



ACUPUNCTURE AND BEE VENOM THERAPY VS. DICLOFENAC IN THE CHRONIC LOW BACK PAIN TREATMENT

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Abstract. Chronic low back pain (CLBP) can be treated by quite a large number of treatment methods, each method with its own advantages and drawbacks and comparable from the standpoint of efficiency, side effects, costs, necessary time, easiness, convenience etc. The aim of this paper is to assess and compare the effectiveness and side effects of three of the most common used therapies in CLBP. A prospective case-control study was conducted over a period of six months. A lot of 127 patients divided in three groups, have each followed one of the three mentioned treatments. The effectiveness was assessed through the pain intensity and pressure pain threshold (PPT), while the side effects were evaluated through clinical approach. The results were statistically processed and analyzed, the significance threshold being $p=0.05$. All the three applied treatments led to an improvement and the differences between the results were not significant. Acupuncture led to better results, but the differences became statistically significant slowly, in the last days of treatment. In what concerns the side effects, these were mostly minor and recorded especially for diclofenac. One major event was recorded in the case of bee venom therapy, namely anaphylactic shock was developed by one patient in the sixth treatment session. The results obtained by acupuncture or by bee venom therapy are not significantly, but due to the fact that they are less invasive than diclofenac, we conclude that these complementary therapies have to be maintained as cost-efficient alternative procedures in CLBP treatment.

Key words: chronic low back pain, diclofenac, acupuncture, bee venom

Introduction

Rheumatic diseases express the largest palette of pain, both under pain physiopathologic mechanisms and the pain intensity level. Among these, the chronic low back pain (CLBP) represents a major health problem having high social impact, characterized by important costs and economic losses, but also an important suffering source at the individual level[1]. In the industrialized countries, back pain affects between 15% and 30% of the population and generates high costs due to the ambulatory care visits[2]. Complementary and alternative medicine (CAM) is commonly used to treat back pain and, among these, acupuncture and bee venom therapy (BVT) are considered one of the most efficient. But, treatment with medicines remains important, mostly because it takes less time and is cheaper for patients.

Despite the multitude of studies and practical evidence, the effectiveness of these CAM therapies in

the treatment of back pain often generates disputes and polemics. However, the health care policy makers from many countries have included acupuncture in the recommended procedures for the incipient chronic rheumatic diseases[3].

The aim of this paper is to assess the relation between effectiveness and side effects for a few common used treatments in CLBP. The prospective case-control study included two complementary therapies (acupuncture and bee venom therapy) versus one pharmaceutical treatment (diclofenac).

Material and method

A prospective case-control study was conducted to investigate and compare the improvements and side effects obtained from the three proposed therapies in the treatment of CLBP. The study protocol included the patients' selection, getting the informed consent (approved by the Ethics Commission of the University of Medicine and Pharmacy "Gr.T.Popa" of Iasi, Romania), the patients' assessment and pain questionnaires.

Three subjects groups were formed by Caucasian adult population, having the age between 20 and 70

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years, the initial total number of subjects being 127. They were selected from the totality of the patients that accessed in the time interval October 2011 -March 2012 the services of two medical centres due the lumbar pains. The selected lot for the comparative study consisted from persons with no psychical affections, unemployed and non-pregnant women. The three subject groups were sequentially completed, as long as patients came and addressed for lumbar pain treatment. Each patient followed a 12 days treatment and was assessed regarding both the pain intensity and sensitivity, before and every three days during the treatment.

The pain intensity was assessed by means of the visual analogical scale (VAS) that ranges from 0 (no pain) to 10 (worst possible pain). The pain sensitivity was measured with a digital algometer (FPIX25 - Wagner, USA), which detects the pressure pain threshold (PPT).

The evaluation of the side effects of the treatment was done through clinical observations every three days during treatments. The clinical evaluation of the patients has been composed by the blood pressure measurement and patient interview.

One group of 52 subjects received the NSAID treatment. The product diclofenac was selected, being a common drug, usually accepted and tolerated by the patients[4]. The treatment consisted in daily oral administration of 100 mg Diclofenac, for a 12 days' cure.

The second group of 49 subjects received 30 minutes daily session of acupuncture treatment during 12 days. Based on a literature review on acupuncture for low back pain, only standard widely accepted and used acupoints were selected[5,6]. The used standard points were:

- in the lumbar region (local points) UB25 and DU3,
- in the lower extremity (distal points) were ST44
- in the upper extremity (distal points) were LI4 and TF5.

Also other points were used: ST36 (analgesic point), UB17, UB40, UB62, DU20 and auricular points: Shenmen and Lombar spine. In the standard acupuncture disposable stainless steel needles (0,2mm x 40mm, Seirin Co.Ltd) were inserted (to a depth of 20mm) into the muscle, and the "sparrow pecking" technique (alternate pushing and pulling of the needle) was applied. When the patient felt dull pain or the acupuncture sensation (de qi), the manipulation was stopped, and the needle was set in the site for 20-30 minutes. In the case of auricular acupuncture auricular needles (0,2mm x10mm) were used.

The third group composed initially by 26 subjects received 12 days of bee venom therapy. A solution that contains pure whole dried bee venom was injected intradermally to imitate the bee sting. The first step was to test the patient for any allergic reaction by injecting 0,1 ml of solution. Then, doses of bee venom were injected daily in trigger points and few acupuncture points. The injected doses and the application points were gradually increased, up to 0,2 ml in one specific spot and up to maximum 2 ml in total, identically for all the subjects.

The compositions of the three groups are quite similar regarding age and gender. As expected, the patients suffering of the lumbar diseases are mostly over 40 years old (47% of our subject between 40 and 59, and 35% over 60). Regarding the gender, women are preponderant, their number being approximately two times higher than the number of men. In the 52 subjects

under treatment with diclofenac 14 men (27%) and 38 females (73%) were registered. In the 49 subjects from the acupuncture group we recorded 19 men (39%) and 30 females (61%) and in the 26 subjects of BVT group we recorded 12 men (48%) and 14 females (52%).

Results

As already mentioned, the subjects have been assessed before treatment and every three days = pain intensity, pain sensitivity, blood pressure, visual aspect and verbal complains were measured

The results in the effectiveness assessment show a similar evolution for the two parameters – pain intensity and PPT - for the all compared procedures. The evolutions are represented in Figure 1 for the pain intensity and in Figure 2 for the PPT. It is very important for the study conclusions to notice that, at baseline, the three groups were characterized by almost similar mean values of the parameters and practically it can be considered that they had the same baseline. This similitude is remarkable mostly because the subjects' collection was a sequential process, which was carried out during a quite long period (18 months).

The experimental results have been also statistically processed and the significance threshold ($p < 0.05$) has been tested. Both Anova and the post-hoc test Bonferoni (multiple comparisons) have been used. The results obtained through the last method are presented in Table I for the pain intensity estimation (VAS) and in Table II for the PPT measurement (pressure-type digital algometer).

The results in the assessment of the side effects are moderate and related to therapy. The most important complains were recorded during treatment with diclofenac. A total number of 13 of 52 patients from this group of subjects, suffered from minor side effects, as

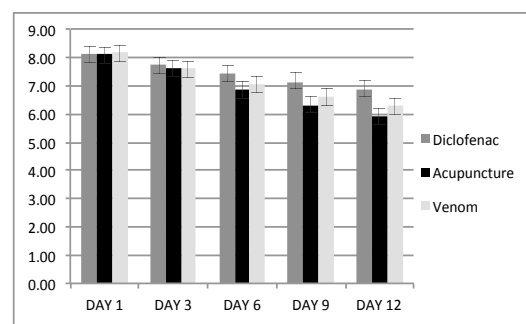


Fig.1. Evolution of the pain intensity

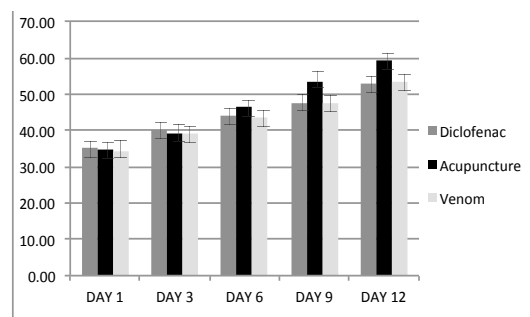


Fig.2. Evolution of the pain intensity (pressure pain threshold)

follows: 6 showed higher blood pressure, 6 recorded water retention, 3 complained for abdominal pains, 3 complained for nausea, 2 reported vomiting sensation.

The acupuncture therapy was accompanied by some minor secondary reactions. From the 49 subjects of the group, few recorded local bleeding (4 subjects), minor hematoma (1 subjects), sweating (2 subjects) and weakness (3 subjects).

The BVT was accompanied by local blushes and erythema, 15 from the 25 subjects recorded this normal reaction. One patient recorded palpitations and two other recorded intense sweating. But surprisingly, major reaction occurred: one patient (female, 36 years old) developed an anaphylactic shock in the sixth treatment session. In consequence, the subject was forced to stop the treatment (consequently was excluded from the BVT study group).

Discussion

The results for all three applied treatments show an improvement for both analysed parameters. It is easy to notice how the parameters' evolution keeps the same trend (monotony), but is not synchronic. Generally, PPT values vary different rhythms than the ones associated to pain intensity, confirming the subjectivity of the patients' perception. The conscious experience of pain may be modulated by mental, emotional and sensory mechanisms. Giesbrecht and Battié [8] proved that possible sensory threshold fluctuations can be influenced by neurobiological and biopsychosocial factors.

Comparing the three treatments' effectiveness, one notices moderately better results in the case of alternative treatments (acupuncture and BVT), suggesting that they have stronger effects on pain relief. But the differences are not so spectacular. It is interesting to notice that during the first 6 days for pain intensity and during the first 9 days for PPT, there were not statistically significant differences between the three groups. Only after these intervals of time, the differences became statistically significant. The findings match the results of other studies. In a review, Chou and Hoffman⁹ found good evidence that NSAIDs are moderately effective for short term pain relief, while the same authors in another review[3] – that didn't take into account the BVT - noticed that efficacy does not clearly differ between acupuncture and massage or analgesic medication. Kaptchiuk et al.[10] admitted that the recent scientific evidence for acupuncture and CLBP has not been so spectacular as the acupuncturists often claim, even if it has provided solid evidence that acupuncture significantly helps patients. In studies dedicated to BVT, like the one of Shin et al.[11], the effectiveness of this kind of therapy for CLBP has been proven. One possible explanation on the efficacy of CAM could be, as Cherkin et al.[12] mention, the longer time spent by a patient (up to one hour) in a relaxed environment, the ongoing attention and the therapeutic touching. Also, acupuncture might enhance mental health independently from its effects on the physical health.

The assessment of the side effects and toxicity of the three studied treatments was performed through clinical observation (blood pressure, visual aspect and

verbal complains).

In the case of diclofenac treatment we recorded mostly minor side effects like water retention, abdominal pains, nausea and vomiting sensation. In the case of 6 patients we recorded higher blood pressure, even though they took specific medication to keep it within normal limits. However, the relatively short period of study didn't allow us to discover severe side effects or toxicity events like gastric or hepatic damages.

One of the main advantages of acupuncture is usually claimed to be the lack of the adverse effects compared especially to drugs administration. In our study, focussed on acupuncture treatment we recorded, for 5.6% from the subjects only minor secondary reactions like: local bleeding, minor hematoma, sweating and weakness. These findings are similar to Ammendolia et al.[14] who, in a comprehensive study, identified twelve trials that reported complications or side effects related to acupuncture for CLBP. All of them were minor and most involved local bleeding or hematoma, the reported rate being between 6 and 8% of the patients.

In our study, BVT was accompanied by local blushes and erythema for more than half of the subjects, just one patient recording palpitations and two other -intense sweating. These are considered normal reactions and based on the literature, there should be no strong objections to the use of bee venom. However, while a limited number of stings is considered safe for non-allergic persons, the danger increases along with the number of stings. Mass inoculation of bee venom may induce acute renal failure (ARF), adult respiratory distress syndrome, liver injury, cardiac damage, pancreatitis, skin necrosis, shock hypertension, bleeding, thrombocytopenia, hemolysis, and rhabdomyolysis[20].

The toxicity can be immediate or can manifest itself days or even weeks after the exposure[21]. In our study, a major anaphylactic shock was recorded in the sixth treatment session by a patient (female, 36-years-old). The patient was stabilised with anti-shock adrenaline dose and transferred to emergency service for surveillance and rehabilitation. The patient abandoned the treatment, but contacted later, she confirmed a normal health condition and the absence of any other symptom, following the shock. A similar case of late reaction, was been analysed by Alqutub et al.[22] regarding a 35-year-old female, following bee sting therapy for multiple sclerosis that developed a hepatotoxicity.

Our study has a number of limitations. The first to mention is that the selection of patients was not a randomised trial. Our work was materialized in a cohort study where patients' preferences were taken into account. The patients that addressed to the family medicine clinic selected medication as a preferred treatment option, while patients that came to the complementary-medicine centre were committed to the alternative treatment methods. No patient was redirected to other kind of treatment outside their option. Even though making changes to the care plan is a key characteristic of maximizing clinical outcomes[23], the study established protocol was strictly followed.

The second limitation is the relatively short period

of time allocated to the study, only 12 days. After this time interval, the majority of patients was lost to follow up, having no possibility to interview and measure their parameters some time after the treatment ended, in order to trace their experience post treatment.

Regarding the results and their generality, it is known that the effectiveness of any manipulation therapy (like acupuncture, BVT, massage etc.) is highly dependent on the therapist's technique and experience. In our study a single therapist was involved hence, the possible variations in treatment were avoided, enhancing the internal validity. On the other hand, the use of a single therapist is considered a threat to external validity, adding a question about the results' generality.

Despite the limitations we believe that the findings in our study are important. To our knowledge, this comparative analysis for the three therapies was performed for the first time meaning that results may serve as a baseline for future studies or therapy management for patients with lumbar pains.

Conclusions

The comparative study has focused on three of the most used therapies for the CLBP: medication (diclofenac), acupuncture and bee venom therapy. All the applied therapies led to pain amelioration and, even if the differences regarding the effectiveness and side effects are not spectacular, acupuncture - followed by the bee venom therapy - recorded better results. On the other hand, diclofenac administration was lower, in terms of performance and recorded the most important side effects. But in the particular case of our study, it was the cheapest and the less time-consuming therapy. The acupuncture or BVT sessions need more daily time as compared with the simple pill administration. Patients that prefer this kind of treatment are either allergic to drug administration or pursue complementary acupuncture positive effects, that usually manifest as an improvement of the tonicity and an overall wellness sensation.

References

Dependent Variable	(I) tratament	(J) tratament	Mean Difference (I-J)	Std. Error	p (Sig.)	95% Confidence Interval	
						Lower Bound	Upper Bound
VAS _ day 1	diclofenac	acupuncture	.00750	.18521	1.000	-.5187	.5337
		BVT	-.02777	.22639	1.000	-.6710	.6155
	acupuncture	diclofenac	-.00750	.18521	1.000	-.5337	.5187
		BVT	-.03527	.22863	1.000	-.6849	.6143
	BVT	diclofenac	.02777	.22639	1.000	-.6155	.6710
		acupuncture	.03527	.22863	1.000	-.6143	.6849
VAS _ day 3	diclofenac	acupuncture	.13293	.17598	1.000	-.3671	.6329
		BVT	.12885	.21512	1.000	-.4824	.7401
	acupuncture	diclofenac	-.13293	.17598	1.000	-.6329	.3671
		BVT	-.00408	.21725	1.000	-.6213	.6132
	BVT	diclofenac	-.12885	.21512	1.000	-.7401	.4824
		acupuncture	.00408	.21725	1.000	-.6132	.6213
VAS _ day 6	diclofenac	acupuncture	.55911*	.16877	.011	.0796	1.0386
		BVT	.36662	.20631	.772	-.2196	.9528
	acupuncture	diclofenac	-.55911*	.16877	.011	-1.0386	-.0796
		BVT	-.19249	.20835	1.000	-.7845	.3995
	BVT	diclofenac	-.36662	.20631	.772	-.9528	.2196
		acupuncture	.19249	.20835	1.000	-.3995	.7845
VAS _ day 9	diclofenac	acupuncture	.84470*	.17177	.000	.3567	1.3327
		BVT	.50454	.20997	.173	-.0920	1.1011
	acupuncture	diclofenac	-.84470*	.17177	.000	-1.3327	-.3567
		BVT	-.34016	.21204	1.000	-.9426	.2623
	BVT	diclofenac	-.50454	.20997	.173	-1.1011	.0920
		acupuncture	.34016	.21204	1.000	-.2623	.9426
VAS _ day 12	diclofenac	acupuncture	.93489*	.17253	.000	.4447	1.4251
		BVT	.58746	.21090	.059	-.0118	1.1867
	acupuncture	diclofenac	-.93489*	.17253	.000	-1.4251	-.4447
		BVT	-.34743	.21299	1.000	-.9526	.2577
	BVT	diclofenac	-.58746	.21090	.059	-1.1867	.0118
		acupuncture	.34743	.21299	1.000	-.2577	.9526

Table I. Bonferroni analysis of the pain intensity

* The mean difference is significant at the 0.05 level.

Dependent Variable	(I) treatment	(J) treatment	Mean Difference (I-J)	Std. Error	p (Sig.)	95% Confidence Interval	
						Lower Bound	Upper Bound
Algometer _ day1	diclofenac	acupuncture	.16146	2.10211	1.000	-5.8112	6.1341
		BVT	.92815	2.56961	1.000	-6.3728	8.2291
	acupuncture	diclofenac	-.16146	2.10211	1.000	-6.1341	5.8112
		BVT	.76669	2.59503	1.000	-6.6065	8.1399
	BVT	diclofenac	-.92815	2.56961	1.000	-8.2291	6.3728
		acupuncture	-.76669	2.59503	1.000	-8.1399	6.6065
Algometer _ day 3	diclofenac	acupuncture	.88069	2.03434	1.000	-4.8994	6.6608
		BVT	1.11938	2.48678	1.000	-5.9462	8.1850
	acupuncture	diclofenac	-.88069	2.03434	1.000	-6.6608	4.8994
		BVT	.23869	2.51137	1.000	-6.8968	7.3742
	BVT	diclofenac	-1.11938	2.48678	1.000	-8.1850	5.9462
		acupuncture	-.23869	2.51137	1.000	-7.3742	6.8968
Algometer _ day 6	diclofenac	acupuncture	-2.45836	2.03031	1.000	-8.2270	3.3103
		BVT	.37854	2.48185	1.000	-6.6731	7.4302
	acupuncture	diclofenac	2.45836	2.03031	1.000	-3.3103	8.2270
		BVT	2.83690	2.50639	1.000	-4.2845	9.9583
	BVT	diclofenac	-.37854	2.48185	1.000	-7.4302	6.6731
		acupuncture	-2.83690	2.50639	1.000	-9.9583	4.2845
Algometer _ day 9	diclofenac	acupuncture	-5.84714*	2.03928	.046	-11.6413	-.0530
		BVT	.08454	2.49281	1.000	-6.9982	7.1673
	acupuncture	diclofenac	5.84714*	2.03928	.046	.0530	11.6413
		BVT	5.93167	2.51746	.195	-1.2211	13.0845
	BVT	diclofenac	-.08454	2.49281	1.000	-7.1673	6.9982
		acupuncture	-5.93167	2.51746	.195	-13.0845	1.2211
Algometer _ day 12	diclofenac	acupuncture	-6.32072*	2.08635	.028	-12.2486	-.3928
		BVT	-.22554	2.55035	1.000	-7.4718	7.0207
	acupuncture	diclofenac	6.32072*	2.08635	.028	.3928	12.2486
		BVT	6.09518	2.57557	.190	-1.2227	13.4131
	BVT	diclofenac	.22554	2.55035	1.000	-7.0207	7.4718
			-6.09518	2.57557	.190	-13.4131	1.2227

Table II. Bonferroni analysis of the PPT

* The mean difference is significant at the 0.05 level

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