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Br. J. Sports Med. published online 9 Apr 2008;
doi:10.1136/bjsm.2007.042044

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The use of prolotherapy in the sacro-iliac joint

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ABSTRACT

Objective: To determine whether prolotherapy is effective in the treatment of deficient load transfer of the SIJ
Design: A prospective descriptive study
Setting: Authors' private practice
Participants: 25 patients who consented to treatment and attended for at least one follow up visit and assessment
Study period: From April 2004 to July 2007
Intervention: Three injections of hypertonic dextrose solution into the dorsal interosseous ligament of the affected SIJ, under CT control, six weeks apart
Main outcome measures: Quebec Inventory, Roland Morris 24, Roland Morris 24 Multiform questionnaires and clinical examination by two authors independently

Results

All patients included in this study attended for at least one follow up visit at 3, 12 or 24 months. The number of patients at follow up decreased at 12 and 24 months. Functional questionnaires demonstrated significant improvements for those followed up at 3, 12 and 24 months ($p < 0.05$). Clinical scores showed significant improvement from commencement to three, 12 and 24 months ($p < 0.001$)

Conclusions

This descriptive study of prolotherapy in private practice has shown positive clinical outcomes for the 76% of patients who attended the 3 month follow up visit (76% at 12 months and 32% at 24 months). Similar results were found in the Questionnaires (Q, RM and RMM) at 3, 12 and 24 months.

Trial registration

Written informed consent was obtained from all participants in the trial. This was conducted as a practice quality project, and as such did not require ethics approval or trial registration.

Keywords: Low Back Pain, Pelvic Girdle Pain, Prolotherapy, Sacro-iliac Joint

INTRODUCTION

Prolotherapy treatment has been advocated for a variety of soft tissue conditions, including non-specific low back pain, chronic musculoskeletal pain and hypermobility of joints [1, 2]. The goal of this therapy is to produce dense fibrous tissue to strengthen the attachment of ligaments, tendons, joint capsules and other fascial structures at their fibro-osseous junctions [3]. Prolotherapy has been defined as “the rehabilitation of an incompetent structure (as a ligament or tendon) by the induced proliferation of new cells” [4]. This procedure was initially used for treatment of spinal pain in the 1930s. Its use continues despite the controversy that has surrounded it. A frequent indication is spinal or low back pain. The

injection techniques, the substances used, the volumes injected and the site or sites injected vary from study to study [5, 6].

The sacroiliac joint (SIJ) is a source of pain in the lower back and buttocks in up to 15% of the population [7], and there is evidence that dysfunction of this joint could, similar to a herniated lumbar disc, produce pain along the same distribution as the sciatic nerve [8, 9]. Schwarzer et al (1995) administered anaesthetic sacro-iliac joint blocks in a low back pain population. Fifty four patients completed the study. They found 10 of them (18.5%) were considered as having pain from sacro-iliac joint origin [10]. Given that the injections were given into the synovial part of the joint and did not involve the posterior ligaments, it is possible that the sacroiliac joint is responsible for chronic low back pain in a higher proportion of subjects.

The purpose of this study is to examine whether prolotherapy injections into the dorsal interosseous ligament of the SIJ can assist patients with a clinical diagnosis of deficient stability of the SIJ that fails to respond to specific exercise therapy. The null hypothesis is therefore that prolotherapy injections, in addition to exercise therapy, do not improve the clinical examination parameters or functional scores.

METHODS

Patients were recruited from the private practices of two sport and exercise medicine (SEM) physicians and two physiotherapists. Patients who fulfilled the entry criteria were invited to participate in the prospective study after the treatment programme was explained in detail. Verbal and written information was provided before patients were asked to make a separate appointment to give their written consent once they had their questions answered and had reached a decision. This study was conducted as a practice quality project and as such did not require ethics approval or trial registration. It has been approved as a maintenance of professional standards (MOPS) activity of the Australasian College of Sports Physicians.

Entry criteria included a diagnosis of persistent suboptimal stability of the sacro-iliac joint following a three months specific exercise program. This diagnosis had to be made independently by a SEM physician (MC, JS) and a physiotherapist (BH, TWR) involved in the study.

Clinical history included localised and/or radiating low back or buttock pain in the vicinity of the posterior superior iliac spine, worse on loading positions such as standing, sitting, walking or negotiating stairs. Symptoms had to be present for a minimum of six months prior to the initial assessment. Exclusion criteria were acute radiculopathy, infection, pregnancy, inflammatory conditions of the sacro-iliac joint and malignancy.

The clinical tests used were the sacroiliac joint (SIJ) glide test (antero-posterior and vertical arm, with and without self bracing) [11], posterior pelvic pain provocation test (PPPP) [12], active straight leg raise (ASLR) [13-15] with and without self bracing and external manual compression and stork support (Gillett) test [16]. A score of one was given for each positive finding. Clinical tests were therefore not graded. Maximum score was nine.

Twenty five patients entered in the study after the exercise program had shown no benefit. They underwent three injections of prolotherapy solution six weeks apart. They were assessed within 24 hours before each injection, by both SEM physician and physiotherapist, and one week after each injection. They continued to carry out the exercise programme under physiotherapist supervision. They filled in pain maps, the Quebec Back Pain Disability Scale, Roland Morris 24 [17] and Roland Morris 24 multi-scale Disability Questionnaires at the point of entry and periodically over the following two years. They were weaned from non steroidal anti-inflammatory medication prior to the first injection and for the duration of the treatment

INJECTION PROTOCOL

Written informed consent was obtained in every case. All injections were done under CT control, by the same radiologist (PL), on a Siemens Somatom plus 4 CT scanner, according to the following protocol [18]:

The patient was positioned in the CT scanner with head first, in the prone position. Pillows were placed under chest and ankles, the head resting on forearms and the face clear of the pillow. Gentle respiration was allowed. Axial slices 5mm apart were obtained over the sacral area, and the appropriate level was selected for injection. The entry point on the patient was localised with use of CT slice laser and axis/distance function from scanner, and marked with pen on the skin. The skin was prepared with antiseptic Betadine and alcohol. The skin was then anaesthetised with 3 ml of 1% Xylocaine.

The prolotherapy solution was prepared by drawing into a 5 ml syringe 1.8ml of 50% Glucose solution, 2.3ml of Bupivacaine 1% and 0.8ml of Isovue® (iopamidol) 300 contrast (approx), and 0.8 ml were injected into the ligament.

After allowing time for the local anaesthetic to work, a 22g spinal needle was inserted with the appropriate angle and depth to interosseous ligament, as close to its ilial attachment as possible. Once the needle was in place the prolotherapy 0.8 ml of solution were injected as the needle was moved up and down in the ligament (Fig 1). Care was taken to ensure that only the ligament was injected, but not the auricular synovial portion of the joint.

Post procedure patients were asked to keep pain records for 14 days. They were also given specific warnings about possible complications such as bruising, and of the rare possibility of infection. No adverse effects were reported.

RESULTS

Twenty five patients were treated between 2004 and 2007, with a 26 month average follow up post injections (range 6-39 months). There were 5 male and 20 female patients (Table 1). Their average age was 40.4 (range 26-67). One male patient was lost to follow up after 12 months when he moved to another country; two others have had no formal follow up assessments, but remained asymptomatic when contacted by phone. Two patients withdrew from follow up at two years, because unrelated medical causes. Their scores had also improved considerably. One male patient received a fourth injection in the sacro-tuberous ligament to successfully settle what were considered to be residual instability symptoms.

The main outcome measures were the negative findings in the clinical examination (patients had improved clinically) carried out independently by two authors (one SEM physician and one physiotherapist), the Quebec Back Pain Disability Scale and Roland Morris 24 and Roland Morris 24 Multi-form Questionnaires. Statistical analysis was carried out with SPSS software.

Clinical Examination scores

Nine clinical testing manouvres were performed independently by two examiners, and a consensus score was given. Each positive test was given a score of one. Maximum clinical score was nine. If a particular testing manouvre was not done, it was scored zero. Scores were analysed with the Student t test for matched pairs. Clinical scores on entry into the program averaged 7.2 (range 4-9, SD 1.5) at the point of decision to proceed to injections. The mean clinical scores showed a significant decrease of 4.5 points at three months, 5.0 points at 12 months ($p < 0.001$) and 6.5 points at 2 years from the commencement score prior to treatment (see Table1).

Clinical	Pre Treatment (SD)	Post Treatment (SD)	Difference in means	95% Confidence Interval	p value
3 months (n=19)	7.2 (1.5)	2.7 (2.2)	4.5	3.5 to 5.5	< 0.001
12 months (n=19)	7.2 (1.4)	2.2 (1.7)	5.0	3.9 to 6.1	< 0.001
2 years (n=8)	7.1 (1.6)	0.6 (0.7)	6.5	5.2 to 7.8	< 0.001

Table 1. Clinical Scores at 3, 12 and 24 months using t test for matched pairs

Interestingly, there was improvement before the course of injections was finished. Some changes were noted after the first injection, and more marked improvement after the second injection. The PPPP test was the first one to become normal, and the ASLR was the last. However when the ASLR test was combined with self bracing and/or external compression of the anterior superior iliac spines (ASIS) by the examiner, it was normal in 80% of cases by the time the third injection was given. The SIJ glide test results improved earlier. The Stork test was negative in two thirds of the patients at the time of the third injection.

Functional questionnaire scores Quebec Back Pain Disability Scale

The mean total score for the Quebec Back Pain Disability Scale at commencement was 58.1 (SD 19.4). The three months post treatment scores were significantly improved, by 20.7 points (95%CI 11.3 to 30.1, $p < 0.001$). At 12 months post treatment the improvement was 18.2 points (95% CI 7.8 to 28.6, $p < 0.002$), and at 24 months 33.3 points (95%CI 13.7 to 52.9, $p < 0.006$). The improvement in Quebec Back Pain Disability Scale scores remained significant at 12 months and 2 years (see Table 2).

Quebec	Pre Treatment (SD)	Post Treatment (SD)	Difference in means	95% Confidence Interval	p value
3 months (n=15)	58.1 (19.4)	37.4 (25.0)	20.7	11.3 to 30.1	< 0.001
12 months (n=15)	57.7 (21.2)	39.5 (20.7)	18.2	7.8 to 28.6	0.002
2 years (n=7)	62.3 (24.7)	29.0 (28.0)	33.3	13.7 to 52.9	0.006

Table 2. Quebec Back Pain Disability Scale Scores at commencement, 3, 12 and 24 months using t test for matched pairs

Roland-Morris Back Pain Questionnaire (RMQ)

The mean total score for the RMQ at commencement was 13.3 (SD 5.0). The three months post treatment scores were significantly improved, by 6.1 points [19] (25)(28) (95%CI 3.0 to 9.2, $p < 0.001$). At 12 months post treatment the improvement was 2.5 points (95% CI 0.0 to 5.0, $p < 0.047$), and at 24 months 4.4 points (95%CI 0.8 to 15.7, $p < 0.035$). The improvement in RMQ scores remained significant at 12 months and 2 years (see Table 3).

Roland Morris 24	Pre Treatment (SD)	Post Treatment (SD)	Difference in means	95% Confidence Interval	p value
3 months (n=15)	13.3 (5.0)	7.2 (5.8)	6.1	3.0 to 9.2	0.001

12 months (n=12)	13.0 (4.1)	10.5 (4.6)	2.5	0.0 to 5.0	0.047
2 years (n=7)	12.7 (4.3)	4.4 (5.9)	8.3	0.8 to 15.7	0.035

Table 3. Roland Morris Questionnaire Scores at commencement, 3, 12 and 24 months using t test for matched pairs

Roland Morris 24 Multi-form Questionnaire

The mean total score for the Roland Morris 24 Multi-form Questionnaire at commencement was 151.4 (SD 55.0). The three months post treatment scores were significantly improved, by 61.5 points (95%CI 30.0 to 93.0, p 001). At 12 months post treatment the improvement was 37.9 points (95% CI 8.2 to 67.7, p <0.016), and at 2 years 90.0 points (95%CI 27.1 to 152.9, p 0.012). The improvement in Roland Morris 24 Questionnaire Multi-form scores remained significant at 12 months and 2 years (see Table 4).

Roland Morris multi	Pre Treatment (SD)	Post Treatment (SD)	Difference in means	95% Confidence Interval	p value
3 months (n=14)	151.4 (55.0)	89.9 (68.5)	61.5	30.0 to 93.0	0.001
12 months (n=14)	146.5 (55.8)	108.6 (44.9)	37.9	8.2 to 67.7	0.016
2 years (n=8)	141.0 (64.2)	51.0 (47.3)	90.0	27.1 to 152.9	0.012

Table 4. Roland Morris multi Questionnaire Scores at commencement, 3, 12 and 24 months using t test for matched pairs

DISCUSSION

Prolotherapy has been advocated in the treatment of low back pain for many years. However, its published results have not been consistent. A large, well conducted RCT concluded that prolotherapy was no better than the injection of normal saline[20]. A Cochrane Collaboration report concluded that: “There was no evidence that prolotherapy injections alone were more effective than control injections alone, but in the presence of co-interventions, prolotherapy injections were more effective than control injections, more so when both injections and co-interventions were controlled concurrently” [21].

Most studies that involve the use of prolotherapy in the treatment of spinal pain do not consider a specific clinical diagnosis for patient selection. Patient selection is based mainly on pain symptoms in the low back region, and the injections are given in the painful sites. Injected volumes depend on the number of sites injected. This could explain the inconsistency of results [20], as there is no evidence that the proliferation of soft tissue is analgesic *per se*. However, if injury to specific structures, such as ligaments or fascia, can be related to a specific clinical presentation and subsequent loss of function associated with pain, a case could be made for the use of prolotherapy. It is important however that appropriate treatment protocols conducted by clinicians experienced in the effective rehabilitation of pelvic disorders be trialed before proceeding to prolotherapy.

Understanding of the role of the SIJ has improved in recent years. The muscular contribution to the dynamic stability of the pelvis has been verified in vivo [22]. In the presence of pain there is evidence of altered muscle recruiting patterns and altered load transfer [23]. Symptoms and muscle recruiting patterns can improve with appropriate exercise therapy [24, 25]. Clinical tests exist to examine the load transfer function of the sacroiliac joint [13-15]. In cases where deficient stability of the SIJ has been established, clinical

experience suggests that specific exercise programs designed to increase lumbo-pelvic stability may not be sufficient decrease pain and improve function.

It has been suggested that when specific exercise programs fail, deficient ligament strength of the posterior elements of the SIJ does not provide a sufficiently stable base to permit an effective muscle recruiting strategy [26]. A mechanism that increases the passive functional stiffness of the joint would contribute to effective muscle recruitment to improve dynamic stability of the pelvis. In these cases the increased ligamentous stiffness would have the effect of providing a more stable anchor for specific strengthening programs to produce the desired outcome. Experimental work in rats [27] indicates that prolotherapy is effective in building up collagen fibres and thus strengthening ligament.

The clinical tests chosen were those used normally by the authors in their clinical daily work. Most of them have been referenced in the literature [11, 13-15, 23], and are specific for the sacro-iliac joint. The results of the main tests (posterior pelvic pain provocation test, active SLR and Stork tests) showed similar progression from altered to normal. In particular the ASLR became normal earlier, before the end of the injection period, when patients actively braced their abdomen, or external lateral compression of the pelvis was applied by the examiner. Two thirds of the patients had normal results for the clinical tests by the time they had the third injection, and the patient feedback was that pain levels had decreased and function increased. This is reflected in the questionnaires scores, which were only done three months after the third injection was given.

This is a novel study of prolotherapy in patients with spinal related pain where the indication for treatment was loss of function from a specific clinical diagnosis, not pain alone. The solution injected (hypertonic dextrose) was easily obtainable and is a common solution used for prolotherapy injections. The time between injections (six weeks) was based on the assumption that the inflammatory reaction and formation of collagen takes up to seven or eight weeks, and it is not necessary for the injections to follow each other closely. Three injections were considered sufficient to ensure a reasonable length of time for regeneration of collagen.

Ongley et al. (1987) [28] carried out a study of prolotherapy on patients with chronic low back pain. There are major differences between Ongley's randomized control trial and our study. The diagnosis was different, subjects had a variety of different combined treatments in both groups, and the location and frequency of injections was also vastly different. It is therefore difficult to compare the results from this study to Ongley et al (1987). Yelland et al (2004) [20] also found no significant difference between prolotherapy and normal saline injections for non-specific low back pain; however diagnosis, indications, injection sites and frequency of injections varied significantly to the present study.

Patients in our study were only included when a diagnosis of failure of load transfer through the sacro-iliac joint was made. The theoretical intended effect of the injections was to increase the stiffness of the dorsal interosseous ligament. The clinical results appear to confirm the hypothesis. The mechanism of action of prolotherapy is not sufficiently understood, and requires further study: an inflammatory response could be triggered by a mechanical insult (volume of fluid injected), by an osmotic effect or by neural pathways (needle in position).

Strengths and weaknesses

The strength of this study is that there were no incentives or secondary gains for patients attending follow up. Patients were either privately funded or funding was approved by the relevant insurance company in work related cases (n=5).

The weakness of the study is that patients acted as their own controls and there was not a non-intervention control group. There was an insufficient cohort of control patients who fitted the

criteria of entry but did not undergo the three injections, and were therefore not entered for statistical analysis.

CONCLUSION

This descriptive study of the use of prolotherapy in combination with a specific exercise programme in private practice has shown improvement in clinical outcome scores for all the patients who attended follow up visits: 76% of patients (n=19) had been followed up at 3 months, 76% (n=19) at 12 months and 32% (n=8) at 2 years). Three other patients were verbally contacted at 12 months and reported good clinical outcomes but were not assessed and therefore not included in the statistical analysis. Similar results were found in the functional questionnaires used in the study at 3 and 12 months and 2 years. This study also showed that it is possible to make a clinical diagnosis of SIJ deficient load transfer of ligamentous origin. Treatment with CT guided prolotherapy injections in the dorsal interosseous ligament of the affected SIJ -in combination with specific core stability training- can successfully correct the deficiency, reduce pain and improve function.

The results of this intervention trial warrant further research in this area.

Information Box

What is already known in this topic

Prolotherapy acts by creating an inflammatory response. It has been used for a long time in the treatment of axial pain. The diagnosis is generally non-specific low back pain, the injection technique, substances, volumes and sites injected vary from author to author, and the results so far have been inconclusive.

What this study adds

This is the first study that uses coherent injection techniques to infiltrate specifically the ligamentous structures of the sacro-iliac joint. The indication for prolotherapy is not pain but a specific clinical diagnosis following strict criteria. The site of injection is also very precise and a very small volume is injected.

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Acknowledgement

Mr. Daniel Wasson, senior CT technician, the RNSH Private Medical Imaging Department for his assistance with all injections.

The authors declare no competing interests.

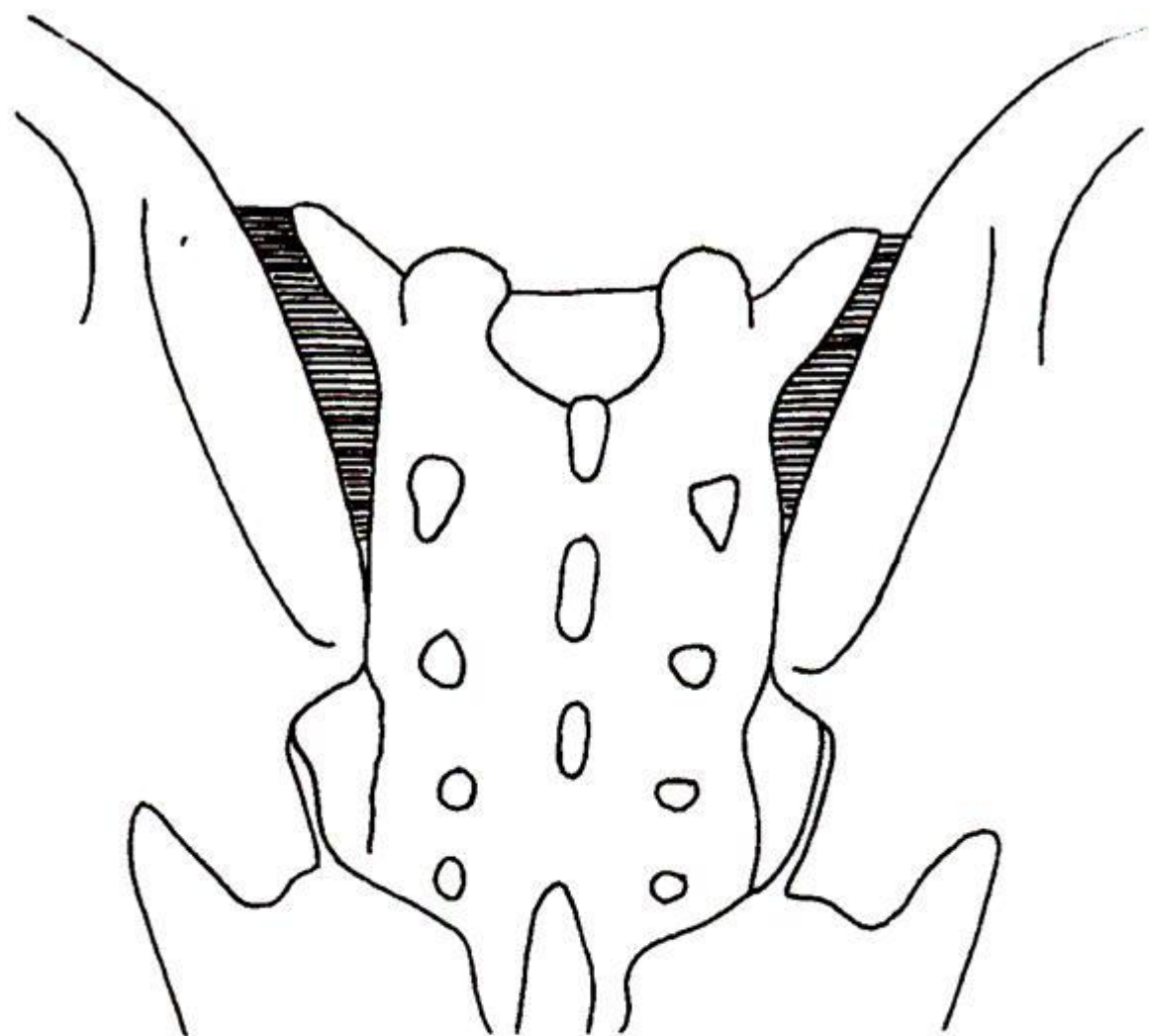
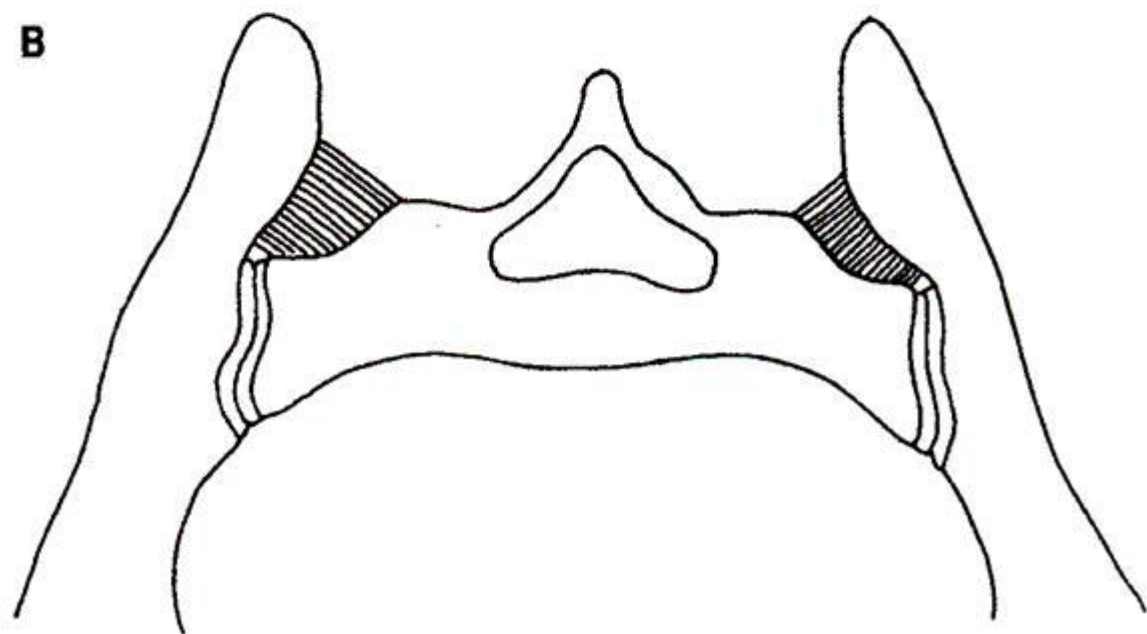
Fig 1 Posterior A and axial B views of the sacro-iliac joint. Auricular part of the joint (arrow)
The superficial posterior ligaments not depicted.

Fig 2. Prolotherapy solution and needle in situ. Solution injected only in the deep interosseous ligament

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185
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L. SIJ PORLOTHESIA
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