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ASSESSMENT OF THE EFFICACY OF SACROILIAC CORTICOSTEROID INJECTIONS IN SPONDYLARTHROPATHIES: A DOUBLE-BLIND STUDY

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SUMMARY

Despite previously carrying out a first open study of sacroiliac injection of long-acting corticosteroid, it was not possible to evaluate the role of a placebo effect. We therefore performed a double-blind study in 10 patients/13 articulations, suffering painful sacroiliitis. At 1 month, 5/6 sacroiliac joints injected with corticosteroid described a relief of >70%, in comparison to 0/7 of the placebo group ($P < 0.05$). Dolometry showed a marked decrease in the corticosteroid group from (mean ± S.E.M.) 6.8 ± 0.6 to 1.3 ± 0.3, and decreases were mild in the placebo group: 7.0 ± 0.6 to 5.2 ± 0.5 ($P < 0.005$). Six of the seven sacroiliac joints of the placebo group and two patients with failure and relapse of the corticosteroid group were reinjected with corticosteroid. At 1 month, 12/14 (85.7%) were assessed as having a good result. Results were still significant at 3 months (62%) and 6 months (58%). Tolerance was good or very good in 86% of the cases, and we did not report any notable complication. This technique is safe and very efficient, and it has to be considered more widely in patients with contraindications or complications with NSAID, or if the medical treatment is unable to control sufficiently the active sacroiliitis.

KEY WORDS: Sacroiliac, Injection, Corticosteroid, Infiltration, Spondylarthropathy.

SPONDYLARTHROPATHIES (SAP) are different types of axial inflammatory rheumatism characterized by a relationship to HLA B27 and sacroiliac involvement. The sacroiliac joint is generally the first symptom and one of the most painful articulations of these axial rheumatic diseases [1, 2]. Other authors have described the disease as peculiarly benign [3–5], but although NSAIDs are generally effective during painful periods, they are often inadequate to provide total pain relief. In some cases, NSAIDs cannot be discontinued or are poorly tolerated, producing secondary gastrointestinal complications. Lehtinen [6] found that these complications contributed to the increased mortality of patients with SAP. As most drugs modifying anti-rheumatic diseases (DMARDs) give disappointing results when there is axial involvement, therapeutics can rapidly prove ineffective, especially for the most severe forms of these diseases.

In a previous open study, we showed that injection of corticosteroids into the sacroiliac joint was technically possible, safe and effective (>80% good or very good results) [7]. As we were unable to assess the role of the placebo effect in these results, the present double-blind study was undertaken to evaluate the effects of intra-articular injection into the sacroiliac joint of corticosteroids versus placebo in SAP.

MATERIALS AND METHODS

Study design

Randomization allowed the possibility of a placebo or corticosteroid sacroiliac injection for each patient. Patients received either a 1.5 ml injection of cortivazol (Roussel Laboratories), a long-acting corticosteroid (equivalent to 62.5 mg of prednisone) or an isotonic saline solution as placebo. In the case of failure at the 1 month clinical control, regardless of the preparation injected, the double-blind protocol was not interrupted and a new injection was scheduled with corticosteroid.

A practitioner performed infiltrations prepared without the knowledge of patients and medical staff. The technique employed was intra-articular injection, as previously described [7]. Under fluoroscopic control and after arthrography (Fig. 1), a water-soluble contrast medium (1–3 ml) containing 1.5 ml of cortivazol or isotonic solution was injected. This technique was always performed without premedication and in an ambulatory state.

Inclusion criteria

Inclusion criteria were a painful sacroiliac joint in association with sacroiliitis and the failure of more than 1 month of anti-inflammatory drug (NSAID or corticosteroid) to provide adequate pain relief. We excluded cases involving degenerative sacroiliac joints, lidocaine or iodine allergy, haemorrhagic risk and, obviously, complete ankylosing of the sacroiliac joint. According to these criteria, 10 patients were recruited and 13 sacroiliac joints injected (three bilateral injections). When both sacroiliac joints were injected, the same preparation was used. The written agreement of patients was obtained after they were informed about the placebo concept. Patients were reviewed by the same practitioner (different from the one who injected the sacroiliac joints) at 1, 3 and 6 months.

In fact, recruitment was discontinued after 1 yr when only one-third of the projected number of patients had been enrolled. Fully informed, long-suffering patients were not easily convinced to cooperate and to recognize the usefulness of this study. Seventy per cent of them preferred to receive corticosteroid injections outside the protocol.

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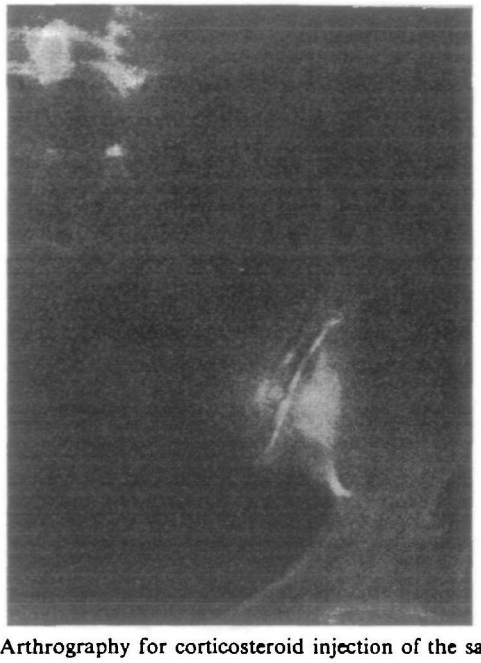

FIG. 1.—Arthrography for corticosteroid injection of the sacroiliac joint, with opacification of the joint space.

Evaluation

Initial examination by the same rheumatologist included dolorimetry (on a scale of 0–10), buttock pain and its spread into the thigh or leg, spinal pain (lumbar, thoracic or cervical), nocturnal awakening, morning stiffness, limping, buttock pain upon unipodal jump, local pressure or flexion adduction of the thigh, the Schober test and NSAID and/or corticosteroid use (with the decision as to the dosage based on the patient's opinion).

The same criteria were evaluated each time. An overall assessment of results for sacroiliac pain was made by the patient and physician: very good (if no or insignificant pain), good (>70% improvement), fair (if 50–70% improvement) and failure (<50% improvement). At the end of the study, before opening double-blind randomization, the examiner was requested to estimate which patients had not improved and which had significant results. We noted the improvement interval, the date of maximal improvement, possible complications and any relapse of sacroiliac pain. In cases of failure or relapse, the same examinations were repeated 1, 3 and 6 months after open corticosteroid injection.

Statistical analysis was performed using the Mann–Whitney test and the *t*-test for comparison of qualitative and quantitative independent parameters, and the critical probability and paired *t*-test for dependent parameters. Probability below 0.05 was considered significant.

RESULTS

Patient characteristics (Table I)

There were no significant differences between the two groups of patients. Seven joints were injected with placebo and six with corticosteroid. All SAP corresponded to Amor and European Spondylarthropathy Study Group (ESSG) criteria [8, 9]. One case with psoriasis and peripheral involvement was treated with corticosteroids and methotrexate. Two cases showed associated pustulosis, sacroiliitis and hyperostosis of the anterosuperior thoracic region. X-rays of sacroiliitis were evaluated according to three stages: I: normal

TABLE I
Features of the 10 patients (13 sacroiliac injections)

Patient	Side	Gender	Age (yr)	SAP	B27	Duration of SAP (yr)	Duration of sacroiliac pain (months)	X-ray stage	Treatment
1	R	F	47	SAPHO	+	10	1	II	NSAID
	L							II	
2	L	M	31	AS	–	1.5	6	I	NSAID
3	R	M	23	AS	+	4	48	III	NSAID
	L							III	
4	R	F	20	AS	–	4	1	I	NSAID
5	L	M	28	AS	+	3	1	II	Corticoid MTX
6	R	M	48	AS	–	8	1	II	NSAID
	L							II	
7	R	F	39	SAPHO	–	9	3	I	NSAID
8	R	F	31	AS	–	4	1	II	NSAID
9	L	M	28	AS	+	2	24	II	NSAID
10	L	M	33	AS	+	4	12	I	NSAID
Total (mean ± S.D.)	6R/7L	6M/4F	34.3 ± 10.3	8 AS/ 2 SAPHO	5 + /5 –	5.5 ± 3.0	11.4 ± 17.5	I:4 II:7 III:2	NSAID: 9 Corticoid: 1 MTX: 1
Placebo group (n = 7)	3R/4L	4M/3F	31.2 ± 8.6	5 AS/ 2 SAPHO	5 + /2 –	5.0 ± 3.5	18.4 ± 21.8	II:2 II:3 III:2	NSAID: 7
Corticoid group (n = 6)	3R/3L	4M/2F	37.8 ± 11.3	5 AS/ 1 SAPHO	2 + /4 –	6.0 ± 2.6	3.2 ± 4.4	I:2 II:4 III:0	NSAID: 5 Corticoid: 1 MTX: 1

SAP, spondylarthropathy; SAPHO, synovitis acne pustulosis hyperostosis osteitis syndrome; AS, ankylosing spondylitis; MTX, methotrexate; R, right; L, left; F, female; M, male. Patients 1–5 were injected with placebo, and 6–10 with corticosteroid.

TABLE II
Results 1 month after sacroiliac injection

Patient	Random	Patient assessment	Practitioner assessment	Dolometry variation (%)	NSAID intake variation (%)	Limping evolution	Unipodal jump evolution	Sacroiliac palpation evolution	Sacroiliac mobilization evolution
1	P	+	+	− 37	=	↓	=	=	=
	P	+	+	− 37	=	↓	=	↓	=
2	P	+	+	− 50	=	/	↓	↓	=
3	P	0	0	+40	=	=	=	=	/
	P	0	0	+40	=	=	=	=	/
4	P	+	++	− 37	− 100	↓	/	↓	↓
5	P	+	+	− 44	=	=	=	=	=
6	C	+++	+++	− 96	− 100	/	↓	↓	↓
	C	+++	+++	− 96	− 100	/	↓	↓	↓
7	C	++	++	− 80	− 50	/	=	↓	=
8	C	++	++	− 75	=	↓	/	↓	↓
9	C	+	+	− 67	=	=	=	=	=
10	C	++	+++	− 80	− 50	↓	↓	↓	↓
Total placebo group	$n = 7$	0: $n = 2$ +: $n = 5$	0: $n = 2$ +: $n = 4$ ++: $n = 1$	− 18 ± 40	− 14 ± 37.8	=: $n = 3$ ↓: $n = 3$	=: $n = 5$ ↓: $n = 1$	=: $n = 4$ ↓: $n = 3$	=: $n = 4$ ↓: $n = 1$
Total corticoid group	$n = 6$	+: $n = 1$ ++: $n = 3$ +++: $n = 2$	+: $n = 1$ ++: $n = 2$ +++: $n = 3$	− 82 ± 12	− 50 ± 44.7	=: $n = 1$ ↓: $n = 2$	=: $n = 2$ ↓: $n = 3$	=: $n = 1$ ↓: $n = 5$	=: $n = 4$ ↓: $n = 4$
P		0.05	0.05	0.003	NS	NS	NS	NS	NS

Results are variations between initial and 1 month evaluation.
0, no improvement; +, 50–70% improvement; + +, >70% improvement; + + +, complete improvement.
/, negative at initial examination; =, no change; ↓, improvement; P, placebo injection; C, corticosteroid injection.

or moderate widening of joint space; II: erosion, destruction and condensation of margins; III: ankylosis. All patients had pathological sacroiliac joint patterns on CT scans. One patient (two joints) had partial ankylosis, which still allowed access to the painful sacroiliac joint.

Results at 1 month (Table II)

Patient assessment showed five good or very good results for the corticosteroid group ($P < 0.05$). Physician assessment showed almost the same estimation for the corticosteroid group, whereas only one case in the placebo group was rated good ($P < 0.05$). Physician estimation of the results before opening double-blind randomization was mistaken for only two of 13 sacroiliac joints injected: one of seven injected with placebo judged as a good result at 1 month, and one of six injected with corticosteroid considered as a fair result at 1 month.

Dolorimetry showed a marked decrease in the corticosteroid group from (mean ± S.E.M.) 6.8 ± 0.6 to 1.3 ± 0.3. The decrease was moderate in the placebo group, from 7.0 ± 0.6 to 5.2 ± 0.5 ($P < 0.005$). Despite improvement in sacroiliac clinical examinations in the corticosteroid group, the statistical probability threshold of 95% was not reached in this small series. Spine assessment showed no differences in the two groups. Use of NSAIDs and oral corticosteroids decreased by 14% in the placebo group and 50% in the corticosteroid group.

Results at 3 and 6 months

Among the seven sacroiliac joints injected with placebo, six were reinjected with corticosteroid at 1 month. The seventh patient, who was not reinjected, had a fair result at 3 and 6 months (assessed as good by the physician).

Among the six patients injected with corticosteroid, four still had a good result at 3 and 6 months. One of these four patients was still suffering from lumbar pain, but buttock and thigh sacroiliac pain disappeared after the injection. One sacroiliac joint, considered as a fair result at 1 month, was reinjected with corticosteroid. The remaining joint had a relapse at 45 days and was reinjected at 3 months.

Analysis of all patients injected with corticosteroid

Fourteen sacroiliac joints were injected with corticosteroid: six initially, with blind follow-up, and eight others at the time of second injection, including six of the seven patients injected initially with placebo and two with failure and relapse, respectively, 1 and 3 months after corticosteroid injection.

At 1 month, 85.7% (12/14) of the sacroiliac joints injected had good or very good results, with only two failures, regardless of assessment (patient or physician). The interval before improvement ranged from 1 to 15 days, with 8/13 patients improving within the first 3 days. Dolorimetry decreased from 6.9 ± 0.6 to 3.4 ± 0.5 ($P < 0.005$). Three clinical features were significantly improved: limping ($P < 0.002$), sacroiliac pain upon unipodal jump ($P < 0.05$) and pain with buttock pressure ($P < 0.05$). Five patients had associated a decrease in lumbar pain without any significant improvement in stiffness and the Schober test. Cervical and thoracic pain were not modified.

At 3 months, 8/13 sacroiliac joints (62%) were still improved, as assessed by the physician or patient. Dolorimetry decreased by 42% ($P < 0.005$). Limping, unipodal jump and sacroiliac mobilization were

significantly improved, but not spinal features. At 6 months, 7/12 sacroiliac joints (58%) were still improved and dolorimetry had decreased by 33% ($P < 0.05$). Unipodal jump was the most significantly improved long-term clinical feature.

Tolerance

Twenty-one injections were performed using 1% lidocaine (10–20 cc) as local anaesthesia. During injection, patients estimated that pain was strong for three sacroiliac joints (14.3%), moderate for 13 and insignificant for five. With this technique, there were no notable immediate or late complications. We noted only transient perineal anaesthesia (during a few hours) and mild, temporary sciatalgia for 3 weeks, which had not been present before injection.

DISCUSSION

Our intention was to find a local approach for the treatment of SAP. Corticosteroid injection and synoviorthesis are well-known efficient treatments for peripheral arthritis. However, the deep location of the sacroiliac joint is apparently less favourable to these techniques. Using a puncture technique adapted to sacroiliac joint conditions [10, 11], we showed in an open study that corticosteroid injections were possible and efficient [7], obtaining 81% good results at 1 month. Failures were more frequent in old SAP, and there were no notable complications. However, despite rapid efficacy (2–3 days), the placebo effect could not be evaluated in this often intermittent rheumatic disease, which led us to perform the present double-blind study. Recruitment was difficult since for ethical reasons we proposed a choice between an open corticosteroid injection of the sacroiliac joint and the double-blind protocol. Despite the low number of sacroiliac joints injected, our results are unequivocal. Patient and practitioner assessments were clearly in favour of the intra-articular injection. Dolorimetry dramatically decreased in the corticosteroid group and was poorly modified in placebo groups. When the six injections performed blindly were pooled with the eight other open injections of corticosteroid (6/7 in the placebo group, one failure and one relapse), the results at 1 month were even better than in our first open study (85.7% success). Despite some relapses, results were still good at 3 and 6 months (62 and 58% success). The two cases which relapsed or failed became successes when a second injection was performed. Although there was no significant improvement in lumbar symptoms (pain, stiffness), these were minimal for all but one patient selected.

This injection technique is not invasive and is well accepted if anaesthesia is performed correctly: superficial and deep, using a very thin needle pushed in slowly and sufficient lidocaine. It appears to be safe since >200 infiltrations have been performed in our centre since 1991 without any notable complications. It can be done either during fluoroscopy, at low cost and with little irradiation when the practitioner is experienced, or CT scan. As the sacroiliac joint is protected by a thick ligament and access to the articulating surfaces is narrow, intra-articular assessment of the injection is important, as shown for other joints in a recent study [12].

At the present time, several medical centres in France employ this technique, and a wider use would seem desirable. It is indicated in three major situations: contraindication of NSAIDs, which is not rare in SAP with a high rate of gastrointestinal complications (associated enterocolopathy such as Crohn's disease or ulcerative colitis with symptomatic sacroiliitis are good indications); inadequate NSAID control of active painful sacroiliitis; and prolonged use of NSAIDs to relieve sacroiliac pain.

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