



ORIGINAL PAPER

The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multi-centre, randomised, double-blind comparative clinical trial

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Acute low back pain is a very common condition in Western industrialised countries. In most cases analgesics or topical medications are prescribed at first encounter with the general practitioner (GP).

The aim of this study was to investigate whether the homeopathic gel Spiroflor SRL[®] gel (SRL) is equally effective and better tolerated than Cremor Capsici Compositus FNA (CCC) in patients with acute low back pain.

A multi-centre, randomised, double-blind, controlled clinical trial was conducted in the practices of 19 GPs in the districts of Bristol and Manchester, UK. One hundred and sixty-one subjects suffering from acute low back pain were treated for one week either with SRL or with CCC. Pain was scored on a 100 mm visual analogue scale (VAS). Main efficacy parameter VAS reduction was compared between treatments. Evaluation of safety was primarily based on the number of subjects with adverse events (AEs), withdrawals due to an AE and adverse drug reactions (ADRs).

The mean difference between the VAS reduction in the SRL group and the CCC group adjusted for VAS at baseline and age was -0.6 mm (90%CI = -6.5 – 5.3 mm). Fewer subjects in the SRL group (11%) experienced an AE than in the CCC group (26%). The same applies to the number of subjects with an ADR (3/81 = 4% vs 18/74 = 24%) and the number of subjects withdrawn due to an ADR (0/81 = 0% vs 8/74 = 11%).

In conclusion, SRL and CCC are equally effective in the treatment of acute low back pain, however, SRL has a better safety profile. Spiroflor SRL[®] gel is preferable to Capsicum-based products for the topical treatment of low back pain, because of the lower risk of adverse effects. *British Homeopathic Journal* (2001) 90, 21–28.

Keywords: Capsici Oleoresin; clinical trials; homeopathy; *Ledum palustre* L; low back pain; *Rhus toxicodendron*; *Symphytum officinale* L

Introduction

Low back pain is a very common condition. In the UK, 7% of the adult population will consult their general practitioner (GP) about low back pain during any 12 months.¹ The yearly prevalence of low back pain varies from 15–20% in the US to 25–40% in

European countries.^{2,3} Among the British population 36% of adults reported a low back pain episode in one year.⁴ Fry⁵ estimated that there may be more than 60 acute episodes annually amongst an average UK general practice population of 2500 patients. Lifetime prevalence is as high as 60–90%.^{2,3}

According to clinical practice guidelines on acute low back pain of, for instance, the Netherlands, UK, New Zealand and the United States,⁶ patients with acute low back pain should be encouraged to continue their routine physical activities. If necessary, analgesic medication can be prescribed. Chavannes *et*

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*al*⁷ found a wide diversity of methods of treatment prescribed in general practice in case of acute low back pain. In most cases (63%) analgesics were prescribed at first encounter with the GP. Topical medications were the second most often medication prescribed (35%). In the Netherlands, SRL[®] gel (SRL)⁸ and Cremor Capsici Compositus FNA (CCC) are frequently prescribed topical medications for the indication of acute low back pain.

Cremor Capsici Compositus FNA is a rubefacient aiming at relieving pain by skin hyperaemia.⁹ It is a combination product based on Capsici Oleoresin, glycol salicylate, histamine hydrochloride and methyl-nicotinate which are the active ingredients of many topical products available for the indication of muscle and joint complaints in several Western countries,^{9–12} for instance Algipan Rub[®], Cremalgin[®], Fiery Jack Cream[®] and Ralgex Cream[®] in the UK.¹² Pain relief is reported after the use of topical Capsici Oleoresin in the treatment of mechanical low back pain.¹³ SRL[®] gel, at present marketed under the trade name Spiroflor SRL[®] gel, is a homeopathic gel containing three homeopathic ingredients: *Symphytum officinale*, *Rhus toxicodendron* and *Ledum palustre*, all frequently prescribed as remedies in conditions of the locomotor system.^{14–17} Products containing these homeopathic ingredients are, for instance, also on sale in the USA, Germany¹⁰ and Belgium.¹¹ Van Haselen *et al.*¹⁸ have reported efficacy of SRL in subjects with osteoarthritis of the knee.

The objectives of this study were (1) to investigate whether SRL was equally effective as CCC in patients with acute low back pain and (2) to compare the tolerability of SRL and CCC.

Methods

Ethics

The study was conducted in accordance with the Declaration of Helsinki of 1964 and its amendments. The study protocol was reviewed by the ‘Welwyn Independent Ethical Committee for the Assessment of Studies in General Medical Practice.’ Written informed consent was obtained from all patients before study participation.

Protocol

Subjects were recruited from the practices of 19 GPs in the districts of Bristol and Manchester. All subjects calling or attending their GP with acute low back complaints were potential subjects for the trial. Enrolment took place according to the criteria listed in Table 1. Baseline characteristics were recorded (see Results), including the intensity of pain on a 100 mm visual analogue scale (VAS) with ‘no pain’ at one end and ‘unbearable pain’ at the other end. If a patient had taken non steroidal anti inflammatory drugs (NSAIDs) or analgesics during the 24 hours previous to inclu-

Table 1 Inclusion and exclusion criteria

Inclusion criteria	
1	Aged 18 to 65
2	Acute attack of low back pain within previous 72 hours
3	Free from low back pain during the previous three months
4	At least moderately painful limitation of movement as determined by physical examination
Exclusion criteria	
1	Radicular symptoms indicating sacral/lumbar nerve root compression
2	Location of pain above T12
3	Rheumatoid arthritis
4	Ankylosing spondylitis
5	Known hypersensitivity to any of the components of both products
6	Use of analgesics other than paracetamol during the treatment period
7	Use of NSAIDs during the treatment period
8	Receiving other treatment (physiotherapy, osteopathy, acupuncture, etc.) aimed at treating the acute low back pain during the treatment period
9	Pregnancy
10	More than 96 hours elapsed since the onset of pain, including washout for analgesic and/or NSAIDs

sion, according to predefined guidelines, a one-day washout period took place before baseline evaluation in some cases.

For one week, patients used SRL or CCC. Three grams was applied three times daily to the affected area. A spatula with a sticker indicating a dose of approximately 1 g was used to measure the dose. The composition of SRL and CCC is given in Table 2. Paracetamol 500 mg tablets were provided as a rescue analgesic up to a maximum of eight tablets a day. Subjects were informed that some redness and heat might occur after application and that this is a normal reaction.

During the treatment period, patients completed a diary recording pain intensity, quality of night’s rest; and use of paracetamol. After seven days, patients reattended their GP for assessment and to return study materials. Finally, patients as well as GPs were asked

Table 2 Composition of the test medications

<i>Spiroflor SRL gel</i> (VSM Geneesmiddelen bv, Alkmaar, Netherlands)	<i>Cremor Capsici Compositus FNA</i> (Pharmachemie, Haarlem, Netherlands)
<i>Symphytum officinale</i> tincture for external use ^a (10 g)	Glycol salicylate (10.0 g)
<i>Rhus toxicodendron</i> tincture for external use ^a (5 g)	Methylnicotinate (1.0 g)
<i>Ledum palustre</i> tincture for external use ^a (5 g)	Capsici Oleoresin (BPC) (0.1 g)
Aqua Hamamelidis	Histamine hydrochloride (0.1 g)
Oleum Pini pumilionis	Sorbitol
Carbopol 980	Methylparahydroxybenzoate
Triethanolamine	Triethanolamine
Sodiumedetate	Lanette wax
	Stearic acid
	Purified water

^aPrepared in accordance with the officially recognised German Homeopathic Pharmacopoeia (HAB1).

to give an overall assessment of the efficacy/usefulness of the product used.

Monitoring of the study was conducted by S-Cubed Clinical Services Ltd., Sheffield.

Analysis

Since the first objective of this study was to investigate whether SRL is equally effective as CCC, this study was considered an equivalence trial aimed at showing therapeutic equivalence of the treatments.¹⁹ Therefore, efficacy analyses were based on comparing confidence intervals (CI) of the differences between treatment groups with a clinically relevant range of equivalence. If the confidence interval lies entirely inside the prespecified range of equivalence, equivalence is demonstrated unequivocally.

Primary efficacy parameters were VAS reduction and proportion of treatment success. VAS reduction was calculated as the difference between VAS at baseline and VAS at day 7. Treatment success was defined as (1) at least 80% VAS reduction and (2) 100% VAS reduction at day 7 compared to baseline. An α of 0.05 was laid down in the protocol, and therefore, 90% CIs¹⁹ were calculated for the difference between means (VAS reduction) and for the difference between proportions (treatment success). For the VAS reduction a range of equivalence of -6 to 6 mm was used, for the proportion treatment success -0.15 to 0.15 . For comparison of VAS reduction, adjustment for differences at baseline (VAS, age, sex, history of low back pain) was considered. Analysis of covariance using the method of forward selection with a cut off of $P < 0.05$ was used for this.^{20,21} We also checked whether there was an effect due to different GPs by using analysis of variance.

Secondary efficacy parameters were the proportion of subjects using paracetamol, number of nights with disturbed sleep, duration of absence from work and the overall assessments of the efficacy/usefulness of the product by patient and GP. These parameters were compared between the treatment groups, if appropriate, using the particular 90% CIs. To allow calculation of CIs, the 2×6 cross tables of the overall evaluation of the products by GPs and subjects were reduced to 2×2 cross tables by recoding: excellent/good/fair vs poor/(worse than) useless.

The second objective of this trial was to compare the tolerability of SRL and CCC. The evaluation was based on the principles of comparative trials using two-sided testing with $\alpha = 0.05$ (Chi squared test or Fisher's exact test) and 95% CI for the difference between proportions.

The number of subjects with an adverse event (AE), the number of subjects with an AE leading to withdrawal as well as the number of adverse drug reactions (ADR) were compared between treatments. AEs were defined as all disorders of health, subjective and objective symptoms of illness including changes in laboratory findings, intercurrent illnesses and acci-

dents which are observed during the study, regardless of a possible relationship to the study medication, including events which occur on placebo or during a non-medical therapy. AEs rated 'definitely' or 'probably' related to the use of SRL or CCC by the GP were considered ADRs.

Analyses were based on the 'intention-to-treat' principle and 'per protocol' analyses for the primary efficacy parameters VAS reduction and proportion treatment success only. All subjects who had a baseline VAS as well as at least one follow-up VAS were included in the intention-to-treat analysis of the primary efficacy parameters using the 'last-value-carried-forward' method. In all other analyses missing values were left blank. Subjects who met the following criteria were included in the per protocol analysis:

- compliance of 80–120% of the prescribed dose per application;
- product use at least up to day 6;
- return to GP between day 6 and day 8; and
- no major protocol violations.

Compliance was calculated as follows. Based on the mean weight of an original tube, the weight of the tube returned and the actual number of applications, an individual average dose per application was calculated which was expressed as a percentage of the prescribed dose of 3 g.

Statistical analyses were performed at VSM Geneesmiddelen by using the program SPSS PC + version 5.1.

Assignment

Randomisation was performed using the randomisation software RCODE (version 3.4), in blocks of four. Each GP received study material in blocks of four in order to obtain an optimal SRL/CCC distribution per GP. Treatment allocation was done at inclusion by the GP based on the lowest unused randomisation number. Each GP was provided with special code envelopes enabling breaking of the treatment code of individual patients, if medically indicated.

Blinding

The trial medications differed with regard to smell, colour and consistency. Therefore, it was intrinsically impossible to make both treatments identical, or to use the double dummy technique. To achieve masking, SRL and CCC were provided by VSM Geneesmiddelen bv in identical white 80 g tubes. It was not necessary to break the code for any individual patient. After completion of the analyses of the primary efficacy parameters, the codes were broken.

Results

Subjects

One hundred and sixty-one subjects, 87 men and 74 women, took part in the trial. Eighty-three subjects were allocated to the SRL group and 78 subjects to the CCC group. Disposition of subjects is given in Figure 1. There were no major differences between the treatment groups at baseline (Table 3).

Due mainly to rather poor treatment compliance, the number of subjects suitable for the per protocol analysis was small. The mean compliance was 56.4% and 61.5% in the SRL and CCC group, respectively. Only 27 subjects (16 SRL, 11 CCC) used between 80 and 120% of the prescribed dose. Due to other protocol violations, only 21 subjects (13 SRL, 8 CCC) met all per protocol criteria.

Primary efficacy parameters

In 154 subjects (80 SRL, 74 CCC), VAS at baseline, as well as at least one follow-up VAS, was available. These patients were included in the intention-to-treat analysis of VAS reduction and treatment success.

In both groups, at day 7 there was a significant VAS reduction compared to baseline (both paired *t*-test $P < 0.001$), on average 38.2 (± 26.0) mm in the SRL group and 36.6 (± 25.5) mm in the CCC group. VAS at baseline and age had no significant effect on the VAS reduction (Table 4). No GP effect could be established. The between treatment difference in VAS reduction, adjusted for VAS at baseline and age, was -0.6 mm, 90% CI = -6.5 to 5.3 mm. The 90% CI does not lie entirely inside the prespecified range of equivalence. Results, including treatment success, are listed in Table 4.

In general, per protocol analyses are important in the analysis of equivalence trials. However, due to the small number of subjects, which were suitable for inclusion in the per protocol analysis, in this study, per

Table 3 Baseline characteristics subjects

		SRL number/%	CCC number/%
Sex	Male	46/55.4	41/52.6
	Female	37/44.6	37/47.4
Age in years		40.6 (± 13.6) ^a	41.0 (± 12.8) ^a
Extent of pain on movement	Slight	0	1/13
	Moderate	66/79.5	59/75.6
	Severe	17/20.5	18/23.1
Extent of tenderness on palpation	None	3/3.6	4/5.1
	Mild	23/27.7	22/28.2
	Moderate	53/63.9	47/60.3
	Severe	4/4.8	5/6.4
Extent of restriction on movement	None	2/2.4	2/2.6
	Mild	7/8.4	7/9.0
	Moderate	64/77.1	57/73.1
	Severe	10/12.0	12/15.4
Visual analogue score		58.9 (± 20.8) ^a	55.7 (± 22.8) ^{ab}
Previous low back pain	Yes	39/47.0	45/57.7
	No	44/53.0	33/42.3

^aMean (\pm standard deviation); ^b $n=77$, one missing.

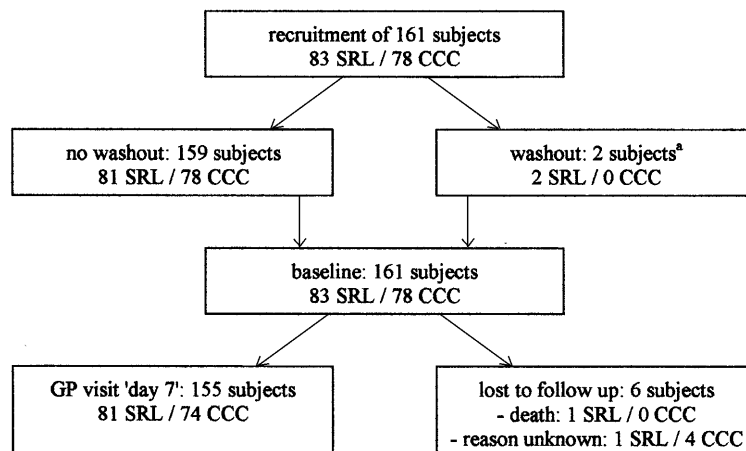
protocol analysis was of less importance. Therefore, results of the per protocol analysis and discussion of the results are omitted.

Secondary efficacy parameters

Results of analyses of secondary efficacy parameters are listed in Table 5. The 90% CI for the difference between proportions was -0.11 – 0.12 for the evaluation of efficacy/usefulness of the product by the GPs and -0.15 – 0.09 for the evaluation by the subjects.

Safety

One subject did not start treatment and in five subjects information about adverse events (AE) was not available. Finally, 81 subjects in the SRL group and 74 subjects in the CCC group were included in the safety and tolerability analysis.



^a use of Anadin Extra[®] (aspirin, paracetamol, caffeine and ibuprofen)

Figure 1 Patient flowchart.

Table 4 Primary efficacy parameters

	SRL n ^a = 80	CCC n ^a = 74	SRL – CCC	90% CI ^b SRL – CCC	Equivalence range
VAS reduction(mm)					
Adjusted ^c	37.2	37.7	–0.6 ^d	–6.5–5.3	–6.0–6.0
Proportion treatment success 80% ^e					
Yes	0.50	0.55	–0.05	–0.19–0.08	–0.15–0.15
No	0.50	0.45			
Proportion treatment success 100% ^f					
Yes	0.18	0.15	0.03	–0.07–0.12	–0.15–0.15
No	0.83	0.85			

^an = number of evaluable subjects.^b90% confidence interval for the difference between means (VAS reduction) or proportions (treatment success).^cAdjusted for VAS at baseline and age analysis of covariance $P_{\text{VAS baseline}} = 0.000$, $P_{\text{age}} = 0.005$, $P_{\text{covariates}} = 0.000$.^dDue to rounding off 37.2–37.7 = –0.6.^eTreatment success defined as VAS reduction at least 80% at day 7.^fTreatment success defined as VAS reduction 100% at day 7.**Table 5** Secondary efficacy parameters

	SRL	CCC	SRL – CCC	90% CI ^a SRL – CCC	Equivalence range
Proportion subjects using paracetamol					
Number of evaluable subjects ^b	82	75			
Yes	0.79	0.75	0.04	–0.07–0.16	–0.15–0.15
No	0.21	0.25			
Proportion subjects still unable to work at the end of the study					
Number of evaluable subjects ^c	36	40			
Yes	0.44	0.40	0.04	–0.14–0.23	–0.15–0.15
No	0.56	0.60			
Number of nights with disturbed sleep					
Number of evaluable subjects ^b	68	60			
Median number of nights	2.00	1.50			
25th–75th percentile	0.25–4.00	0.00–4.00			
	<i>GP</i>		<i>Subject</i>		
<i>Overall evaluation of efficacy/usefulness of product used</i>	<i>SRL number/%</i>	<i>CCC number/%</i>	<i>SRL number/%</i>	<i>CCC number/%</i>	
Excellent	6/7.7	6/8.3	5/6.5	3/4.2	
Good	29/37.2	39/54.3	27/35.1	34/47.9	
Fair	25/32.1	10/13.9	23/29.9	16/22.5	
Poor	10/12.8	14/19.4	13/16.9	12/16.9	
Useless	7/9.0	2/2.8	8/10.4	2/2.8	
Worse than useless	1/1.3	1/1.4	1/1.3	4/5.6	
Total	78 ^b /100.1 ^d	72 ^b /100.0	77 ^b /100.1 ^d	71 ^b /100.1 ^d	

^a90% confidence interval for the difference between proportions.^bn_{SRL} < 83 and n_{CCC} < 78 due to missing data.^cSubjects with a paid job and which were absent from work due to acute low back pain at study start only.^d> 100.0 due to rounding off.

Significantly less subjects in the SRL group experienced an AE, namely, nine subjects (11%) in the SRL group versus 19 subjects (26%) in the CCC group including one subject who experienced two AEs ($P_{\text{Chi-squared (Pearson)}} = 0.019$, 95% CI = –27% to –2%). There were also fewer adverse drug reactions (ADRs) in the SRL group. Three subjects (4%) in the SRL group experienced an ADR compared to 18 subjects (24%) in the CCC group ($P_{\text{Chi-squared (Pearson)}} = 0.0002$, 95% CI = –31% to –10%), all involving the skin.

Furthermore, there was a clear difference regarding the severity of the ADRs; four ADRs in the CCC were

rated ‘severe’ compared to none of the ADRs in the SRL group. In the SRL group, none of subjects (0%) were withdrawn due to the ADR compared to eight subjects (11%) in the CCC group.

Discussion

Blinding

Although several precautions were taken, masking was inevitably imperfect in this trial. However, it was felt that the imperfect masking was unlikely to be a major cause of bias because neither products are

available in the UK market and furthermore, both the patient and the investigators were assuming that two active products were being compared.

Compliance

In this study compliance was poor, this may have been due to several aspects of the protocol. It appears that a rapid improvement took place during the first three to four days treatment after which the condition stabilised. The stabilisation of pain may have led to non-compliance. Furthermore three applications of 1 g may have been inconvenient, and lead to non-compliance. It might have been better to replace this by a single application of 3 g. However, because the treatment groups did not differ in compliance, the poor compliance has not biased the comparison of the two treatments.

Efficacy

Looking at the primary efficacy parameters, only when treatment success is defined as 100% VAS reduction, was equivalence established unequivocally (CI entirely inside the range of equivalence). However, in the between-treatment difference, the exceeding of the equivalence range is only marginal. Furthermore, the secondary efficacy parameters give no support to assume a difference between the treatments. The conclusion that SRL and CCC are equally effective in the treatment of acute low back pain seems justified.

Comparison with results of other studies

The absence of a placebo and a non-treated group is a major weakness of this study. Acute low back pain is often self-limiting,¹² therefore, based on this study, one could conclude that both treatments are equally efficacious or that both treatments are equally inefficacious because improvement will be seen after any therapy, effective or not. The placebo effect as well as the phenomenon of 'regression to the mean' may have affected the results. Therefore, an attempt was made to compare the results of this study with results of placebo-controlled trials evaluating the efficacy of, preferably topical, or otherwise oral treatments for the indication of non-specific acute low back pain, paying special attention to comparability of the trials regarding aspects such as time between onset of symptoms and treatment start, instructions regarding bed rest/exercises, the use of VAS scores to evaluate pain, etc.

For that purpose several systematic reviews were studied.^{22–25} The study of Ginsberg and Famaey¹³ was the only trial studying the efficacy of a topical treatment for the indication of non-specific acute low back pain. Postacchini *et al.*²⁶ used anti-oedema gel as placebo therapy for spinal manipulation, however no VAS scores were used and assessments were done only after 3 weeks. Several placebo-controlled trials evaluated the efficacy of oral treatments in acute low

back pain. Most trials, however, differed too much from the present trial to allow a useful comparison of results^{27–29} leaving only a limited number of studies for comparison.

Ginsberg and Famaey,¹³ compared the topical product Rado-Salil[®] (containing Capsicum oleoresin) plus paracetamol with placebo plus paracetamol, showing a mean VAS reduction of 37.9 mm after 14 days treatment in the Rado-Salil[®] group compared to 4.0 mm in the placebo group ($P < 0.001$). The VAS reduction in the Rado-Salil[®] group is similar to the VAS reduction in the present study. In the studies of Berry and Hutchinson,^{30,31} the efficacy of tizanidine/aspirin was compared with placebo/aspirin³⁰ and tizanidine/ibuprofen was compared with placebo/ibuprofen.³¹ Pain at night, at rest and on movement/walking was assessed using a VAS. In neither of the two studies significant differences in VAS reduction were found after 7 days treatment. However, after verum treatment as well as after placebo treatment, VAS reductions were slightly but consistently smaller than the reductions found in the present study. In Amlie *et al.*,³² comparing the efficacy of piroxicam/paracetamol with placebo/paracetamol, VAS reduction was expressed as percentage reduction compared to baseline regarding pain in lying, sitting and standing position as well as while walking. However, no exact figures are given, only graphs are available. To allow a comparison of the results, we analysed our results in a similar fashion. In the study of Amlie *et al.*,³² there was more pain reduction in the piroxicam group (estimate from graph: 80%) compared to the placebo group (estimate from graph: 70%) without reaching significance. The mean percentage VAS reductions as calculated for the present study were smaller (SRL 64%, CCC 59%) compared to Amlie *et al.*³² However, in the latter study, subjects who were withdrawn or discontinued prematurely were left out of the analysis. In the present study the intention-to-treat principle combined with the last-value-carried-forward method was used, giving a more conservative estimate.

Possibly due to differences in study design, the results of the trials are not entirely consistent. However, the results give no cause to change the conclusion that there are strong indications that both treatments are effective in the treatment of acute low back pain.

Safety

Regarding the safety and tolerability of the two products, the picture is clear. SRL is much better tolerated than CCC. In nine (11%) of the subjects treated with SRL an AE occurred, whether or not related to the use of gel and/or paracetamol, compared to 19 (26%) subjects in the CCC group. Furthermore, only three (4%) subjects in the SRL group experienced an AE considered to be an ADR versus 18 (24%) subjects in the CCC group. Finally,

four ADRs in the CCC group were rated 'severe', compared to none in the SRL group. Compared to other treatments tested in acute low back pain, the safety results show a favourable safety profile for SRL. For instance, four out of 20 subjects (20%) showed an AE concerning the skin after use of Rado-Salil[®],¹³ 41% of subjects treated with tizanidine/aspirin³⁰ reported an AE and in Berry and Hutchinson³¹ at least 33% of the subjects treated with tizanidine/ibuprofen showed an AE.

On the other hand, it is well known that Capsici Oleoresin causes discomfort and irritation in the initial stage of treatment and that benefits only appear subsequently, associated with depletion of substance P. Because this study only ran for one week, one could argue that the comparison of side effects is invalid. However, Cremor Capsici Compositus FNA is a rubefacient aiming at pain relieve by hyperaemia, an effect which occurs almost immediately after application. It is very unlikely that depletion of substance P is the mode of action. The concentration of capsaicin in Cremor Capsici Compositus FNA (0.008%) is far below the concentration needed to deplete substance P (US FDA approval 0.025–0.25%). In several clinical trials which were studying study pain relieve by substance P depletion, creams containing 0.025% and/or 0.075% capsaicin were used.^{33,34}

It could still be argued that salicylate (which is included in the formulation of CCC) acts as a synergist, and that the mode of action could nonetheless be depletion of substance P. Due to the low concentration of capsaicin, we think it is unlikely that depletion of substance P could be the mode of action, even if such synergy does occur. Finally, even if the cream used in this trial acted by depletion of substance P, so that the benefits only appear after several days or even a week, comparison of side effects during the first week remains relevant, because it is well established that side effects are an important factor in whether patients carry on a particular treatment or not. In our trial eight subjects (11%) using the capsicum cream stopped treatment because of an ADR (all skin reactions) compared to none of the subjects in the SRL group. It is quite conceivable that this difference is even more pronounced in day-to-day practice.

We concluded that Spiroflor SRL[®] gel and Cremor Capsici Compositus FNA are equally effective in the treatment of acute low back pain, however, Spiroflor SRL[®] gel is better tolerated. Therefore it appears that Spiroflor SRL[®] gel and comparable products are preferable to Capsicum-based products for the topical treatment of low back pain, due to the lower chance of adverse effects.

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