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A Double-blind Study of Topical Massage with Rado-Salil® Ointment in Mechanical Low-back Pain

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Forty patients with acute mechanical low-back pain were treated i double-blind manner with either Rado-Salil® or placebo for 14 da Statistically significant improvements in spontaneous pain, muscu contracture and in both the patient's and physician's opini occurred by day 3. These improvements persisted at day 14 and, addition, there were statistically significant improvements in the fing floor distance and the degree of lumbar extension. Treatment w Rado-Salil® also allowed significant reduction in the use of o analgesics. Only a few localized transient side-effects, requiring specific treatment, were observed.

INTRODUCTION

Treatment of painful rheumatic conditions by the localized use of various irritant balms and ointments has been carried out empirically for many centuries. There have been, however, very few controlled studies to assess the various indications and efficacy of the different irritants used in these topical preparations.[1] Notwithstanding th empirical origin, the rationale behind t use of these substances can be found the localized neurogenic inflammati promoted by compounds such camphor, menthol, eucalyptol, capsaic and nicotinic acid.[2–4]

The revulsive action of these irrita ointments is a result of cutaneous vas dilatation at the site of application due an axonal reflex resulting in the relea of chemical mediators, such as sul stance P, neurokinins A and I calcitonin gene-related peptid histamine and prostaglandin.[2, 5, 6] Vasc dilatation relieves congestion of th underlying and neighbouring tissue induces a local rise of temperature resul ing in analgesia[7] and produces a counte

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irritating analgesic and anti-inflammatory action similar to analgesic techniques such as acupuncture or low-frequency transcutaneous electrical stimulation.[8–10]

The aim of this study was to assess the efficacy and tolerance of a revulsive stick-presented ointment, Rado-Salil®, containing rubefacients with counter-irritating analgesic properties.[11–13]

PATIENTS AND METHODS

Patients (40) with acute mechanical low-back pain were selected on the basis of clinical examination, standard radiological examination of the lumbar spine and routine laboratory tests (including blood count, erythrocyte sedimentation rate, blood urea nitrogen and creatinine). They were treated at random either with Rado-Salil® (n=20) or placebo (n=20) for 14 days. Rado-Salil® was presented as a 40 g stick with composition as in Table 1. Placebo was identical in appearance yet contained only the excipient with three times the amount of lavendula and bergamot essences. Each patient was also given 45 paracetamol 250 mg tablets, and was asked to return any remaining at the end of the trial to the physician. No other analgesic, anti-inflammatory drug or physical treatment was allowed during the 2-week trial period.

Assessment visits were made on days 3 and 14, the following assessments being made at each visit: pain evaluation by the patient on a 10 cm linear scale; duration of confinement to bed; muscular reflex contracture evaluation by the physician on a scale of 0–4; and spine mobility by determination of Schober's index, the finger–floor distance and the degree of lumbar extension. All these were statistically analysed using the Student's t-test. In addition, a global appreciation of the treatment by the patient and the physician was also made on days 3 and 14 using the following classifications: exacerbation; no effect; moderate effect; good effect; or excellent effect. This was statistically analysed using the χ^2-test.

An estimate of the area of skin surface smeared with the Rado-Salil® or placebo ointments was made by calculating the average consumption of ointment per square centimetre, in addition to the total consumption, which was estimated by weighing the sticks at the end of the trial. The number of paracetamol tablets returned was assessed at day 14.

Any side-effects were recorded at each assessment visit.

RESULTS

Before treatment

Apart from the length of confinement to bed, there was no significant difference between the two groups of patients. No further evaluation of bed confinement was made at the assessment visits.

At days 3 and 14

At day 3, spontaneous pain, muscular contracture, and the patient's and physician's opinions were significantly improved in the group given Rado-Salil® compared with placebo. These improvements were maintained at day 14 (Tables 2–4).

Consumption of ointment and paracetamol

Total ointment consumption and the amount applied to the skin were significantly higher in patients given Rado-Salil®, whereas paracetamol consumption was significantly lower in this group compared with placebo (Table 5).

Tolerance

One pruriginous reaction with placebo was observed after 1 week of treatment. Another pruriginous reaction after 1

week and three cases of a slightly burning erythematous reaction after 10–12 days occurred in the group given Rado-Salil®. These local reactions resolved spontaneously after the end of the trial. They did not require any symptomatic topical treatment and the trial was not interrupted.

Table 1
Composition of 1 g of Rado-Salil®

Ingredient	Quantity (mg)
Ethylsalicylate	17.64
Methylsalicylate	26.47
Glycolsalicylate	8.82
Salicylic acid	8.82
Camphor	4.41
Menthol	55.14
Capsicum oleoresin	15.44
Cera emulsificans, oleylium oleinic, paraffinum solid, oleum officinale, lavendula essence bergamot essence, vaselinum album.	To make up to 1.00 g

Table 2
Assessment of patients at days 3 and 14

Test	Placebo	Rado-Salil®	*P**
Improvement in pain score (0–10 cm linear scale)			
Day 3	0.15	1.90	<0.001
Day 14	0.40	3.79	<0.001
Improvement in muscular contracture score (0–4 scale)			
Day 3	0.00	0.80	<0.001
Day 14	−0.05	1.40	<0.001
Finger–floor distance (cm)			
Day 3	0.55	1.70	NS
Day 14	−0.25	2.95	<0.001
Extension (degrees)			
Day 3	−0.25	1.25	NS
Day 14	−0.50	1.50	<0.01

*Statistical significance was analysed using the Student's *t*-test (NS, not significant).

Table 3
Patient's opinion at days 3 and 14

	Exacerbation	No effect	Moderate effect	Good effect	Excellent effect	*P**
Placebo (n=20)						
Day 3	1	17	2	0	0	NS
Day 14	3	12	3	2	0	NS
Rado-Salil® (n=20)						
Day 3	2	4	9	5	0	<0.001
Day 14	0	4	6	8	2	<0.001

*Statistical significance was analysed using the χ^2-test (NS, not significant).

Table 4
Physician's opinion at days 3 and 14

	Exacerbation	No effect	Moderate effect	Good effect	Excellent effect	*P**
Placebo (n=20)						
Day 3	1	17	2	0	0	NS
Day 14	3	13	3	1	0	NS
Rado-Salil® (n=20)						
Day 3	1	7	6	6	0	<0.001
Day 14	0	5	6	7	2	<0.001

*Statistical significance was analysed using the χ^2-test (NS, not significant).

Table 5
Consumption of ointment and paracetamol

	Placebo	Rado-Salil®	*P**
Total ointment consumption (g)	3.0	4.8	<0.05
Ointment application to the skin (mg/cm^2)	26.4	48.4	<0.05
Total no. of paracetamol tablets used	36	24	<0.02

*Statistical significance was analysed using the Student's t-test.

DISCUSSION

This double-blind parallel study of Rado-Salil® versus placebo in the treatment of mechanical low-back pain showed that this revulsive ointment is safe and efficacious in this indication. Statistically significant improvements in spontaneous pain, muscular contracture and both the patient's and physician's opinions were observed by day 3. These improvements persisted at day 14 and, in addition, statistically significant improvements were noted in the finger–floor distance and the degree of lumbar extension. Treatment with Rado-Salil® also resulted in a significant reduction in the use of oral analgesics. Only a few localized transient side-effects requiring no specific treatment were observed. Consequently, Rado-Salil® is a valuable localized treatment for low-back pain.

Desensitization of the cutaneous nociceptors on application of Rado-Salil® might be partly responsible for its analgesic effect. This might be due to: depletion of the local neuromediators needed for further pain transduction as a consequence of the substantial secretion of these mediators after application of the ointment,[14] or to a direct deleterious effect of these irritants on the membranes of the unmyelinated fibres involved in pain transmission.[15] Classic analgesic physiotherapy techniques used in low-back pain, such as low frequency electrostimulation,[10] electro-acupuncture[9] and, perhaps, massage,[16] in addition to effects on the central nervous system which can be explained both by the gate control theory and an increased production of opioid-like peptides, might also desensitize the peripheral nociceptors.[17–19]

The local temperature increase due to vasodilatation is another consequence of the local release of these neuromediators and also contributes to pain release.[7] In addition, by reducing the activity of γ-fibres which causes a reduction in the neuromuscular spindle excitability, the temperature increase partly suppresses the lumbar contracture.[16] In fact, thermotherapy in the form of ultrasound, hot pack or mud applications, short- or microwaves and infra-red radiation is part of the classic physical treatment of low-back pain.[20]

In conclusion, as an adjuvant therapy in the treatment of low-back pain, topical applications of irritant ointments, such as Rado-Salil,® might be an effective alternative to certain physical treatments particularly in patients unable to follow regular courses of physical treatment or when physiotherapeutic facilities are unavailable.

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