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Steroids Versus Steroids With Dexmedetomidine In Ultrasound Guided Sacroiliac Joint Injection In Patients With Chronic Low Back Pain

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Abstract:

The goal of this study is to evaluate the effect of adding dexmedetomidine as an adjuvant to steroid injection versus steroid alone in chronic low back pain caused by sacroiliac joint arthritis. Sixty patients of both sex, ASA grade 1 and 2, between the ages of 18-70 years, BMI less than 30 kg/m2, after diagnosis of sacroiliac joint dysfunction and failure of conservative management were randomly allocated into two groups (n=30). Group (1): patients received SI injection with 2ml of long-acting corticosteroid (14 mg Betamethasone) and 0.5 ml of normal saline and group (2): patients received SI injection with 2ml of long-acting corticosteroid (14 mg Betamethasone) and 0.5ml dexmedetomidine (50 mcg). Patients were observed for vital signs, pain intensity and possible side effects in the recovery room for 4 hours then discharged. The patient's pain intensity using Numerical Rating Scale, or functional improvement using Oswestry Disability Index and Functional Rating Scale and complications were followed up at 2 weeks, 4 weeks and 12 weeks. While, short assessment of patient satisfaction was assessed 2 weeks after injection. The results revealed that addition of dexmedetomidine to steroids in sacroiliac joint injection is of low value. There was no statistically significant difference between the steroid group and the dexmedetomidine group regarding the changes in the NRS, ODI and FRI scores at 2 weeks, 4 weeks and 12 weeks after injection.

Keywords: Steroids; dexmedetomidine; sacroiliac joint injection.

1. Introduction

Sacroiliac joint is one of the major axial joints connecting the sacral spines and the pelvis. This joint has an essential role in maintenance of body stability. 27% of low back pains bellow L5, contributed to SIJ dysfunction. Patient presentation is often non-specific and diagnostic physical examination maneuvers have low diagnostic value [1]. The

international association for the study of pain proposed the following criteria for making the diagnosis of sacroiliac joint pain:

● Pain present in the region of the SIJ.

● Stressing the joint by clinical tests. Most common used tests are: Patrick's test, Gaenslen's test, Thigh Thrust test, Distraction test, Compression test, Fortin's finger test and Gillet test [2].

● Local anesthetic injection completely relives pain.

Pain usually results from degeneration, inflammation or trauma. Management options could be: conservative, interventional or surgical. One of the most promising interventional methods is sacroiliac joint injection. However, intra-articular injection of SIJ remains a challenge because it's difficult accessible site and the anatomical modifications so image guidance is necessary. Side effects related to injection may include: temporary leg weakness or numbness, infection at site of injection, allergic reaction to the drug, tenderness and bruises of skin at site of injection or nerve damage [3].

Ultrasound guidance recently has played an important role in intra-articular joint injection especially in difficult accessible joints such as sacroiliac joints and hip joints in which blind palpation techniques are of low accuracy. Nowadays, Ultrasound guidance preferred than CT or fluoroscopic guidance because the risks of repeated radiation exposure, high cost, as they assess the bony components only not the soft tissue and injection of the contrast causes drug dilution [4].

Dexmedetomidine is α2 adrenoceptor agonist, has two site of actions it stimulates presynaptic α2 adrenoceptor, thus inhibiting the release of norepinephrine and hence the progression of pain signals and works post synaptic to decrease blood pressure and heart rate. It can be given by intravenous or intra-articular routes. It is metabolized in the liver so dose adjustment in hepatic failure is needed. Also, it should be used carefully in patients with preexisting cardiac conduction defect, bradycardia or hypovolemia. It is used in a dose of 0.5-2 µg /kg [5].

Betamethazone is a corticosteroid that can be administrated systemically or locally. Recommended doses for intra-articular steroid injection are: Large joints (knee, hip, shoulder) 1-2 ml; medium joints (elbow, wrist, ankle) 0.5-1 ml; small joints (foot, hand) 0.25-0.5 ml. Steroids are injected due to its anti-inflammatory action. Side effects due to injection are rare but can happen, they include allergic reactions, infection, redness or pain at the site of injection, bruising or swelling, skin or soft tissue thinning at site of injection, near tissue damage such as joint cartilage and bone

so it is recommended to limit number of injections to 3 – 4 per year [6].

2. Patients and Methods:

This was a randomized study performed in Beni-Suef university hospital within twelve months from November 2018 to November 2019 involving 60 patients. Written informed consents were obtained.

2.1 Inclusion criteria:

1- Both sexes.

2- ASA grade 1 and 2.

3- Age group between 18-70 years.

4- BMI less than 30 kg/m².

5- After diagnosis of sacroiliac joint dysfunction and failure of conservative management.

2.2 Exclusion criteria:

1- Patient refusal.

2- Patients with uncontrolled diabetes.

3- Patients with coagulopathy.

4- Renal or hepatic failure.

5- History of allergy to local anesthetics or steroids.

6- Patients on opioid medications for pain management before and during period of study.

7- Presence infection at the site of injection.

8- History of surgical procedure involving SIJ.

9- Addicts.

10- Patients receiving β blockers.

11- Pregnant females.

2.3 All patients were subjected to:

A. Patient preparation;

A routine pre-procedural checkup, hematological and biochemical testing, along with electrocardiogram were performed for the patient. The procedure, pain score and functional activity scores (ODI and FRI) were explained to the patient and the informed written consent was assigned. A small needle cannula was placed on the back of the hand then the patient was asked to wear a gown to enter the treatment room. The ultrasound machine and the equipment's were prepared before patient entry to the operating room. Patient was randomly assigned into one of the two groups by using closed envelope technique.

B. At the treatment room;

1- On arrival to the operating room, standard monitoring was established (pulse oximetry, electrocardiography, and non-invasive arterial blood pressure monitoring).

2- The patient was placed in prone position with a billow under his/her hip for proper placement and pre-procedural sedation in the form of 5 mg dormicum was given.

3- The area of the back is exposed and cleaned with antiseptic solution.

4- Warm water-based gel was applied to the examined area and the curved transducer of

PHILIPS HD5 ultrasound in a sterile coverage was placed on the sacral hiatus, then the transducer was moved in a lateral direction until the lateral edge of the sacrum was identified then in upward direction until the bony contour of the ilium was identified this space between the ilium and sacrum represents the posterior aspect of the SI joint which is the site of injection.

5- 3 ml of 1% lidocaine was injected subcutaneously at the site of needle insertion, 22 gauge spinal needle was inserted in a medial to lateral manner guided into the sacroiliac joint. 6-The study drug was injected:

Group (1): patients received injection of 2 ml Betamethasone 14mg and 0.5ml normal saline.

Group (2): patients received injection of 2 ml Betamethasone and 0.5ml Dexmedetomidine (0.5 μg/kg).

7- Patient was observed for vital signs, pain and possible side effects in the recovery room (PACU) for 4 hours then discharged. Complications include the occurrence of hypotension (systolic blood pressure < 90 mmHg) corrected by rapid infusion of 500mL crystalloids and ephedrine 25mg, bradycardia (HR < 50 b/min) treated with 0.6 mg atropine, extensive sedation (any sedation score above 1; 1 = sedated, but easily to be aroused), or hypoxemia (oxygen saturation below 90%). Any other side effects were treated symptomatic.

8- The patient's pain intensity using Numerical Rating Scale, functional improvement using Oswestry disability index and Functional rating scale and complications was followed up at 2 weeks, 4 weeks and 12 weeks. Short assessment of patient satisfaction was assessed 2 weeks after injection.

Statistical methodology:

• Analysis of data was done Statistical Package for Social Science (SPSS) version 22. Parametric data were expressed as mean ± SD. The comparison of the mean ± SD of two groups was done using the paired and unpaired Student's -test (Oswestry disability index, age, weight, and height). Nonparametric data was expressed as a number of patients or median (interquartile range). Determining the extent of a single observed series of proportions and difference from a theoretical or expected distribution was done using the Chi-square test (sex) and Mann-Whitney test (NRS). Value < 0.05 was considered statistically significant.

3. Results:

The current study was conducted at Beni-Suef university hospital within twelve months from November 2018 to November 2019. A total of 60 patients were randomly grouped into two groups, 30 in each group. Group 1: patients were received injection of 2 ml long acting corticosteroid Betamethasone (14mg)

and 0.5ml of normal saline and group 2: patients were received injection of 2ml long acting corticosteroid Betamethasone (14 mg) and 0.5 ml Dexmedetomidine (0.5 μg/kg).

Table (1): Demographics of patients in both Steroids and DMET groups

		Steroid group (n=30)	DMET group (n=30)	P-value
Age [Mean (SD)]		[49.4(13.87)]	[53.90(14.62)]	0.23
Sex	Males [N (%)]	[17(56.7%)]	[10(33.3%)]	0.07
	Females [N (%)]	[13(43.3%)]	[20(66.7%)]	

P-value > 0.05 (Non-significant)

Table (1): show no statistically significant difference between both groups in either age or sex.

Table (2): Clinical characteristics of patients in both Steroids and DMET groups.

		Steroids group (n=30)	DMET group (n=30)	P-value
Duration of pain[Mean(SD)]		[23.23(25.17)]	[24.8(18.32)]	0.78
Number of prolapsed discs		[2.47(0.94)]	[2.50(1.11)]	0.90
Discogenic pain	Yes [N (%)]	[14(46.7%)]	[12(40.0%)]	0.60
	No [N (%)]	[16(53.3%)]	[18(60.0%)]	
Radicular pain	Yes [N (%)]	[13(43.3%)]	[14(46.7%)]	0.80
	No [N (%)]	[17(56.7%)]	[16(53.3%)]	
Spinal canal stenosis	Yes [N (%)]	[11(36.6%)]	[10(33.3%)]	0.79
	No [N (%)]	[19(63.3%)]	[20(66.7%)]	
Spondylosis	Yes [N (%)]	[7(23.3%)]	[7(23.3%)]	1.00
	No [N (%)]	[23(76.7%)]	[23(76.7%)]	

P-value > 0.05 (Non-significant)

Table (2): show no statistically significant difference between both groups regarding the duration of pain, number of prolapsed discs, the presence of discogenic pain, radicular pain, spinal canal stenosis or spondylosis.

Table (3): Pain assessment scales in both Steroids and DMET groups.

		Steroids group (n=30)	DMET group (n=30)	P-value
NRS [Mean(SD)]	Before injection	[8.60(1.16)]	[8.93(1.14)]	0.26
	After 2 weeks	[4.87(2.40)]	[5.40(1.87)]	0.34
	After 1 month	[3.93(2.52)]	[5.10(2.02)]	0.05
	After 3 months	[3.63(2.43)]	[4.73(2.73)]	0.10
ODI [Mean(SD)]	Before injection	[64.35(14.34)]	[68.10(12.55)]	0.29
	After 2 weeks	[45.67(20.69)]	[46.20(18.04)]	0.92
	After 1 month	[36.10(18.38)]	[40.20(19.45)]	0.41
	After 3 months	[34.93(18.62)]	[38.47(21.19)]	0.50
FRI [Mean(SD)]	Before injection	[66.48(11.84)]	[71.10(12.24)]	0.14
	After 2 weeks	[49.13(16.89)]	[48.10(14.95)]	0.80
	After 1 month	[40.33(16.50)]	[44.00(18.75)]	0.43
	After 3 months	[36.97(18.43)]	[39.43(20.29)]	0.62
SAPS [Mean(SD)]		[22.33(6.79)]	[19.87(5.91)]	0.14

**** P-value < 0.05 Significant, P-value > 0.05 Non-significant.***

Table (3): show that in both steroid and dexmedetomidine groups the mean values of NRS, ODI and FRI after injection (2w, 4w, 12w) were lower than before the injection.

Table (4): Comparison between Steroids group and DMET group regarding the changes in the scores of pain assessment scales over

		Steroids group (n=30)	DMET group (n=30)	P-value
Changes in NRS [Mean (SD)]	Before - after 2w	[3.73(2.52)]	[3.53(1.57)]	0.73
	Before - after 4w	[4.67(2.72)]	[3.83(1.72)]	0.16
	Before i- after 12w	[4.97(2.67)]	[4.20(2.48)]	0.25
Changes in ODI [Mean (SD)]	Before - after 2w	[18.68(14.40)]	[21.57(13.50)]	0.43
	Before - after 4w	[27.92(15.70)]	28.23(15.79)]	0.94
	Before - after 12w	[30.12(19.22)]	[29.30(16.90)]	0.86
Changes in FRI [Mean (SD)]	Before - after 2w	[17.35(12.50)]	[23.00(10.56)]	0.64
	Before - after 4w	[26.15(15.19)]	[26.87(10.77)]	0.83
	Before - after 12w	[29.52(19.60)]	[30.97(13.56)]	0.74

P-value > 0.05 (Non-significant)

Table (4): show no statistical significant difference between the steroid group and dexmedetomidine group regarding the changes in the assessment scores (Numerical Rating Scale, Oswestery Disability and Functional Rating Scale) at 2 weeks, 4 weeks and 12 weeks after injection.

Figure (1): Comparison between Steroids group and DMET group regarding the changes in the Numerical Rating Scale.

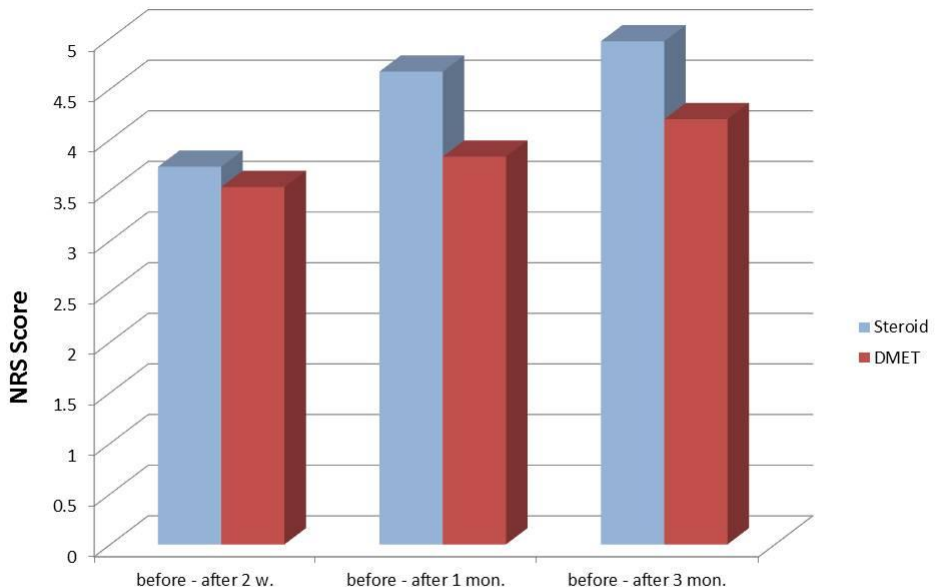

Figure (1): show no statistically significant difference between Steroid group and DMET group regarding the change in the score of NRS at 2w, 4w, and 12w after injection.

Figure (2): Comparison between Steroids group and DMET group regarding the changes in the Oswestery Disability Index.

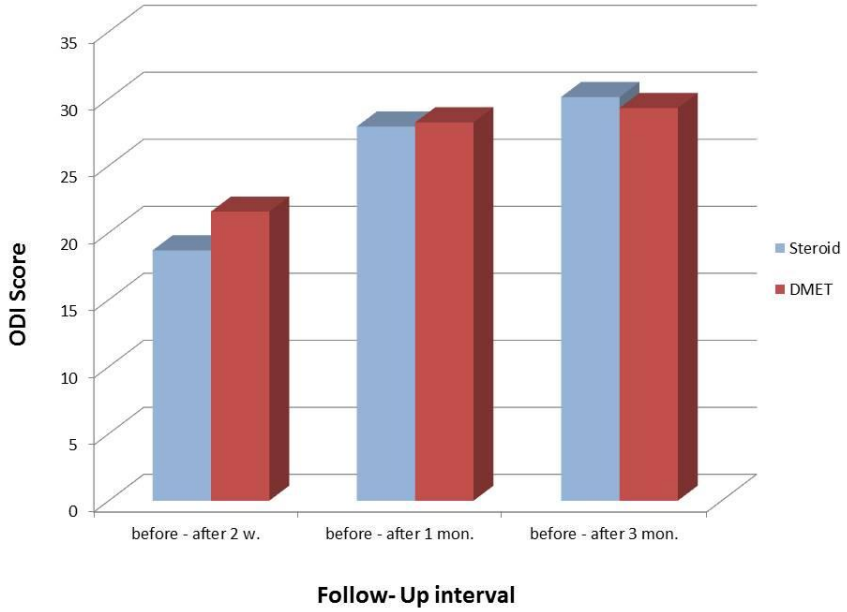

Figure (2): show no statistically significant difference between Steroid group and DMET group regarding the change in the score of ODI at 2w, 4w, and 12w after injection.

Figure (3): Comparison between Steroids group and DMET group regarding the changes in the Functional Rating Index.

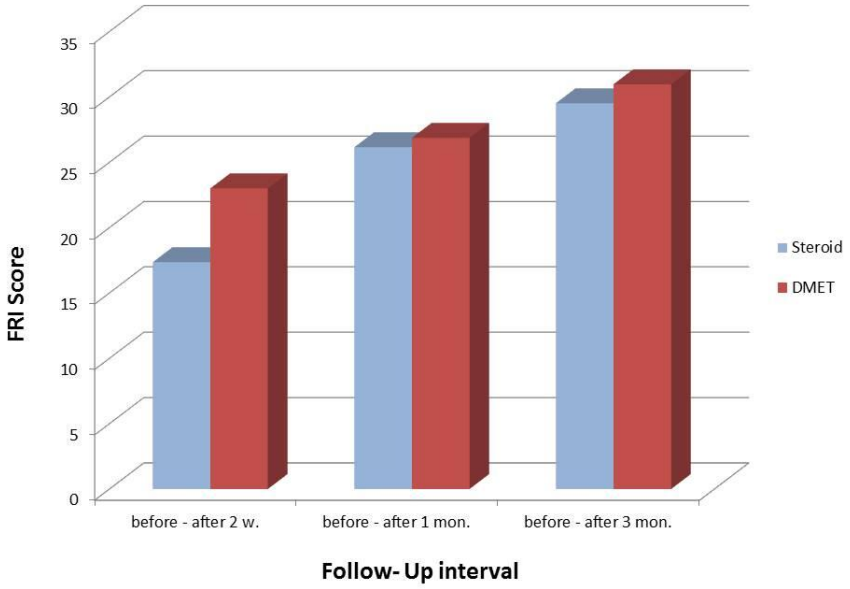

Figure (3): show no statistically significant difference between Steroid group and DMET group regarding the change in the score of FRI at 2w, 4w, and 12w after injection.

4. Discussion:

Sacroiliac joint pain is a common cause of the annoying low back pain. However, its diagnosis is a challenging issue. Interventional treatment methods may be considered after failure of conservative/ non-interventional treatments. Interventional management of sacroiliac joint pain includes sacroiliac joint steroid injection, non-corticosteroid injection and radiofrequency ablation [1, 3].

This study aimed to compare the benefits of dexmedetomidine as an adjuvant to steroid injection versus steroid alone in chronic low back pain through pain score (VAS) and function improvement (ODI and FRI). In this study a total of 60 patients ASA I-II were enrolled in it. They were divided into two groups (n=30 in each group). They received SI intra-articular injection as the following, group (1): long acting corticosteroid Betamethasone 14mg and 0.5ml of normal saline and group (2): long acting corticosteroid Betamethasone 14mg and 0.5ml dexmedetomidine (0.5 μg/kg).

To our knowledge till the time of conduction of this study, this is the first study to compare the effect of dexmedetomidine as an adjuvant to steroid injection versus steroid alone in sacroiliac joint injection. We observed that there was no statistically significant difference between steroid group and dexmedetomidine group regarding the change in the score of NRS, ODI and FRI at two weeks, four weeks, and twelve weeks after injection.

However, similar study done by Eskandr A and AbdelMaseeh S has used DMET as an adjuvant to betamethasone but in epidural injection in failed back surgery syndrome. Eskandr et al studied 50 patients with failed back surgery were divided to 2 groups, group (C) received epidural injection of 20 mL of: betamethasone (14 mg) and bupivacaine 0.5 mg or a mixture of betamethasone (14mg), and group (D) received bupivacaine 0.5mg, and dexmedetomidine (0.5 μg/kg).The effect was evaluated using Visual Analogue Scale, analgesic requirement, and Oswestry Disability Index 2 weeks, 4 weeks, 8 weeks, and 12 weeks after injection. The study showed that the VAS and ibuprofen consumption is lower in group D. The Oswestry disability index was improved in group D with no records of side effects in the form of hypotension, bradycardia, sedation, or hypoxemia in both groups. In our study we discharged the patients after 4 hours and used the DMET in a dose of 0.5 μg/kg on the basis of Eskanders study [8].

Also, dexmedtomidine was used intra-articularly but to control acute pain following arthroscopic knee surgery. Das PB and Samal S

found that intra-articular buprenorphine 100µg provides longer duration of analgesia with decreased postoperative rescue analgesic requirement as compared to 100µg intra-articular dexmedetomidine. A study done on 60 patients undergoing arthroscopic knee surgery. Patients were allocated into two groups,
group B: receiving 100µg of intra-articular buprenorphine and group D: receiving 100µg 0f intra-articular dexmedetomidine. Parameters observed were the time to first rescue analgesia, the number of patients requiring rescue analgesia with in next 24 hours, Visual analogue scale (VAS) at rest and on mobilization at 1st, 2nd, 4th, 8th, 12th and 24th hour. Time to first rescue analgesia was significantly longer in patients receiving in group B. VAS scores at rest were comparable between the groups at 1st, 2nd, 4th and 8th hour but significantly low with intra-articular buprenorphine than intra-articular dexmedetomidine at 12th and 24th hour. VAS scores on ambulation were comparable at 1st, 2nd and 4th hour but significantly higher in dexmedetomidine group as compared to buprenorphine at 8th, 12th and 24th hour [9].

Moeen SM et al concluded that addition of dexamethasone or dexmedetomidine to a solution of bupivacaine 0.25% provided better analgesia than using bupivacaine alone, after patients' observation for 3 days post arthroscopic knee surgery. They divided Into 3 groups which received a total volume of 20 ml, 18mL intra-articular bupivacaine 0.25% either with dexamethasone 8 mg (group I), or dexmedetomidine 1 ug/kg (group II), or 2 mL of normal saline (group III) [10].

Manuar MB et al founded that intra-articular ropivacaine has better postoperative pain relief, with increased time of first analgesic request and decreased need of total postoperative analgesia compared to fentanyl and dexmedetomidine. This study was done on 99 patients undergoing arthroscopic knee surgery were randomly assigned into three groups (A, B, C). In which group (A) received 10 ml of 0.75% ropivacaine, while Group (B) received 50µg fentanyl, and Group (C) received 100µg of dexmedetomidine through the intra-articular route at the end of procedure. Pain assessed using visual analog scale and diclofenac sodium given as rescue analgesia when VAS >4. Time of first analgesic request and total rescue analgesic used in 24 hours were calculated [11].

In a study done by Mujallid et al, 51 patients undergoing arthroscopic knee surgery were divided into three groups receiving a total volume of 20 ml intra-articularly either dexmedetomidine 1 µg/kg (group D), bupivacaine 0.25% (group B), or saline (group S) . The VAS scores showed a significant decrease in groups D and B compared to group S. Times to first analgesic were 343±27

vs.440±3 vs. 43±5 min for groups D, B, and S, respectively and the total dose of rescue tramadol were 180±56 vs. 160±51 vs. 413±52 mg, respectively [12].

Al-Metwalli et al perform a study on 60 patients undergoing arthroscopic knee surgery; they were divided into three groups. A (control group) received I.V and intra-articular saline, (I.A group) received I.V saline and intra-articular dexmedetomidine, and (I.V) group received I.V dexmedetomidine and intra-articular saline. The hemodynamic changes, visual analogue scale for pain (VAS), sedation score, the time to first postoperative analgesic request, and the total postoperative analgesic were assessed during the first 24 h. They found that I.A Dexmedetomidine has a significant role in decreasing pain score for 6 h after the operation but only for 1 h in the I.V group. The time of first postoperative analgesic request was longer in the I.A DMET group [312.0 (120.7) min] then in I.V group [102.1 (54.4) min] then in control group [71.0 (50.1) min] and the total analgesic dose was lower in the intra-articular group [90.0 (46.2) mg] than in the I.V group [129.3 (54.3) mg] and in the control group [165.0 (52.2) mg]. With no patients showed any significant side effects [13].

Also, another α2-adrenergic agonists drug "clonidine" injected caudally in children compered to bupivacaine and saline groups. In Wanda Joshi et al study, they found that there is no significant difference in haemodynamic, pain score, or analgesic duration between the groups. Also, there were more vomited children in the clonidine group than in the bupivacaine 0.125% and saline groups during the first 24 postoperative hours [14]

In our study we found that the mean value of NRS, ODI and FRI after injection was significantly lower than before injection in both steroid and dexmedetomidine groups.

In Karabacakoglu et al study, 17 patients with ankylosing spondylitis were fluoroscopy-guided intra-articular injection with corticosteroid without LA. 15 of 17 patients reported good relief 1 month after injection, with 2 reporting fair relief (Fluoroscopy-guided intra-articular corticosteroid injection into the sacroiliac joints in patients with ankylosing spondylitis) [15].

Luukkainen et al, randomized 24 patients to receive either peri-articular corticosteroid with local anesthetic (n = 13), or local anesthetic and saline (n = 11). One month after the intervention, visual analog scale (VAS) pain scores had decreased significantly in the corticosteroid group compared with the control patients [16].

Ojala et al, performed a study on 20 patients with low back Pain underwent MR-guided sacro-iliac joint arthrography. They used corticosteroid with LA in the injection and a significant short-term pain reduction was observed after injection in 60% of patients [17].

Dussault et al, performed 31 joints injection with fluoroscopic guidance by corticosteroid and LA. Pain decreased by 80% in 7 joints, by 50%–70% in 11 joints and <50% in 10 joints. More than 50% relief was obtained in 55% of joints with normal radiographs, in 62% of joints with degenerative joint disease, and in the only pt. with ankylosing spondylitis. Complications have occurred in 1 pt. the joint could not be penetrated and 2 pts developed lower extremity weakness [18].

Gunaydin et al, perform a Prospective observational study on 9 pts. with spondylarthropathy in which 16 joints are injected with corticosteroid without LA. 7 out of 9 pts reported improvement regarding 49% decrease in the VAS scores and duration of pain relief 10.8±5.6 months [19].

Hanly et al, 19 pts with spondylarthropathy (randomized by radiologic imaging: 13 had radiologic evidence of sacroiliitis and 6 had normal imaging studies) underwent bilateral CT guided injections with corticosteroid without LA. Both groups show a significant pain relief

1 month after injections, with no difference between groups 6 months post injection, there was no difference in pain or stiffness compared to baseline in either group [20].

Maugars et al, treated 13 SI joints in 10 patients. Intra-articular corticosteroids were injected into 6 SI joints, while the remaining 7 joints received physiological saline solution. After 1 month, pain reduction of >70% was noted in 5 of the 6 SI joints treated with corticosteroid, whereas no benefit was noted in the placebo group. In all control patients and 2 in the treatment group who had short-term symptom palliation, a repeat corticosteroid injection was performed. After 1, 3, and 6 months, significant pain reduction was observed in 86%, 62%, and 58% of patients, respectively [21].

In our study we observed some side effect in the form of drug allergy (in one patient of DMET group) and hypotension (in 3 three patients of DMET group). While no bradycardia, sedation or hypoxemia were observed. All side effects didn't interfere with patient discharge from the hospital 4 hours after the injection. This study had some limitations. First, SIJ pain diagnosis is difficult and usually sacroiliac pain is associated with other causes of low back pain; Second, chondrotoxic effects of the drugs were not tested however, Akça Başak et al, reported no adverse effects of dexmedetomidine on rat knee cartilage but no information about any effects in humans [22].

Third, post injection assessment scales are patient reliable. However, our study had some positive points as patient assessment was done by more than one assessment scales with a special scale for assessment of patient

satisfaction after the injection, and the relative long follow-up period.

5. Conclusion and Recommendations:

This study concluded that no benefits were obtained from addition of dexmedetomidine to steroids in sacroiliac joint injection. There was no statistically significant difference between the steroid group and dexmedetomidine group regarding the changes in the scores of Numerical Rating Scale, Oswestry Disability Index and Functional Rating Index at two weeks, four weeks, and twelve weeks after injection.

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