DO LUMBAR FACET JOINT INJECTIONS PROVIDE SYMPTOM RELIEF FOR LOW BACK PAIN AND DOES THIS RELATE TO PATIENT RECORDED OUTCOME MEASURES? – A SINGLE SURGEON COHORT

ABSTRACT

BACKGROUND: In light of recent changes to NICE guidelines regarding the use of facet joint injections in the management of low back pain, we performed a retrospective analysis of the outcomes of facet joint injections performed by a single Consultant Spinal Surgeon and used Patient Recorded Outcomes Measures (PROMs) to determine which factors predict good / poor outcome. **METHODS:** We analysed data obtained from previously gathered pre- and post-injection PROMs questionnaires and outpatient consultation letters. **RESULTS:** Seventy-nine patients were included in the final cohort (mean age 54.6 years, male n=39). 42% reported a clinical improvement in their back pain, 81% believed it helped overall. There was no significant correlation between outcome and depression or anxiety, however the average level of disability (measured using the Oswestry Disability Index) was lower in the group of patients who said they felt an improvement in their symptoms both initially and at 3-month follow-up ($p \leq 0.05$). **CONCLUSIONS:** 42% showed a reliable improvement in the severity of their back pain and 81% said their injection helped them overall. But further high-quality research and clearer guidelines are still needed in this area.

INTRODUCTION

The facets joints of the spine have been recognised as a source of back pain for many years (1). Like most joints in the body, they are at risk of osteoarthritic changes. The prevalence of Facet Joint Osteoarthritis (FJOA) within the general population is incredibly common, particularly in older age groups (2). Up until November 2016, Facet Joint Injections were commonly used as a short-term pain-management option for patients experiencing back pain thought to be due to FJOA. This procedure involves the injection of steroids and/or local anaesthetic into the problematic facet joints using x-ray image guidance. However, due to lack of sufficient evidence for their clinical benefit, NICE have decided that they should no longer be offered to patients with low back pain (3). This decision has been met with some controversy, with many of the professionals performing these procedures blaming their apparent poor performance on a failure in the NHS treatment pathway rather than the procedure itself. Before receiving their injection, patients are informed that they are not intended as a 'cure' for their back pain, but to hopefully reduce their symptoms to a more manageable level so that they may begin more effective, long-term, conservative treatment regimes, such as physiotherapy. It is well documented that the main benefits of FJIs in the treatment of back pain are seen within the first few weeks, and effects are rarely still seen after more than 3-months (4). But with waiting times for physiotherapy on the NHS being an issue of their own, patients often miss this window of opportunity and so begins a painful cycle of referrals back and fore between surgeons, GPs, and physiotherapists.

We decided to perform a retrospective evaluation of a sample of patients who had received facet joint injections, to see how much they felt the injections had helped their symptoms, if at all. We were interested in whether or not these results supported NICE's findings, or, controversially, the use of FJIs in practice. As well as possibly identify any factors which predict good or poor outcomes in patients with low back pain.

AIMS/OBJECTIVES

Determine whether facet joint injections offer symptom relief and which factors predict good / poor outcome using previously gathered Patient Recorded Outcome Measures data.

METHODS

APPROVAL

Ethical approval was not required for this project as it was a service evaluation, approved by the Department of Orthopaedics and Trauma.

SAMPLE SELECTION

A list of all spinal injection procedures performed by a single Consultant Spinal Surgeon between September 2012 and September 2016 was generated using the BlueSpier operative database (n=533). This was then narrowed down to include only Facet Joint Injections or Facet Joint Injections with concomitant Root Blocks of the lumbar spine. Seventy-nine patients were included in the final cohort and all patient data was anonymised (identifiable only by patient hospital number). Clinical information was obtained from the outpatient consultation letters via Clinical Portal. This included diagnosis/es, smoking status, post-injection follow-up time, whether the injections helped initially and if they were still providing some benefit at follow-up. All of the selected patients had clinical and radiological evidence of facet joint degeneration. The patients' PROMs (Patient Reported Outcome Measures) were identified from the surgeon's prospective database of over 2000 patients. Routinely, each patient had completed a questionnaire upon admission to the care of the Consultant, and then a separate follow-up questionnaire at any future consultation. As many of the patients had multiple outpatient consultations, pre- and post-injection data was interpreted as those gathered most recently before and after the date of their injection. Of the patients who received multiple facet-joint injections during this time period (n=12), only the data relating to their first injection was included for analysis. Any patients missing both outpatient consultation letters and corresponding PROMs data were removed from the dataset (n=9).

MEASURING VARIABLES AND OUTCOMES

Severity of back and leg pain was measured using a numerical Visual Analogue Scale ('VAS'). Patients were asked 'How much back/leg pain have you felt over the last month?' and selected their answer from a scale of 0-10, with 0 being 'no pain' and 10 being 'worst pain'.

Patient disability/function was measured using the Oswestry Disability Index (ODI) tool. Patients can choose from 6 options relating to how pain affects 10 aspects of their life: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and traveling. This is then converted to a percentage, with 100% being most severe (5).

Quality of life was also measured using the EQ-5D-5L questionnaire, including the EQ VAS. This is a tick-box questionnaire where the patient rates their problems in five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each domain has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. This was recorded on the database as a score from 1 to 5 in each domain, e.g. 'I have no problems in walking about' = 1, and 'I am unable to walk about' = 5. The patient can then rate their health on a scale of 0 to 100 on the EQ VAS: 0 being 'The worst health you can imagine' and 100 'The best health you can imagine' (6-7).

The overall outcome of the procedure, i.e. how well the patient felt it worked, was interpreted from both the PROMs database and outpatient consultation letters. As part of the PROMs questionnaire, patients were asked how well the patient felt the intervention helped their problem, with a choice of 5 different answers ranging from 'helped a lot' to 'helped a little' or even 'made things worse'. These were scored 1 to 5. Information obtained from clinic letters was recorded as 'yes' or 'no' to whether the patient felt it had made any improvement initially, and if it was still making a positive difference to their symptoms at follow-up.

IDENTIFYING PSYCHO-SOCIAL FACTORS

Smoking and disability benefit status was obtained from the clinic letters and PROMs questionnaire. The PHQ-9, a self-administered Patient Health Questionnaire, was used to detect depression. Recipients are asked to record, for 9 different items, how often they have been bothered by a problem over the last 2 weeks (0=not at all, up to 3=nearly every day). This produces a depression severity score on a scale of 1 – 27, which then corresponds to a description and proposed treatment plan; e.g. a score of 15-19 is classed as 'moderately severe' depression. Anxiety was screened for using a similar tool, the GAD-7 (8-9).

STATISTICAL ANALYSIS

The data was compared and analysed using Microsoft Excel and IBM SPSS Statistics software (version 23).

Differences between individual pre- and post-injection descriptive measures were calculated using Microsoft Excel. Clinically important changes were regarded as ≥2 in VAS back/leg, ≥5 points in the PHQ-9, ≥10 points ODI, ≥20 EQ VAS for pain severity, depression, functional disability and quality of life, respectively. (10-12)

IBM SPSS Statistics software was used for more detailed data analysis: the differences between means were calculated and analysed using Students T-Test. The statistical significance of the differences was assessed by the 95% confidence intervals, which were also represented graphically. Comparison between categorical variables was performed using the chi square and Fisher's exact test. Statistical significance was accepted as no overlap in confidence intervals or $p<0.05$.

RESULTS

PATIENTS

Seventy-nine patients were included in the final cohort (age range 24-83, mean 55 years); with an equal male to female ratio (39:40). Of these, 46.8% had injections of the facet joints only, with the remainder receiving a concomitant nerve root block. Twelve patients received further injections during the period of time studied. 16.7% were smokers (10/60, missing data n=19).

In addition to facet joint degeneration, 74.7% had evidence of degenerative disc disease, 25.3% foraminal stenosis, 19.0% canal stenosis and 21.5% had spondylolisthesis. There was no correlation between patients diagnosed with spondylolisthesis and those who received a concomitant nerve root block (table 1).

Table 1 - Correlations between diagnoses and receipt of concomitant NRB

	FJI only	FJI+NRB	*p* value	Total
Spondylolisthesis	8	9	.599	**17**
Foraminal stenosis	5	15	.021	**20**
Spinal stenosis	7	8	.609	**15**
DDD	26	33	.278	**59**

More than 90% of respondents recorded ≥5 out of 10 on the VAS for back pain prior to injection; just over 70% ≥7. The average ODI pre-injection was 54.9%, or 'moderate disability' (normal 0-20, mild 21-40, moderate 41-60, severe 61-80, exaggerated >81%) (5). 1 patient scored 0% on the ODI, whilst the maximum recorded was 96% (n=1). The number receiving disability benefits was higher than expected at 42.4%.

The prevalence of major depression was also found to be high amongst the cohort – the average patient scoring 14.7 on the PHQ-9 questionnaire, i.e. bordering on 'moderately severe depression' (none 1-4, mild 5-9, moderate 10-14, moderately severe 15-19, severe 20-27) (8). Five patients scored the maximum of 27. The average GAD-7 score was 10.7 out of a maximum of 21 – 10 being the cut-off for the detection of Generalised Anxiety Disorder/'GAD' (sensitivity and specificity >0.80). 36.5% (21 out of 59) scored ≥15, indicative of severe GAD (9). The average time between injection and follow-up consultation with the consultant, spinal fellow or physiotherapist was 3 months (12.1 weeks).

Table 2 Summary of the demographic data, pre-injection PROMs and average follow-up times

Descriptive	Mean	95% CI	n
Age / years	54.6	51.3-57.9	79
Sex, male:female (% male)	39:40 (49.4%)	N/A	79
Smoker, yes:no (% yes)	10:50 (16.7%)	N/A	60
Disability benefit, yes:no (% yes)	28:38 (42.4%)	N/A	66
Injection, FJI:FJI+NRB (% FJI only)	37:42 (46.8%)	N/A	79
Repeat injection, yes:no (% yes)	12:67 (15.2%)	N/A	79
VAS-back, pre-injection (10 total)	7.1	6.5-7.6	57
ODI, pre-injection, %	54.9	49.8-59.9	59
PHQ9, pre-injection (27 total)	14.7	12.5-16.9	59
GAD7, pre-injection (21 total)	10.7	8.7-12.6	59
Follow-up time (weeks)	12.1	10.2-14.0	77

STATISTICALLY/CLINICALLY SIGNIFICANT CHANGES

Post-FJI, 42% and 39%, respectively, reported a clinically important difference in their back and leg pain-intensity (≥2 on the VAS) (10). There was a significant difference between the average pre- and post-injection VAS score for back pain ($p<0.005$), and leg pain ($p<0.05$), as demonstrated in figure 1.

Respectively, 35%, 35% and 27% of patients reported a clinically important difference in their depression, functional disability and quality of life (table 6). However, the overall average differences in ODI, PHQ-9, GAD-7 and EQ-5D-VAS scores were not statistically significant (p=NS).

The overall pattern for the change in Quality of Life, as measured by the EQ-5D-5L, showed some improvements, with the most significant changes seen in the Mobility domain ($p<0.005$). Changes in problems with usual activities, pain/discomfort, and anxiety/depression were also significant ($p<0.05$). However, there was no significant overall improvement in problems with self-care (p=NS). These findings can be visualised in figure 2.

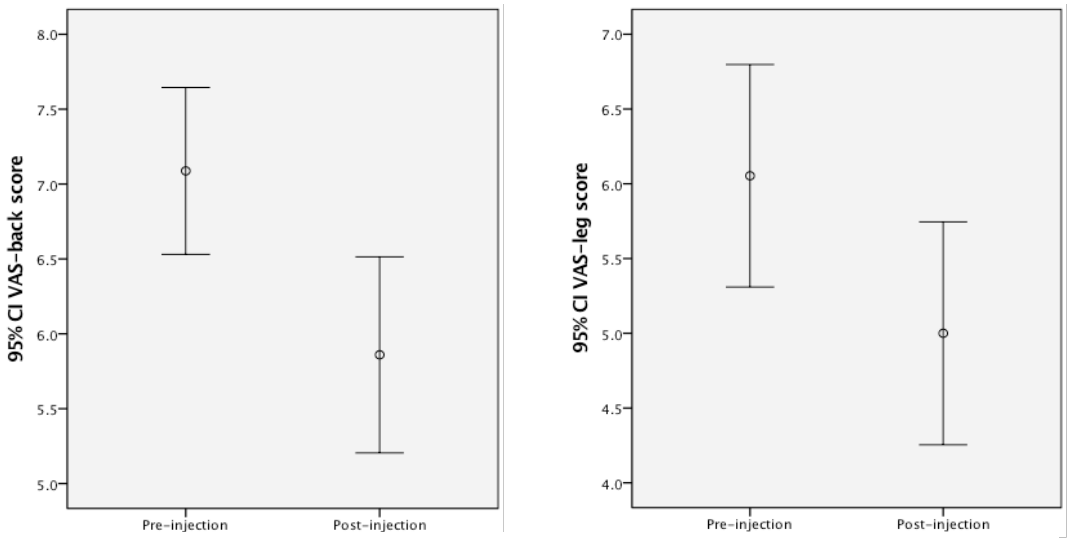

Figure 1. Changes in VAS scores for back and leg pain

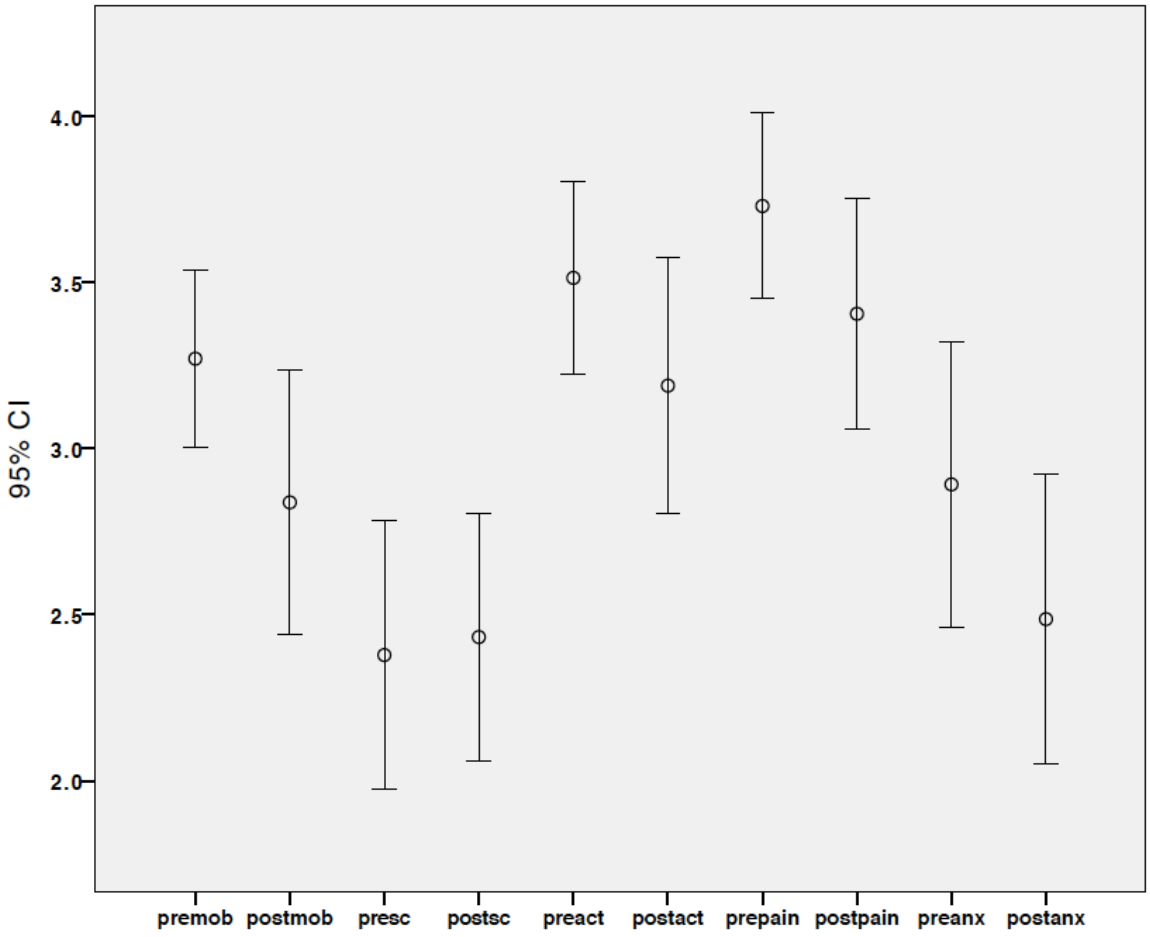

Figure 2 - Changes in EQ-5D-5L domains pre- and post-FJI. *Abbreviations*: 'pre' / 'post' = pre- or post-injection, 'mob'= mobility, 'sc' = self-care, 'act' = usual activities, 'pain'= pain/discomfort, 'anx' = anxiety/depression.

OVERALL OUTCOMES

Forty-two of the patients included in this study (53.2%) answered 'Overall, how much did the intervention / surgery in our hospital help your problem?'. The average response score was 3.5 ±0.4 ('helped'/'helped a little'), with 81% stating that the injection helped over all ('helped a little', 'helped' or 'helped a lot'). Four patients felt the injection 'didn't help', whilst the remaining 4 patients said that it actually 'made things worse'. There were no reported complications. The was no difference between the overall outcome and whether the patient had a concomitant nerve root block (p=NS) (Figure 3).

Thirty-seven out of 42 respondents (83%) said they would have the procedure again.

Table 3 – PROMs database Overall Outcome data

Overall Outcome (Score)	n	%	FJI	FJI + NRB
Helped a lot (5)	12	28.6%	4	8
Helped (4)	9	21.4%	4	5
Helped a little (3)	13	31.0%	4	9
Sub-total	**34**	**81%**	**12**	**22**
Didn't help (2)	4	9.5%	3	1
Made things worse (1)	4	9.5%	1	3
Sub-total	**8**	**19%**	**4**	**4**
Total	42	100%	16	26

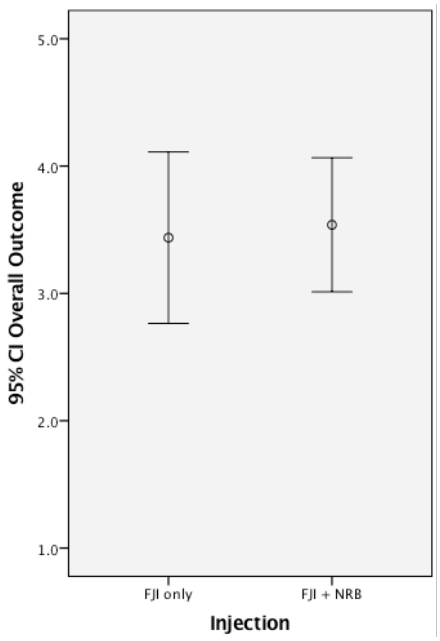

Figure 3 - Overall Outcome score and presence of NRB

An almost complete data set (n=78) was obtained from the clinic letters regarding whether or not the patient felt the injection had helped improve their symptoms (one patient was found on the PROMs database but had no outpatient consultation letter; presumably the dictation was lost). The results were as follows: 70.5% of patients said they felt some sort of improvement in their symptoms after their injection. This was reduced by almost half at follow-up (37.2%, average follow-up = 3 months). Again, there appeared to be no relationship between these outcomes and whether or not the patients received a concomitant nerve root block (p=NS). Of the 37 patients who received a Facet-Joint Injection *only*, 67.6% saw an initial improvement in their pain, and 37.8% still felt an improvement at 3-months follow-up (table 4).

Table 4 - Improvements in symptoms initially and at follow-up

Type Injection / Number	FJI only / 37	FJI+NRB / 41	Total / 78
Initial improvement, yes:no (%yes)	25:12 (67.6%)	30:11 (73.2%)	55:23 (**70.5%**)
Improvement at follow-up, yes:no (%yes)	14:23 (37.8%)	15:26 (36.6%)	29:49 (**37.2%**)

ASSOCIATIONS

As expected, patients who received disability benefits scored significantly higher in the ODI questionnaire ($p<0.001$). More interestingly, however, more patients with a lower ODI (cut-off <60%) said that they felt an improvement in their symptoms initially after the injection ($p<0.05$) and at 3-months follow-up ($p<0.05$). These differences can be seen in table 5.

In the group of patients who felt an improvement in their symptoms *initially*, there was no significant difference in ODI (pre-injection) compared to those who said they hadn't felt an improvement (p=NS). However, *at follow-up*, the average ODI (pre-injection) of those who said it helped was significantly less than those who said it didn't ($p<0.05$).

Patients with at least 'moderately severe' depression (PHQ-9 ≥15) also less frequently felt an improvement in their symptoms at 3-months follow-up, as did patients with severe anxiety (GAD-7 ≥15), however neither of these differences were significant (p=NS). (Table 5)

Table 5 - number of patients at various cut-offs and overall improvement of symptoms

		Initial improvement		Improvement at follow-up		
		No	Yes	No	Yes	Total
Pre-ODI, %	**<60**	5	26	14	17	31
	≥60	11	16	21	6	27
Pre-PHQ-9, 27 total	**<15**	3	22	12	13	25
	≥15	13	20	24	9	33
Pre-GAD-7, 21 total	**<15**	8	29	21	16	37
	≥15	8	13	15	6	21

Table 6 provides a summary of all the relevant PROMs, including number of CIDs.

Table 6 - Summary of pre- and post-injection PROMs and clinic letter interpretations. *Abbreviations:* CI = Confidence Interval, CID = Clinically Important Difference.

	Pre-injection			Post-injection			Difference	%CID (MCID)
PROM	**Mean**	**95% CI**	**n**	**Mean**	**95% CI**	**n**	***p-value***	
VAS back, 10 total	7.1	±0.5	57	5.9	±0.6	57	<0.005	42% (2)
VAS leg, 10 total	6.1	±0.7	56	5.0	±0.7	56	<0.05	39% (2)
PHQ9, 27 total	14.7	±2.2	59	12.8	±2.1	55	NS	35% (5)
GAD7, 21 total	10.7	±1.9	59	9.6	±1.9	55	NS	N/A
ODI, %	54.9	±5.0	59	50.9	±6.0	54	NS	35% (10)
EQ-5D VAS, %	45.4	±8.5	33	50.2	±9.9	33	NS	27% (20)

DISCUSSION

In terms of the global effectiveness of their injection, 81% of respondents agreed it helped them overall, yet only 42% reported a clinically important difference in the severity of their back pain post-injection (2 in the VAS back). Both of these figures could be affected by the poor compliance with the full PROMs questionnaire – only 42 and 57 patients completed each section, respectively. The difference could also be explained by an element of 'satisfying the surgeon' – i.e. patients saying the injection helped more than it actually did. Furthermore, during the interpretation of the results of this study, patients classed as having been 'helped overall' included those who said the procedure 'helped a little' – over one-third of this 81% (see table 3). As Mannion A et al. would suggest, perhaps we should have regarded these patients as having a poor overall outcome instead (13).

The information obtained from outpatient consultation letters about whether or not the patients felt any initial improvement and any relief at follow-up was more widely available, but potentially less reliable; It is technically not a patient-reported measure so may be more susceptible to a surgeon-reporting bias. Although, the concordance between those who reported a clinically important difference in their back pain (VAS back) and those who felt an improvement at follow-up was statistically significant ($p<0.005$). Interestingly, there was also a significant correlation between those patients who said it helped overall and those whom it helped initially ($p<0.05$), and less so in those who said it helped at follow-up ($p=0.05$).

With this in mind, the fact that 71% of patients felt an initial improvement in their symptoms, compared to only 37% by follow-up, could be important. This suggests that the best period of pain control post-injection is during the first three months, supporting the idea that patients should be seen as soon as possible after their injection to begin alternative treatments. Recommendation 32 in the most recent NICE guidelines for the management of low back pain and sciatica (3) simply states 'do not offer spinal injections for managing low back pain'. This includes Facet Joint Injections, Medial Branch Blocks (injections of local anaesthetic on to the medial branch nerves that supply the facet joints), Intradiscal therapy, 'Prolotherapy' (proliferation therapy or regenerative injection therapy, involving injecting tissue with an irritant solution) and Trigger Point Injections (into a painful or irritable knot in a muscle). The clinical evidence for this recommendation came from a review of thirty-one studies, however upon closer examination of these studies, only six were studies of facet joint injections. This recommendation also mentions that facet joint injections are primarily intended for use 'in conjunction with an exercise programme', yet only one of the studies used as part of their review compared the outcomes of exercise regimes with and without prior facet joint injections (14). Another, smaller, study (sample size=18) compared the outcomes of patients who received either facet joint injections or exercise alone (17). Furthermore, recommendations 33-34 go on to support the use of 'medial branch blocks' as a tool for diagnosing pain originating from the facet joints prior to receiving radiofrequency denervation of the facet joints (14). This contraindicates the preceding recommendation, discussed above, as medial nerve blocks are equivalent to facet joint injections in terms of diagnostic purposes (16).

Evidently, more high quality research into the effectiveness of FJIs is needed, more specifically their use in conjunction with exercise regimes. This could begin with a simple audit of the number of patients who receive physiotherapy treatment after their injection, and the average waiting time for those patients who are referred. Whether there is any correlation between the length of time between injection and start of exercise regimes and overall patient outcome may also be of interest.

In terms of identifying factors which may predict the outcome of these procedures, the main findings were that patients who are already physically disabled due to their pain (ODI ≥60), moderately-severely depressed or suffer from severe generalised anxiety disorder are even less likely to benefit from FJIs in the long-term. I think it is therefore important that patients are screened for these co-morbidities, although, as NICE already suggests, decisions for treatment should not be made on their presence/absence alone. (3)

CONCLUSION

The relatively small number of purely facet joint injections performed by this Consultant Spinal Surgeon over a 4-year period is suggestive of them having already being phased out of use in clinical practice, even before the change in NICE guidance. Although there is obviously no argument for performing injections/procedures that are not likely to be of clinically significant benefit to patients, the withdrawal of spinal injections will probably be disheartening for many patients suffering from chronic low back pain, whose options for treatment are becoming increasingly narrower. The most important outcome of this study was whether FJIs provided symptom relief of low back pain – 42% showed a reliable improvement, and 81% said their injection helped them overall. But there is definitely a need for more high quality research in this area, and clearer guidelines for the management of these patients. The impact chronic low back pain has on the population is increasingly evident, in both financial aspects e.g. the number of people receiving disability benefits or out of work, and in terms of psychological health and well-being of its sufferers. However, the growing evidence for the association between patient psychology and chronic low back pain provides hope for alternative targets and, potentially, more success in the management of this endemic condition.

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