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Local sacro iliac injections in the treatment of spondyloarthritis. What is the evidence?

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Summary

Local sacro iliac injections represent an available treatment option in spondyloarthritis (SpA). There is no synthetic data about efficacy of this procedure in SpA. The aim of this review is to analyze the available data of the literature of local sacro iliac injections in SpA.

Methods. A Pubmed search of papers published after 1990 was performed.

Results. Pubmed search retained 15 publications in spondyloarthritis, 12 with corticosteroids (total of 468 injections in 268 patients), including 2 small-sized controlled studies, and 3 with TNF blockers (24 patients in open studies). With steroids, the two controlled studies (with a total number of 30 patients only) demonstrated significant results over placebo. In open studies, good response was reported in more than 80% of the cases, with a mean duration of improvement over 8 months. Reduction of sacro iliac inflammation on MRI was also found in several studies after injection. There is no consensus about the technique of injection or the type of steroid injected. No particular safety concern was reported. Many limitations have to be considered in the interpretation of these results.

Conclusion. This kind of procedure should be kept in the therapeutic armament in the current setting of costly targeted systemic treatments of spondyloarthritis. However, definition of a clear position in the treatment strategy needs further well conducted studies.

Key words : spondyloarthritis, treatment, sacro iliac joint, intra articular injection, steroids, anti TNF agents

1.Introduction

Spondyloarthritis (SpA) is a chronic inflammatory disease characterized by predominantly axial (sacro iliac and spine) involvement [1,2]. The term spondyloarthritis encompasses several subsets (ankylosing spondylitis, reactive arthritis, psoriatic arthritis, Inflammatory Bowel Disease (IBD) related arthritis, juvenile and undifferentiated spondyloarthritis). Currently, the several forms are defined more on the phenotypic presentation: axial SpA (radiographic axial SpA = ankylosing spondylitis (AS), or non radiographic axial SpA), peripheral arthritic SpA, peripheral enthesitic SpA, with the possibility of extra articular manifestations (uveitis, psoriasis, IBD) in each subset [3].

Inflammatory involvement of the sacro iliac joints represents a cornerstone in the disease, leading to clinical symptoms (buttock pain) and imaging features (radiographic and Magnetic Resonance Imaging (MRI)), part of the several classification criteria sets [4]. An international definition of a positive sacro iliitis in MRI is available [2]. Inflammatory changes in sacro iliac joints represent a major argument in favor of the diagnosis, even in the absence of radiographic findings or absence of HLA-B27, but also a prognosis factor for subsequent evolution towards radiographic changes and for a better response to systemic treatment, particularly anti TNF agents.

The treatment strategy is based on non pharmacological and pharmacological options [5]. For the latter, NSAIDs represent the first line option. In case of non response to NSAIDs, disease modifying anti rheumatic drugs may be proposed pending the phenotypical presentation. Local peri articular and articular (including sacro iliac joints) injections may also be indicated [5]. The aim of this review is to look at the results and evidence of sacro iliac injections in the treatment of spondyloarthritis, based on literature data.

2.Methods.

The literature analysis was performed through Medline/pubmed search, using « spondyloarthritis », « sacro iliac joint », « intra articular injection »(("sacroiliac joint"[MeSH Terms] OR ("sacroiliac"[All Fields] AND "joint"[All Fields]) OR "sacroiliac joint"[All Fields]) AND ("injections"[MeSH Terms] OR "injections"[All Fields] OR "injection"[All Fields])) AND ("spondylarthritis"[MeSH Terms] OR "spondylarthritis"[All Fields] OR "spondyloarthritis"[All Fields]), limited to English, French and German language, dealing with adults, published after 1990. The investigation was completed with hand search in references of published papers. Publications in abstract form only were not taken into account.

3.Results.

We found 46 references through Pubmed, and three through manual search. Finally 15 papers were kept for analysis [6-20]. The other publications were excluded for several reasons: no local injection, not concerning sacro iliac joint, dealing with children, reviews on treatment in SpA, not concerning SpA, but mechanical disease.

The available analyzable data are summarized in tables 1 and 2. Two kinds of pharmacological agents have been used: steroids mainly [6-17] and TNF blockers anecdotally [18-20].

For steroid injection, there are only two controlled, small sized studies [9,17], all the other studies are open, rarely prospective [12,16]. Different kinds of steroids were used : Acetonide Triamcinolone (40 mg) [7,8,10,13-16], Cortivazol [6,9], Betamethasone [11]. Different injection procedures were performed: guided with CT, fluoroscopy, MRI, or US, or not guided [14].

Outcome was mainly the evaluation of local pain using a visual analogic scale (VAS), but some studies used also MRI evaluation (reduction of bone marrow edema after steroid injection) [7,8,10,12,13].

3.1.Global results :

The first controlled study included 10 patients with 13 sacro iliac joints injected, seven with placebo and 6 with corticosteroids (Cortivazol, equivalent of 62.5 mg of prednisone) in patients with SpA and sacro iliac pain not controlled by at least one month of general anti inflammatory treatment [9]. Injections were performed under fluoroscopic control and after arthrography. Results were significantly better in the corticosteroid group, compared to placebo: decrease in pain and anti inflammatory drugs use at one month, and good results were maintained at 3 and 6 month in around 60 % of the joints injected. The second controlled study has 20 patients randomized between methylprednisolone acetate and placebo (10 patients each). Injection was unguided and presumed periarticular. Significant reduction in pain was observed at the 2 months evaluation in the treatment group compared to placebo [17].(Table 3)

Taking all these data together with open labeled studies, a total number of 457 sacro iliac injections with corticosteroids were performed in 268 patients with spondyloarthritis. An improvement is reported in the majority of cases at short time: good response (defined as a significant reduction in pain VAS, Table 3) in 80 to 95 % of patients [6,8,11,12]. Duration of improvement remained at 3 and

6 months [9,16], and the mean duration of improvement was over 8 months [6,7,8,10,12,13]. MRI evaluation demonstrated reduction in bone marrow edema or in contrast enhancement in sacro iliac joint after injection in the majority of the cases [7,8,10,12,13]. Reduction in CRP and ESR levels after injection were found in some studies [7], but no in other [13]. Reduction in NSAID use was also described [7]. No serious adverse event has been reported, and no particular safety concern was mentioned, particularly no nerve injury.

3.2. Comparison with steroid injection in non inflammatory conditions.

The efficacy of sacro iliac injection of triamcinolone was assessed in patients without spondyloarthritis. This study showed that 66% out of 39 patients with presumed sacro iliac pain after local anesthesia block experienced significant pain reduction for a mean duration of 36.8 ± 9.9 weeks [21].

3.3. Repeated injections was evaluated in one study [13]. A second injection seems to be effective in patients with primary non response, and in case of relapse, with longer efficacy duration after the second injection.

3.4. Factors associated with good response to this therapy were found in some studies. Maugars et al found that patients with a shorter SpA duration and patients with an immediate relief after the injection demonstrated good therapeutic results [6]. Braun et al suggested that more severe sacro iliitis on MRI at baseline was associated with a better response to corticosteroid injection [7]. The precise location of injection may influence the results. This is suggested by Althoff et al [16], reporting that in patients with confirmation of intra articular position a significant reduction of pain scores were observed over 6 months after injection, whereas no significant reduction was seen in patients with periarticular position of the needle (verified by CT scan). However, this is not in accordance with the results of two other studies (one controlled) finding significant improvement after injection in periarticular position [14,17], and the study by Hartung et al [15] with similar mean pain relief in cases of intra or peri articular position (verified by ultrasound). Although there is no comparative study available, there seems no apparent difference in efficacy related to the type of corticosteroid injected.

3.5. Anti TNF injections in the sacro iliac joints have also been reported. There are only few data and two TNF blockers were used. One case report illustrates clinical and radiological improvement over 2 years after sacro iliac injection of Infliximab (monoclonal antibody directed against TNF-alpha) [18]. Two other series are available. One with CT guided injection of 25 mg Etanercept (soluble receptor

for TNF alpha), three injections (weeks 0,4,8) in 16 patients with active ankylosing spondylitis [19]. A significant improvement of BASDAI at weeks 8 and 12 was observed, with reduction in sacro iliac SPECT and MRI scores (edema and fatty signal reduction in all patients at week 8). Tissue expression of TNF alpha and TGF beta mRNA in sacro iliac joint decreased significantly in half of the patients at week 8, compared to baseline. No adverse event was reported.

Another study, with single bilateral sacro iliac injection of 20 mg Infliximab in 7 patients with SpA and active sacro ileitis on MRI has been published, with evaluation at 12 and 24 weeks after injection [20]. Significant improvement in pain, stiffness, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) was found at the two time points, compared to baseline. ASAS 20 response was reached in all patients, and ASAS40 in 5 out of 7. A non significant decrease in functional index (BASFI), CRP levels, sacro iliac bone marrow edema score was also reported.

Taken together, the results of these open studies suggested an improvement in clinical and imaging outcomes, not only locally, but also on general outcome measures such as BASDAI or ASAS response.

4. Comments

The analysis of the literature concerning this therapeutic modality is difficult, in view of the globally low number of patients, in majority included in open, often retrospective studies. A great heterogeneity of the procedure (injection technique, pharmacologic product injected) should also be taken into account. Detailed information about the phenotype of SpA, global disease activity level, previous treatments is frequently lacking. Moreover, there is a variability in the principal outcome measure of response to treatment among the studies. Pain assessment represents this outcome of evaluation in most of the studies, but there is no validated specific response criteria for sacro iliac pain.

There is a low level of evidence, but two controlled small-sized studies are available [9,17]. However, there are concordant results of many open studies, with high percentage of patients improved, and results lasting several months. This treatment option appears safe, but we have to bear in mind the possibility of septic arthritis after local sacro iliac corticosteroid injection for mechanical disease [23,24].

Some questions arise from these results.

What is the level of confidence that the pain described by the patient generates from sacro iliac joint ? Sacro iliac suspected origin of pain was confirmed by anesthetic block only in about 30 % of

patients not having spondyloarthritis [22]. This raises the question of the relevance of a prerequisite anesthetic block.

Which is the best procedure for injection, from the results and taking into account radiation exposure ? In a randomized controlled trial, Jee et al [25] included 120 patients with non-inflammatory sacro iliac dysfunction and compared ultra sound-guided versus fluoroscopic-guided injection. The authors found no differences in improvement of pain and function, between the two groups. However, fluoroscopy-guided injection demonstrated greater accuracy compared to ultrasound-guided injection (98.2% and 87.3% respectively). In the perspective of availability, simplicity and absence of irradiation, ultrasound-guided injections should be encouraged, but this supposes trained operators.

Sacro iliac injection of Anti TNF agents do not seem to bring more efficacy than steroids, even if there is no comparative study available. So far, we ignore what is the right dosage of anti TNF and which anti TNF agent is more suitable. There might be a rationale for using local injection of TNF blockers, since local production of TNF in the sacro iliac joint was demonstrated on sacro iliac biopsies [26]. Nevertheless, the cost is far superior for anti TNF agents, compared to injectable steroids, and this needs to be considered.

5. Finally, there are many limitations in the interpretation of the available data in this field.

The number of cases reported is low, concerning mainly open evaluations, often retrospective; only two small-sized controlled studies are available including a total of 30 patients. Biases may interfere with the impact and interpretation of the results, such as lack of diagnostic ascertainment, various patients characteristics and follow-up duration, heterogeneity in injection techniques. Moreover, there are no comparative studies between local SI injections and systemic treatment (with biologic agents , for example).

These considerations may represent a research agenda and may pave the way for further studies on sacro iliac steroid injections, an ambulatory, low cost procedure.

Disclosure

- Financial interests: none
- Durable or permanent links: none

- Occasional interventions: AbbVie, BMS, MSD, Pfizer, Roche Chugai, Amgen, Nordic Pharma, UCB, SOBI, Sanofi Aventis, Novartis, Janssen, Celgene, Hospira, Lilly, Sandoz, Grünenthal
- Indirect interests (hospitality, research grants) : Abbvie, Pfizer, Roche Chugai, MSD, UCB, Mylan

Significance and innovation :

- sacro iliac injection is a simple technique, widely available, inexpensive
- data from the literature, including two small controlled studies with corticosteroids, provide interesting results
- many limitations deem the meanings of these results.

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Table 1 : data from the literature : steroid injection in the sacro iliac joint in spondyloarthritis : reference;

Author Year [ref]	Injected agent	Number	Disease	Injection	Results	Duration	safety
Maugars 1992 [6]	Cortivazol 1.5 ml 62.5 mg prednisone open	22 patients 42 injections	SpA	Fluoroscopic	Good response in 81% of injected joints	Mean duration of improvement : 8.4 +/- 4.5 months	No safety problem
Braun 1996 [7]	Acetonide Triamcinolone 40 mg open	30 patients 54 injections	SpA, AS	CT guided	Improvement in pain and contrast enhancement SI MRI	83% of patients at 5.2 months Subjective improvement lasted a mean of 8.9 months	
Bollow 1996 [8]	Acetonide Triamcinolone 40 mg open	66 patients 103 injections	Inflammatory back pain	CT guided	Significant pain reduction in 92.5% of patients at 1.7 weeks Reduction in contrast MRI enhancement	Clinical improvement lasted for 10 +/- 5 months	
Maugars 1996 [9]	Cortivazol 1.5 ml 62.5 mg prednisone Double blind vs placebo	10 patients 13 injections	SpA	fluoroscopy	Relief > 70% at 1 month : 5/6 steroid 0/7 placebo	More than 50 % good results at 3 and 6 months	Tolerance good or very good in 86%
Gunaydin 2000 [10]	Acetonide Triamcinolone 40 mg open	9 patients 16 injections	SpA	MRI guided	7 of 9 patients reported subjective improvement Resolution of bone marrow edema in 8	Improvement lasting 10.8 +/- 5.6 months	No SAE
Karabacakoglu 2002 [11]	Betamethasone 14 mg	17 patients 22 joints	AS	fluoroscopy	Improvement in 90% of joints injected	1 month	No safety problem
Fritz 2005 [12]		26 patients	AS	MRI guided	85% of patients improved (predefined VAS reduction) 38% reduction in bone marrow	Mean remission time : 12 (4-18) months	

					edema		
Gunaydin 2006 [13]	Acetonide Triamcinolone 40 mg open	31 patient s 50 injection s 15/31 received a second injection	SpA	MRI guided	Improvement : 20/31 (1 injection) 9/15 (2 injections) Bone marrow edema resolution in 15 of 20 patients improved after first injection	Improvem ent duration : 8.7 +/- 10.9 months (1 injection) and 16.1 +/- 15.8 months (2 injections)	No safety proble m
Sadreddini 2009 [14]	Acetonide Triamcinolone 40 mg open	29 patient s, bilater al	SpA	unguided	Pain , morning stiffness significantly decreased	Pain reduction maintained at week 20	No SAE
Hartung 2010 [15]	Acetonide Triamcinolone 40 mg open	14 patient s 20 SI injection s	Active sacro iliitis	Ultra sound guided (MRI verificati on)	40% correctly positioned, 60% periarticular Mean pain relief similar in the two groups	Pain relief maintained at day 28	
Althoff 2015 [16]	Acetonide Triamcinolone 40 mg open	29 patient s 50 SI injection s	SpA with active sacro iliitis	CT guided	Intra articular :22, with pain score reduction peri articular :7 no improvement	Intra articular : pain reduction maintained at 3 and 6 months	
Luukkaine n 1999 [17]	Methylprednisolone acetate 60 mg Randomised	20 patient s	SpA	unguided	Significant improvement VAS and pain index versus placebo at 2 months		

SpA : spondyloarthritis; AS : ankylosing spondylitis; CT : computed tomography; MRI : magnetic resonance imaging; SAE : serious adverse event

Table 2 : sacro iliac injection of TNF blockers in spondyloarthritis. Data from the literature.

Author Year [ref]	Injected agent	Number	Disease	injection	Results	Duration	Safety
O'Shea 2009 [18]	IFX 20 mg	1	Sacro iliitis, HLA-B27 negative		Improvement Clinical and radiographic	2 years	
Cui 2010 [19]	Eta 25 mg W0,W4,W8	16	AS	CT guided	Improvement : BASDAI SPECT, MRI Reduction SI mRNA TNF, TGF	12 weeks	No AE
Soliman 2015 [20]	IFX 20 mg bilateral	7	nonRx-axSpA MRI+		ASAS 20: 100% ASAS 40 : 71% Pain and BASDAI improvement	24 weeks	

IFX : infliximab ; ETA : etanercept ; AS : ankylosing spondylitis ; nonRx-axSpA : non radiographic axial spondyloarthritis ; MRI : magnetic resonance imaging ; CT : computed tomography ; BASDAI : Bath ankylosing spondylitis disease activity index ; ASAS : assessment in spondyloarthritis international society; AE : adverse event.

Table 3 : Quantitative results (primary outcome measure : visual analogic scale sacro iliac pain) of sacro iliac injections of steroids in the two controlled studies and two open studies.

VAS pain	Baseline (BL)		After treatment		
Study [ref]	Steroids	Placebo	Steroids	Placebo	p
Maugars [9] RCT Mean (SEM)	6.8 (0.6) (n = 6)	7.0 (0.6) (n = 7)	1.3 (0.3) (1 month)	5.2 (0.5) (1 month)	< 0.005 (Steroids vs placebo)
			Change BL – 2 months		
Luukkainen [17] RCT Median (range)	5.45 (2.2 – 8.8) (n = 10)	3.85 (0.4 – 5.8) (n = 10)	-2.65 (-8.2, -1.3)	-0.15 (-4.7, -3.8)	0.02 (Steroids vs placebo)
Althoff [16] open Mean (SD)	7.3 (1.3) (n = 29)		4.3 (3.3) (1 month)		0.01 (After vs BL)
Braun [7] open Mean (SD)	8.5 (1.5) (n = 30)		3.0 (2.3) (3 months)		< 0.01 (After vs BL)

RCT : randomized controlled trial