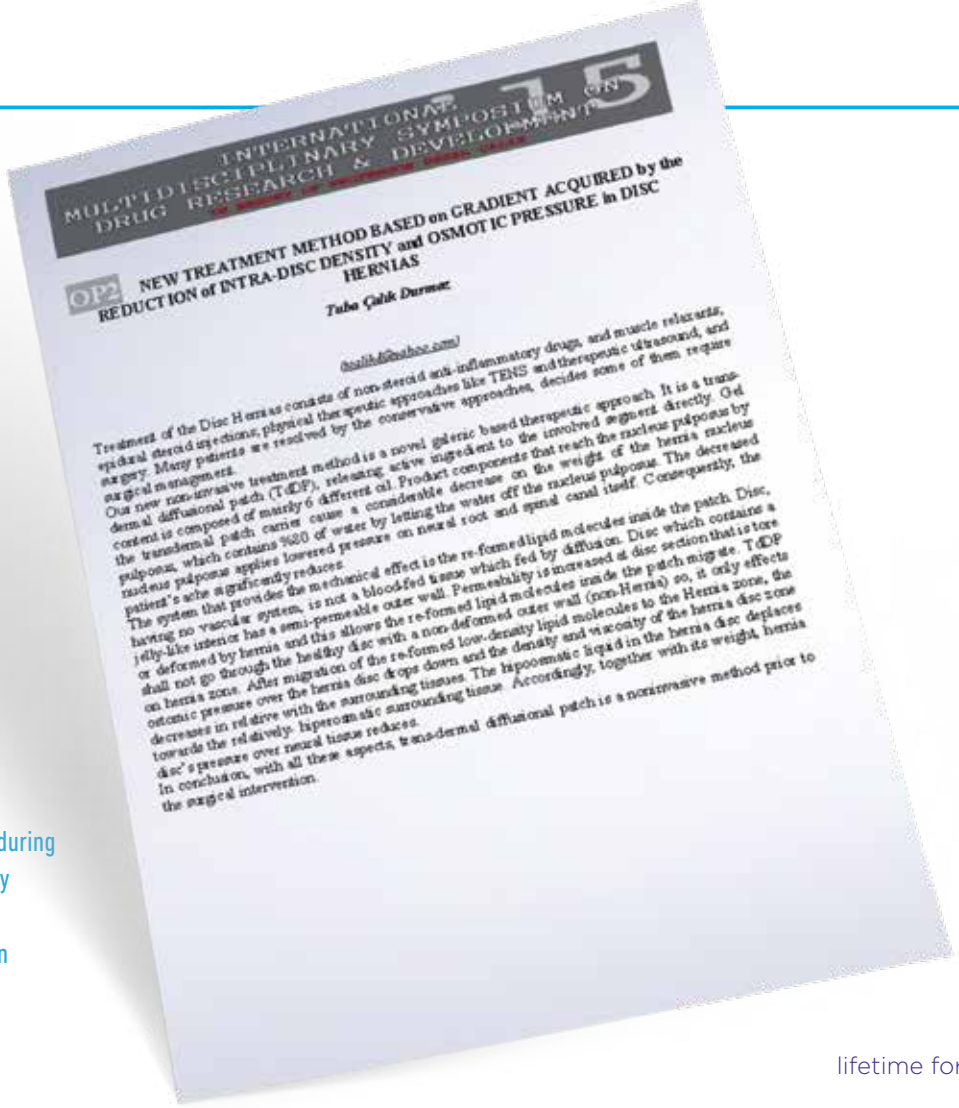
THE EFFICACY OF A TRANSDERMAL HERBAL PATCH (ARTCUREB) IN THE TREATMENT OF LUMBER DISC HERNIATION: A RANDOMIZED PLACEBO-CONTROLLED CLINICAL AND MR IMAGING-BASED STUDY
FOREFOOT PAIN CORRELATES WITH THE SESAMOID ROTATION ANGLE EVALUATED BY ULTRASOUND IMAGING



INTERNATIONAL MULTIDISCIPLINARY SYMPOSIUM ON DRUG RESEARCH & DEVELOPMENT 15

OP2

NEW TREATMENT METHOD BASED on GRADIENT ACQUIRED by the REDUCTION of INTRA-DISC DENSITY and OSMOTIC PRESSURE in DISC HERNIAS

Tuba Çalık Durmaz

(tcalik@mubac.com)

Treatment of the Disc Hernias consists of non-steroid anti-inflammatory drugs, and muscle relaxants, epidural steroid injections, physical therapeutic approaches like TENS and therapeutic ultrasound, and surgery. Many patients are resolved by the conservative approaches, decides some of them require surgical management.

Our new non-invasive treatment method is a novel galenic based therapeutic approach. It is a trans-dermal diffusional patch (TdDP), releasing active ingredient to the involved segment directly. Gel content is composed of mainly 6 different oil. Product components that reach the nucleus pulposus by the transdermal patch carrier cause a considerable decrease on the weight of the hernia nucleus pulposus, which contains %80 of water by letting the water off the nucleus pulposus. The decreased nucleus pulposus applies lowered pressure on neural root and spinal canal itself. Consequently, the patient's ache significantly reduces.

The system that provides the mechanical effect is the re-formed lipid molecules inside the patch. Disc, having no vascular system, is not a blood-fed tissue which fed by diffusion. Disc which contains a semi-permeable outer wall. Permeability is increased at disc section that is torn jelly-like interior has a or deformed by hernia and this allows the re-formed lipid molecules inside the patch migrate. TdDP shall not go through the healthy disc with a non-deformed outer wall (non-Hernia) so, it only effects on hernia zone. After migration of the re-formed low-density lipid molecules to the Hernia zone, the osmotic pressure over the hernia disc drops down and the density and viscosity of the hernia disc zone decreases in relative with the surrounding tissues. The hypoosmatic liquid in the hernia disc replaces towards the relatively hiperosmatic surrounding tissue. Accordingly, together with its weight, hernia disc's pressure over neural tissue reduces.

In conclusion, with all these aspects, trans-dermal diffusional patch is a noninvasive method prior to the surgical intervention.

Declared as verbal presentation during 15. International Multidisciplinary Symposium on Drug Research & Development which took place on 15-17 October.


Fiziksel Tıp ve Rehabilitasyon Bilimleri Dergisi
JOURNAL OF PHYSICAL MEDICINE AND REHABILITATION SCIENCES
5. TIBBİ REHABİLİTASYON KONGRESİ
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19
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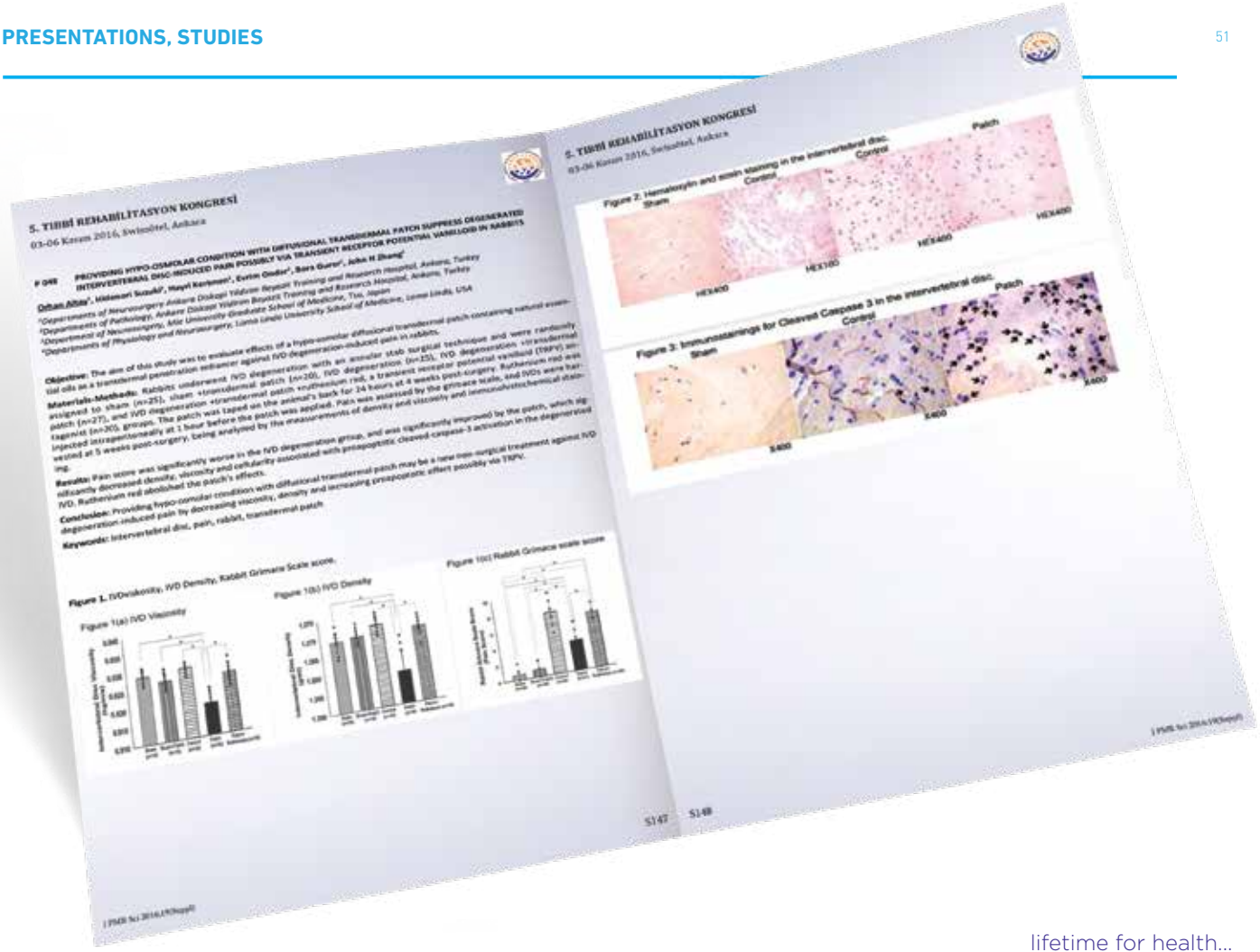
2
ekidir
ISSN: 1309-3843



5. TIBBİ REHABİLİTASYON KONGRESİ
03-06 Kasım 2016, Swissôtel, Ankara

P 048 **PROVIDING HYPO-OSMOLAR CONDITION WITH DIFFUSIONAL TRANSDERMAL PATCH SUPPRESS DEGENERATED INTERVERTEBRAL DISC-INDUCED PAIN POSSIBLY VIA TRANSIENT RECEPTOR POTENTIAL VANILLOID IN RABBITS**

Orhan Altin[a], Hidenori Suzuki[b], Hayri Kerimoğlu[c], Evrim Oktay[d], Sora Gurer[e], John H Zhang[f]
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[b]Departments of Pathology, Ankara Diskapi Yildirim Beyazit Training and Research Hospital, Ankara, Turkey
[c]Departments of Neurosurgery, Mie University Graduate School of Medicine, Tsu, Japan
[d]Departments of Physiology and Neurosurgery, Loma Linda University School of Medicine, Loma Linda, USA

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Figure 1. IVDviskosite, IVD Density, Rabbit Grimace Scale score.

Figure 1(a) IVD Viscosity

Figure 1(b) IVD Density

Figure 1(c) Rabbit Grimace scale score

5. TIBBİ REHABİLİTASYON KONGRESİ
03-06 Kasım 2016, Swissôtel, Ankara

Figure 2: Hematoxylin and eosin staining in the intervertebral disc.

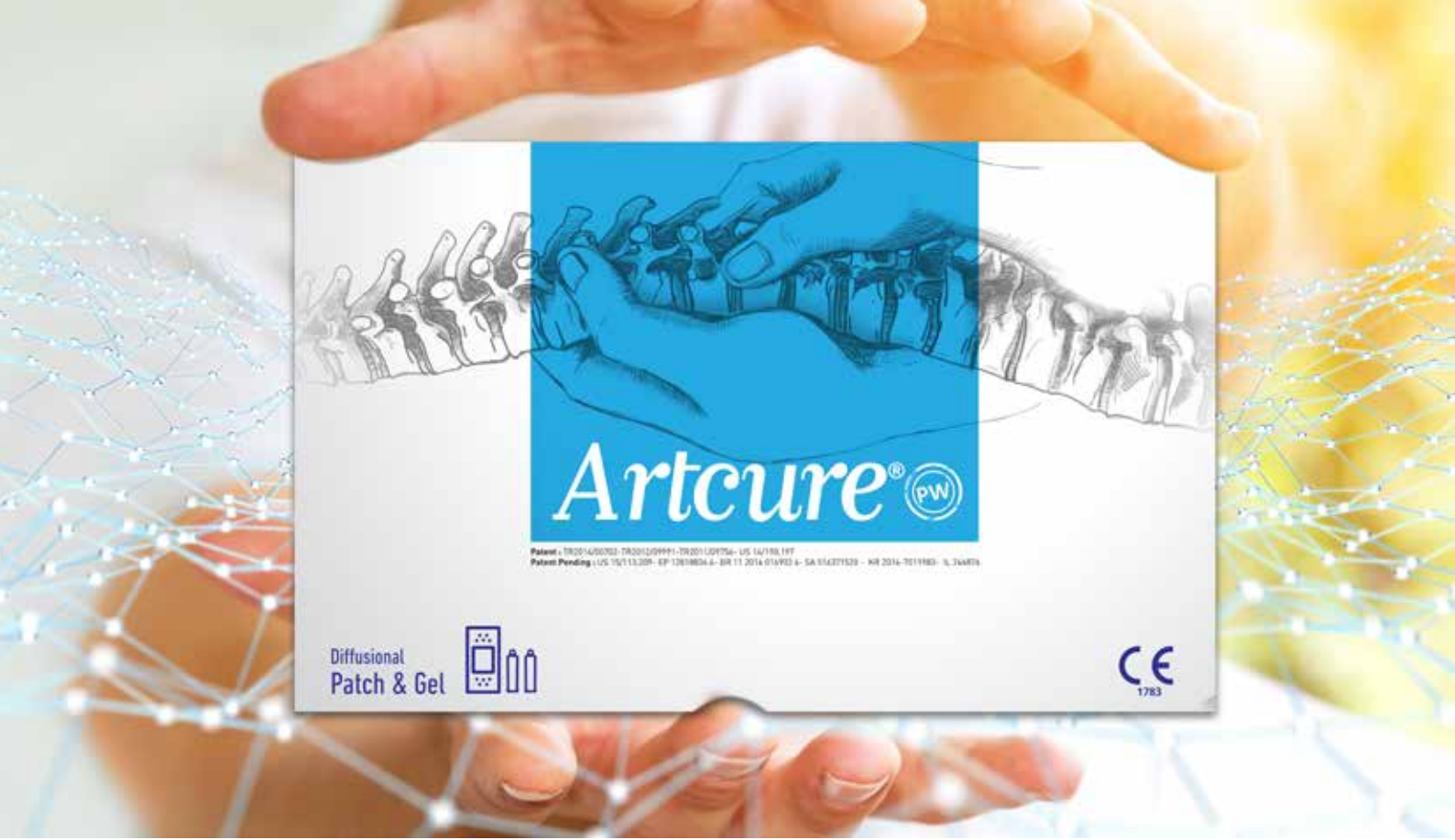
Sham | Control | Patch

HE X400 | HE X100 | HE X400

Figure 3: Immunostainings for Cleaved Caspase 3 in the intervertebral disc.

Sham | Control | Patch

X400 | X400 | X400



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