Effect of Traumeel S associated with conventional treatment in patients with low-back pain

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Abstract. The current study aims to assess the effects of associating Traumeel S to the classical treatment with physiotherapy, massage and kinetotherapy, in order to facilitate the recovery in patients with low back pain. Until now, we included in the study a total of 20 patients, aged between 20-86, divided into two groups (study and control group).
During the study, a clinical improvement was faster found in patients treated complementary with Traumeel S, with better values, in the 6th day of the treatment, but in the end, patients experienced similar conditions in terms of quality of life and VAS score. Larger number of patients have to be included in the study in order to make a relevant statistical evaluation and confirm with certainty the effects of the complementary treatment with Traumeel S in patients with low back pain.
Key-words*: Traumeel S, complementary medicine, low back pain, quality of life*.

Introduction

Low-back pain is a common musculoskeletal symptom, often accompanied by sciatica, which affects more than 40% of the population during life, caused by a variety of diseases of the lumbar spine, usually having as substrate the degenerative damage of intervertebral discs and/or facet joints of the lumbar region.
In present, treatment options for the patients affected by this problem include medicines like NSAIDs, acetaminophen, muscle relaxants and additional therapies like physiotherapy, massage, kinetotherapy (1-5). All these therapeutic methods can be extremely effective, but they have also side effects, especially on digestive tract and kidneys.
Traumeel S, on the other hand, is a homeopathic preparation made up of 14 natural ingredients, namely (6), Achillea millefolium TM, Aconitum napellus D1, Arnica montana D3, Atropa belladonna D1, Bellis perenis TM, Calendula officinalis TM Echinacea angustifolia TM, TM Echinacea purpurea, Hamamelis virginiana TM, Hepar sulfuris D6, Hypericum perforatum D6, Matricaria recutita TM, Mercury solubilis Hahnemanni D6, D4 Symphytum officinale.
Traumeel S is free of side effects and contributes to a faster recovery of patients in complete safety.
Traditionally, it is used for relieving symptoms of inflammatory pain resulting from an injury or repeated microtraumas of the locomotor apparatus.
In 2012, TAASS study about the use of Traumeel (ointment or gel) in acute ankle sprain confirms that it has the same effectiveness as Diclofenac gel and in 2015, the MOZarT trial presented at EULAR Congress in Rome showed that Traumeel has a statistically significant effect on pain from osteoarthritis of the knee, compared with placebo (7-11).
In addition to standard treatment, the current study aims to assess the effects of associating the administration of Traumeel S to the classical treatment with physiotherapy, massage and kinetotherapy, in order to facilitate the recovery, in patients with low back pain, considering that microtraumas of the spine play an important role in the onset of pain, and for this reason, we count on the therapeutic effect of the medicine.

Material and method

Until now, we included in the study a total of 20 patients, aged between 42-86 years old, divided into two groups (study and control group). The situation of the patients from both groups, considering their age, gender and diagnostic. The control group included patients treated exclusively by the classical method, while the study group contained patients where Traumeel S treatment was associated to standard treatment (physiotherapy, massage, kinetotherapy). They received 3 tablets Traumeel S daily for 7 days.

Classical treatment consisted of 10 sessions of low and medium frequency currents, lumbar massage and kinetotherapy (Williams flexion exercises I, II or III representing kinetotherapeutic programmes for lumbar pathologies depending on the stage of the disease, subacute or chronic; they stabilise mainly the posture of the trunk by stretching and elongating the tight muscles as back extensors, hamstrings and flexors of the hip).

Our study was prospective, with successive clinical cases. Patients were treated in the order of the arrival to the consultation, with one of the variants proposed, alternatively.

Criteria for inclusion in the study*: a*ge between 20 - 86 years, subacute or chronic low back pain. Criteria for exclusion from the study*:* allergies to components of Traumeel S, systemic diseases like systemic lupus, multiple sclerosis, rheumatoid arthritis, ankilosing spondilitis, cancers, TB, HIV infection, low back pain which requires surgery (presence of the motor deficit).

First evolution was recorded at the middle of the treatment (day 6); 2) Second evaluation was registered at the end of treatment (day 10). Criteria for assessing the changes were*:* the Oswestry test score (quality of life) - (12-16); VAS pain score (score from 0 to 10) - where 0 represents no pain and 10 the maximum degree of pain (17-18).

VAS is the Visual Analogic Scale of the pain, with scores from 0 to 10, where 0 represents the absence of pain and 10 is the worst form of pain. Oswestry index scoring is one of the principal specific measures used in the assessment of the quality of life in spinal disorders, especially in low-back pain. The questionnaire used for the assessment consists of 10 items, designed to realize how the pain affects every day's life. Each of the items is scored from 0 to 5. If the first section is marked, the score of the whole section is 0. If the last statement is marked, the score of the section is 5. The final scores were interpreted as it follows: 0-4 points no disability; 5-14 mild disability; 15-24 moderate disability; 25-34 severe disability; > 35 complete disability (maximum possible score is 50).

Data Analysis. The data was processed with PSPP (SPSS version of the open source community).

Results

The study was conducted on a total of 20 patients with low back pain, all from the urban areas, aged 42-86 years, divided in two groups, consisting of 10 patients each. Results of the distribution by age in the study group was as follows (Figure 1). There is a high percentage of patients aged between 50 and 86 years in both groups (90% in the study group and 70% in the control group). No patient age was beyond 40 years in both groups. Distribution of cases by sex is represented in Figure 2, where it can be observed a preponderance of female gender.

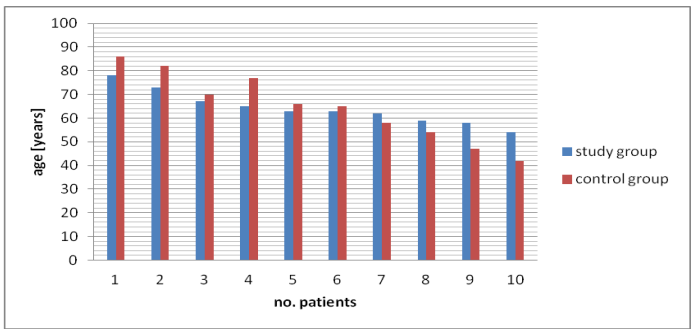

Figure 1. Distribution of patients by age

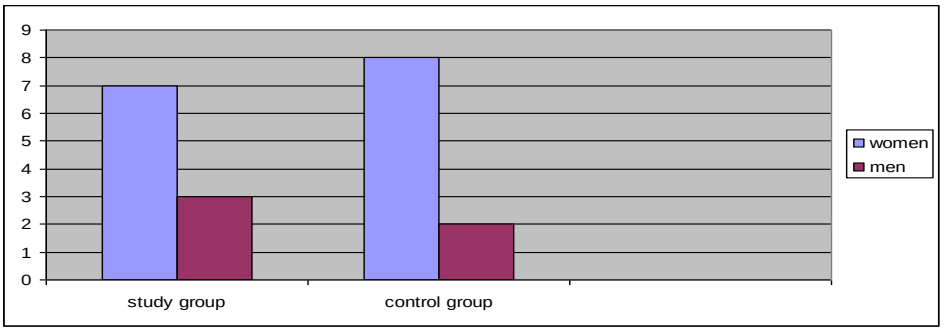

Figure 2. Distribution of patients by gender

To compare the control group with the study group we used t test for independent samples and also a bootstrap-type process to verify the results. VAS score: we compared the two groups of data from the first day, and from day 6 to day 10. Both on the first day, ($p = 0.07 > 0.05$) and on the 6th day ($p = 0.00 < 0.05$) we noticed significant differences between the scores of the two groups, and on the 10th day we also obtained significant differences between the groups ($p = 0.02 < 0.05$), as shown in annex 1.

Annex 1. VAS scores- statistics

Group Statistics

	groups	N	Mean	SD	S.E. Mean
date	Control. d01	10	8.8	.35	.06
	Studiu. d01	10	9.0	.32	.06

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
date	Equal variances assumed	.01	.92	-1.88	56.00	.07	-.02	.09	-.34	.01
	Equal variances not assumed			-1.88	55.73	.07	-.02	.09	-.34	.01

Group Statistics

	groups	N	Mean	SD	S.E. Mean
date	Control. d06	10	5.4	.51	.10
	Study. d06	10	4.0	.68	.13

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
date	Equal variances assumed	3.07	.09	8.27	56.00	.00	1.40	.16	.99	1.63
	Equal variances not assumed			8.27	52.11	.00	1.40	.16	.99	1.63

Evolution of VAS scores. Table I and Figure 3 show that in all patients from the study group, the VAS score decreased by more than 3 points until day 6, and in 50%, VAS score fell by more than 4 points. On the 10th day, the final score was 3 points (20% of patients), 2 points (30% of patients), one point (10%), and in 40% of the patients was 0 points. The control group is presented in Table 2.

Table I. VAS score of patients in the study group

VAS score / Patients	Age	Sex	Diagnostic	Day 1	Day 6	Day 10
N.E.	65	f	lumbar spondylosis with chronic low back pain	9	6	3
A.S.	62	f	lumbar spondylosis with chronic low back pain	8	4	0
S.S	58	f	lumbar spondylosis with chronic low back pain	8	5	2
B.V.	73	f	lumbar spondylosis with subacute low back pain	10	6	2
C.N.	63	f	lumbar spondylosis with chronic low back pain	9	2	1
D.E.	63	f	lumbar spondylosis with subacute low back pain	10	7	3
G.N	78	m	lumbar spondylosis with chronic low back pain	8	2	2
A.M.	67	f	lumbar spondylosis with subacute low back pain	10	4	0
M.N.	59	m	lumbar spondylosis with chronic low back pain	9	2	0
B.F.	54	m	lumbar spondylosis with chronic low back pain	9	4	0

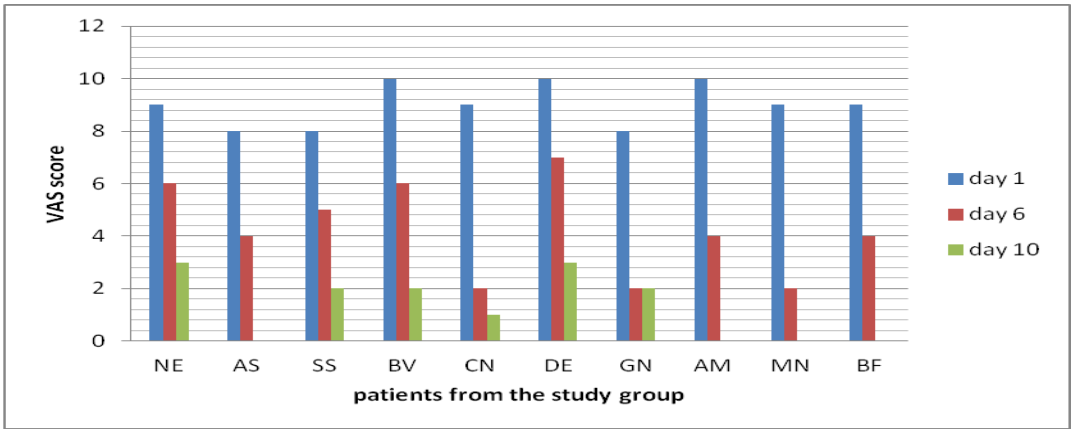

Figure 3 - Evolution of VAS score in the study group

From Table II and Figure 4, it was found that the pain score VAS decreased with one point in the 6th day in one patient (10%), in two patients with 2 points (20%) and in 70% of the patients it decreased by at least three points (70%). On day 10, the VAS score was 3 points in 3 patients (30%), 2 points in 3 patients (30%), 1 point in 3 patients (30%), and 0 points in one patient (10 %).

Table II. VAS score in patients of the control group

VAS score / Patients	Age	Sex	Diagnostic	Day 1	Day 6	Day 10
R.A.	58	f	lumbar spondylosis with chronic low back pain	7	4	2
D.M.	70	f	lumbar spondylosis with chronic low back pain	8	6	0
A.G.	42	f	lumbar spondylosis with chronic low back pain	9	6	3
T.D.	77	f	lumbar spondylosis with subacute low back pain	10	8	3
B.M.	65	m	lumbar spondylosis with chronic low back pain	8	5	1
S.E.	66	f	lumbar spondylosis with chronic low back pain	8	4	2
M.D.	54	f	lumbar spondylosis with chronic low back pain	8	3	1
G.N.	86	f	lumbar spondylosis with subacute low back pain	9	5	1
N.S.	47	f	lumbar spondylosis with subacute low back pain	9	5	2
P.R.	82	m	lumbar spondylosis with chronic low back pain	9	8	3

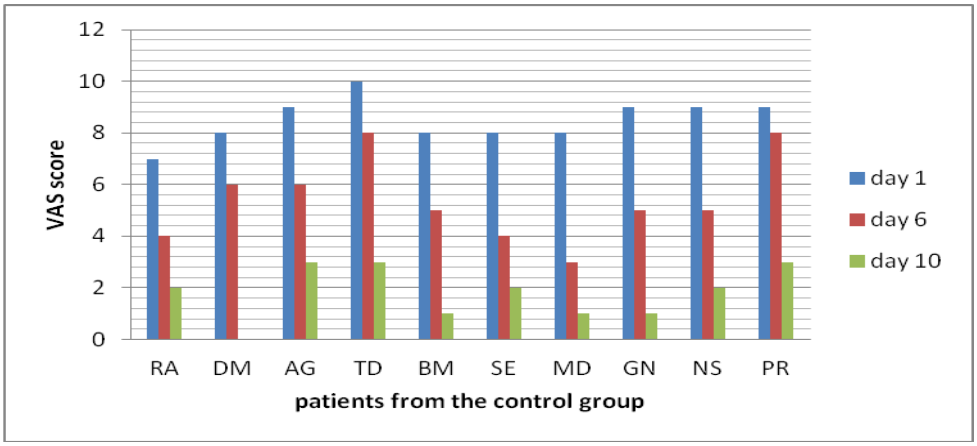

Figure 4. Evolution of VAS score in the control group

Evolution of Oswestry score in patients of the two groups. The quality of life in patients from both groups was assessed through Oswestry questionnaires which led finally to the assessment of the degree of disability due to the painful symptoms (Table III). In the 10 patients, two had initially a severe disability, which in the 6th day was transformed into mild disability, and finally have reached remission (no disability). Three patients had average disability, and two had mild disability. On day 6 of treatment, the following levels of disability were observed: three patients with no disability, six patients with mild disabilities, a patient with moderate disability. Finally, of the 10 patients, only two (20%) of them presented a mild disability (scores of 5 and 12), while the rest had remained with no disability (scores below 4) - Table III.

Oswestry score / Patients	Day 1	Day 6	Day 10
N.E.	14	8	3
A.S.	13	4	0
S.S	13	11	3
B.V.	17	12	5
C.N.	9	2	1
D.E.	24	18	12
G.N	8	2	2
A.M.	30	13	1
M.N.	17	10	3
B.F.	31	13	2

Table III. Oswestry score in the study group

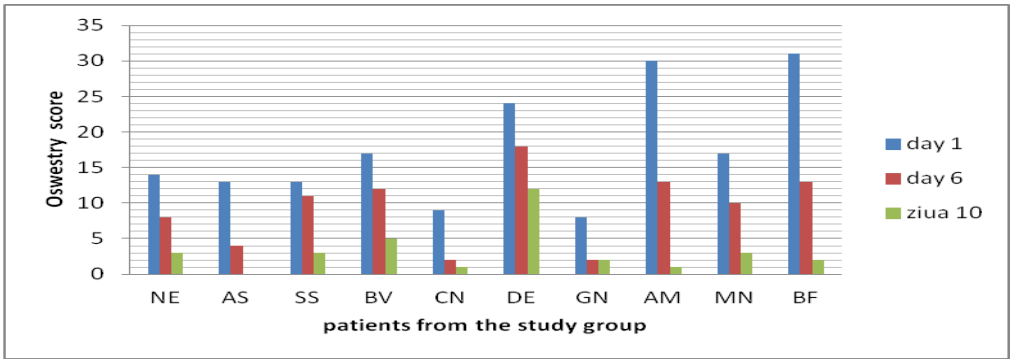

Figure 5. Evolution of Oswestry score in the study group

From Table IV, it is observed that in the control group, at the end of treatment, the situation resembles the study group, only two (20%) patients had mild disabilities, the rest had no disabilities. In the 6th day, only one patient had no disability, seven patients had mild disability, and the rest 2 had moderate disability.
Of the 10 patients, two had initially severe disabilities, which in the 6th day turned into moderate disability in a patient, and a mild disability in the second one.

Oswestry score / Patients	Day 1	Day 6	day 10
R.A.	9	7	2
D.M.	28	12	4
A.G.	24	11	3
T.D.	35	20	6
B.M.	14	5	2
S.E.	12	5	2
M.D.	12	4	2
G.N.	13	5	2
N.S.	14	5	2
P.R.	24	21	5

Table IV. Oswestry score in the control group

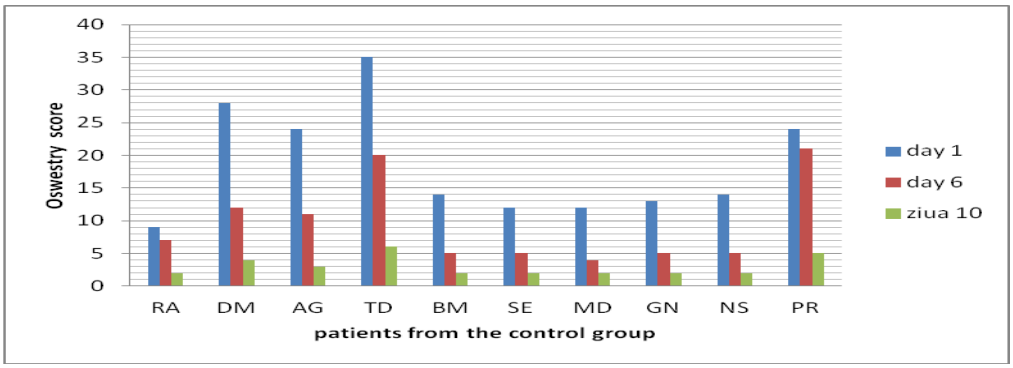

Figure 6. Evolution of Oswestry score in the control group

We did not get significant differences for the Oswestry score between the mean scores of the two groups for any of the days when measurements were performed (for day 1, p = 0.12> 0.05, for the 6th day, p = 0.98> 0.05, for the10-th day, p = 0.09> 0.05), as shown in annex 2.

Annex 2. Oswestry scores statistics

Group Statistics

	groups	N	Mean	SD	S.E. Mean
Date	Control.d1	10	18.9	2.27	.42
	Study .d1	10	17.9	2.71	.50

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Date	Equal variances assumed	.72	.40	1.58	56.00	.12	1.0	.66	-.28	2.35
	Equal variances not assumed			1.58	54.33	.12	1.0	.66	-.28	2.36

Group Statistics

	groups	N	Mean	SD	S.E. Mean
Date	Control. d6	10	9.3	2.16	.40
	Study. d6	10	9.3	1.50	.28

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Date	Equal variances assumed	4.84	.03	.02	56.00	.98	.01	.49	-.97	.99
	Equal variances not assumed			.02	49.82	.98	.01	.49	-.97	.99

Group Statistics

	groups	N	Mean	Std. Deviation	S.E. Mean
Date	Control.d10	10	3.0	.46	.09
	Study .d10	10	3.5	1.28	.24

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Date	Equal variances assumed	17.07	.00	-1.76	56.00	.08	-.50	.25	-.95	.06
	Equal variances not assumed			-1.76	35.10	.09	-.50	.25	-.96	.07

Discussion and Conclusion

We found in patients from the study group better values in the VAS score, in the 6th day of the treatment and also in the 10th day, which shows a better effect of Traumeel used in combination with conventional therapy in patients with low back pain, comparatively with the conventional treatment used separately.

The Oswestry score was not influenced by Traumeel, the values being the same in the study and the control groups, which can be understood as a less quick change of perception in terms of quality of life in an interval of study of 10 days of treatment and we suggest that a longer period of time could be necessary for a clearer evaluation.

The current study shows that homeopathic treatment used as a complementary method leads to encouraging clinical results, comparatively with the classical treatment with massage, physio- and kinetotherapy, at least in terms of speed of installation of the therapeutic effect, but requires further research on a larger number of patients, to confirm or refute with certainty the effectiveness of the drug combination in the treatment of low back pain with Traumeel S associated to conventional treatment. Till present time, we could not find any other references concerning the treatment of low back pain with Traumeel in the specialty literature (19-24).

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