DISCOGENIC BACKPAIN; OUTCOME OF INTRADISCAL STEROID INJECTION

Dr. Asrizuzairudin Bin Muhammad Ali

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ABSTRAK

Pendahuluan; Sakit belakang discogenic adalah satu masalah kesihatan yang biasa dialami dan memberi kesan negative kepada kualiti hidup pesakit dan seterusnya menyebabkan kehilangan kerja dan pendapatan Negara. Suntikan steroid intradiscal adalah prosedur yang kurang berbahaya dan memberikan alternative kepada pesakit yang gagal rawatan secara konservatif. Kami menjalankan kajian untuk menentukan hasil suntikan steroid intradiscal pada pesakit sakit belakang discogenic berdasarkan skor kesakitan(Visual Analog Score) dan skor ketidakupayaan (indeks Kecacatan Oswestry).Dari kajian ini juga kami ingin menentukan hubungan antara penilaian gred diskografi(Adam's Grading) dengan peningkatan /perubahan skor kesakitan dan ketidakupayaan.

Methodology ; Ini adalah kajian kohort retrospektif yang melibatkan 70 pesakit yang mempunyai sakit belakang discogenik yang dari 1 Disember 2015 hingga 31 September 2018.Data klinikal dinilai menggunakan Visual Analog Scale dan Oswestry Disabilty Index.Analisis statistik dilakukan dengan menggunakan SPSS ver 24.0 untuk menjalankan ujian paired t untuk membandingkan prasuntikan VAS dan ODI pada sebelum suntikan intradiscal dan pada 6 bulan selepas suntikan .Semua nilai p kurang dari 0.05 dianggap siginifikan secara statistik.

Hasil; Sebilangan besar pesakit (usia min 56.4+9.2) mengalami penurunan skor kesakitan dari skor VAS pra suntikan 66.3+16.1 ke skor 32.2+ 17.4 selepas 6 bulan suntikan .ODI menunjukkan pengurangan 67.9+14.5% (ketidakupayaan teruk) kepada 33.1+ 13.6% selepas 6 bulan suntikan dikategorikan sebagai ketidakupayaan sederhana. Berdasarkan analisis ujian 'Spearman correlation' perubahan skor kesakitan VAS dan perubahan skor kecacatan ODI adalah lemah dan tiada hubungan secara signifikan degan klarifikasi Adam.

Kesimpulan; Suntikan steroid intradiscal adalah rawatan tambahan yang berpotensi pada pesakit dengan sakit belakang discogeniK yang gagal dalam perubatan konservatif .Kajian kami

menunjukkan bahawa suntikan steroid intradiscal dapat meningkatkan hasil klinikal jangka pendek pada pesakit dengan sakit belakang discogenic.

ABSTRACT

Introduction : Discogenic lower backpain and lumbar radicular pain is a common presentation with great disability and a negative impact of quality of life of the patient and subsequently toward working limitation. This minimally invasive intradiscal steroid injection provide an alternative to patient whom failed conservative treatment. We conducted a study to determine the outcome of intradiscal steroid injection in discogenic back pain patient based on the pain score(Visual Analog Score) and the disability score (Oswestry Disability Index).Finally we want to determine the correlation of discography grading (Adam grading with improvement /changes in pain and disability score

Methodology :This was a retrospective cohort study involving 70 patients with chronic discogenic back pain evaluate from 1st December 2015 till 31st September 2018 .the clinical data evaluate using Visual Analog Score and Oswestry Disability Index(ODI).Statistical analysis was performed using SPSS VER. 24 to run paired t test to compare the VAS and ODI pre injection and at 6 months post injection .All p value less than 0.05 were considered as statistically significant.

Result : Most patient (mean age of 56.4+9.2 years)significantly had reduction of pain score from pre injection VAS score of 66.3+16.1 to 32.2+17.4 6 months post injection. ODI show reduction of67.9+14.5% (severe disability) to 33.1 +13.6% ,6 months post injection were categorized as moderate disability. B ased on Spearman's correlation analysis change of pain score VAS and change of disability score ODI weak and not significantly correlated with Adam' classification.

Conclusion: The intradiscal steroid injection is potential adjunt treatment in patient with chronic discogenic backpain who failed conservative management.Our study shows that result suggested that

intradiscal steroid injection can improved the short term clinical outcome in patient with discogenic backpain.

Keyword : ODI (Oswestry Disability Index) VAS (Visual Analog S

Chapter 1

INTRODUCTION

1.1 INTRODUCTION AND LITERATURE REVIEW

Chronic low back pain has become a major disabling condition in the US, with increasing prevalence as well as social and economic impact . In fact, the state of US Health, from 1999 to 2010 assessing risk factors as well as the burden of disease and injuries, shows low back pain to be the number one cause of disability in US . Accurate cause of low back pain is determined in a very small proportion of patients, with the disc herniation contributing to a minute Proportion, which can be readily identified and managed with proven therapies. Consequently, discogenic pain arising from the disc itself without disc herniation, radiculitis, facet joint pain, or sacroiliac joint pain has been described as axial, nonradicular, chronic low back pain in the absence of spinal deformity, instability, and signs of nerve root irritation . Thus, in the absence of evidence of disc herniation, localization of the painful disc based on the symptoms and signs elicited on physical examination may be extremely difficult.Axial low back pain without radiculitis is similar to the pain produced by zygapophysial joints, the sacroiliac joint, or musculoligamentous origin of pain. Consequently, it is widely believed that lumbar disc herniation is not the major cause of low back pain, and that discogenic pain caused by annular disruption is one of the most important causes of chronic axial low back pain. Intervertebral disc degeneration is an age-related process that is asymptomatic in most individuals. Pathologic degeneration, however, can be a major cause of pain and disability. At present, the term “discogenic low back pain” refers specifically to the pain caused by internal disc disruption (IDD) as described by Crock [1] . Crock [1] proposed the concept of IDD as a condition marked by alteration in the internal structure.

Discogenic back pain has been defined clinically as chronic low back pain of a deep aching, nagging, or throbbing character, not completely relieved with rest. For the purposes of this manuscript, discogenic pain is defined as pain resulting from internal derangements of the intervertebral disc without associated herniation or impingement of nerve roots. A proposed mechanism of discogenic back pain is an inflammatory change of the intervertebral disc, and multiple studies indicate that nerve endings penetrate into the nucleus pulposus.

Inflammation, either from direct chemical irritation or secondary to an autoimmune response to the nucleus pulposus has been implicated as the primary pain source. Both steroids and non-steroidal anti-inflammatory drugs have partial effectiveness in treating pain associated with inflammation. When the symptom of pain is thought to result from inflammation, it is natural to think that an anti-inflammatory agent can be useful for treatment. Therefore, the rationale for using intradiscal steroids is to suppress the inflammation within the disc, thereby alleviating the patient's symptom.

3. Problem statement & Study rationales

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There are many literate that show effect of intradiscal steroid injection but mostly show that intradiscal steroid injection show minimal or no benefit in treating discogenic backpain. Few literature that involved in study to measure outcome of intradiscal injection for discogenic backpain .Intradiscal steroid injection do not improve the clinical outcome in patient with discogenic backpain compared to placebo Knot et al .2004[2]. Transforaminal steroid injections were shown to be significantly effective and safe in discogenic low back pain, and moderately effective in spinal stenosis [Rosernberg et al 2000][3]. Aoki et al [4] followed these studies in 1997 and evaluated histologic changes in intervertebral discs of rabbits after intradiscal injection of corticosteroids .They concluded that methylprednisolone causes degeneration and primary calcification in discs. [Aoki et al .1997][4].

But some study support our hypothesis that intradiscal steroid injection give good outcome for lumbar discogenic backpain patient. Zhuang CY et al 2009[5] show that Intradiscal steroid injection can relieve discogenic low back pain and improve ODI between 3 to 6 months post injection.

Friedly et al[6] reported that as many as 36% of patients with persistent axial low back pain receive epidural injections and this percentage may be continuing to rise, especially in the Medicare population. Fluoroscopy improves the efficacy of these injections by ensuring

proper needle positioning and targeted delivery of the therapeutic agent as well as preventing complications.

1.2 JUSTIFICATION OF STUDY

Lacked of local data that support that intradiscal steroid injection give best short term and long term outcome with discogenic back pain. Inflammation, either from direct chemical irritation or secondary to an autoimmune response to the nucleus pulposus has been implicated as the primary pain source. Both steroids and non-steroidal anti-inflammatory drugs have partial effectiveness in treating pain associated with inflammation. When the symptom of pain is thought to result from inflammation, it is natural to think that an anti-inflammatory agent can be useful for treatment. Therefore, the rationale for using intradiscal steroids is to suppress the inflammation within the disc, thereby alleviating the patient's symptom.Lacked of clinical data regarding treatment for discogenic backpain in Malaysia since most of the earlier studies in patients with lumbar back pain are focused on patients with radicular pain.In society, low back pain e.g discogenic back pain lead to work loss, healthcare use and sickness benefits. The economic loss to the nation due to loss of productivity and healthcare expenditure .

Our study finding will support and provide evidences to support of benefit and effective treatment for discogenic low back pain and reduce need for more invasive procedure and surgery

We hope that this study helps society to reduces the work losses, healthcare use and sickness benefits from the negative impacts of lumbar backpain and meanwhile to prevent further economic losses to the nation due to loss of productivity and healthcare expenditure. Finally,

for the treatment of patient, a correct pre intervention diagnosis is crucial in order to obtain satisfactory management .

Chapter 2

STUDY PROTOCOL

CHAPTER 2- STUDY PROTOCOL

2.1 DOCUMENT SUBMITTED FOR ETHICAL APPROVAL

STUDY PROTOCOL

DISCOGENIC BACKPAIN; OUTCOME OF INTRADISCAL STEROID INJECTION

DR ASRIZUZAIRUDIN BIN MUHAMMAD ALI
Postgraduate Student
M. Med (Orthopaedic)
Pusat Pengajian Sains Perubatan
Universiti Sains Malaysia

Supervisor:

PROFESOR DR.MOHD IMRAN BIN YUSOF
Senior Orthopaedic Lecturer
Orthopaedic Department
Pusat Pengajian Sains Perubatan
Universiti Sains Malaysia

Co-supervisors:

DR JOEHAIMEY BIN JOHARI
Senior Orthopaedic Lecturer
Orthopaedic Department
Pusat Pengajian Sains Perubatan
Universiti Sains Malaysia

STUDY PROTOCOL

Study Title:
Discogenic back pain ;outcome of intradiscal steroid injection

Protocol number, version number and date:
Protocol number

Name and Institution of Principal investigator:
Dr Asrizuzairudin Bin Muhammad Ali MMC No;48887
Hospital Universiti Sains Malaysia, Kubang Kerian

Name and address of Sponsor:
Self-funding

Study site:
Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan

Objectives

General objectives

To determine the outcome of intradiscal steroid injection in discogenic back pain patients admitted in HUSM from Jun 2015 to Dec 2018.

6.2 Specific objectives

1. To compare the pain score before injection and at 6 month after intradiscal steroid injection in discogenic back pain patient.
2. To compare the disability score before injection and at 6 month after intradiscal steroid injection in discogenic back pain patient
3. To determine the correlation of discography grading (Adam grading)with improvement/change in pain and disability score

Research design

Study Design:

Retrospective study which will involving folder only to collect data.

Study Period

1st Jun 2018 to 31st Jun 2019.

Study area

Orthopaedic clinic/ward in Hospital University Sains Malaysia

Study population

All adult patients aged 18 years old and above presented in the HUSM Orthopedic clinic with clinical presentations suggestive of discogenic backpain and was subjected for intradiscal steroid injection after assessments by Orthopaedic Spine Surgeons.

Methodology

This was retrospective study carried out at Hospital Universiti Sains Malysiaand all the sample were selected from the orthopaedic operation thearthe and clinic registry obtained from ist December 2015 to 31st January 2019.The subjects involved all patient with chronic LBP and lumbar radicular pain who under went intradiscal steroid injection.All patient who underwent the procedure were assess clinically with the aid of magnetic resonance imaging to confirm the presence of degenerative dics prior to injection, patient were given trial of conservative management with oral medication and physiotherapy.Those patient with primary diagnosis of malignancy,recent spinal fractuerwithin 3 month,lumbosacral spinal surgery,infective spondylitis and congenital spine anomaly were excluded from this study

Sample size calculation using SPSS VERSION 24 .Based on our first objective to assess efficacy of intradiscaal injection in patient with discogenic backpain before and at 6 month post injection using Visual Analog Score .Sample was calculated using SPSS software and Alpha level of significance =0.05 and Power of Study =0.8.SD of mean disability change=16.87(Khot et al,2004)[2] Detectable difference =6,n=64 +10 % for drop out= 70

From the previous study by Knot et al 2004[2]standard deviation of mean of disability was 16.87.Based on Type 1 error probability(alpha)of 0.05,power of study of 0.8 and detectable difference was 6.

For the first objective the out come of intradiscal steroid injection after 6 month was based on pain score (VAS).The sample was calculated as 70 patient .For second objective,to see outcome of intradiscal steroid injection based on disability score(ODI) we use the same sample as 70 patients. For our last objective to see correlation between change of disability score and changes in pain score with Adam's Classification,we will measure the correlation in the same sample with first and second objective study were chosen as 70 sample based on

the first objective. Consindering drop out rate of 10% for patient with cognitive impairment prohibiting completion of questionairee ,miss appointment and misplacement of record system calculated total sample size were 70 subjects.

Data will be entered and analysed using SPSS version 24 for both descriptive statisticaly significant for study objectves.Statisatical analysis for first objective and second objective to assess the relationship betweenthe effect of fluoroscopic guidance contrast intradiscal steroid injection and Marcaine injection at 6 month post injection by comparing VAS score and ODI using paired t test, A value of $P<0.05$is considered statisaticaly significant

Subject criteria

Inclusion Criteria

1. All adult patients aged 18 years old and above presented with axial back pains or predominant back pain subjected to radiological evaluation.
2. All patients who failed the conservative treatment over 3 months.
3. Underwent intradiscal steroid injection June 2015 to December 2018.

Exclusion Criteria

1. Primary diagnosis of malignancy, recent spinal fracture within 3 months, lumbosacral spinal surgery, infective spondylitis and congenital spinal anomaly.
2. Patient presence with axial back pain but pain from other site such as facet joint,spinal canal stenosis.

3. Patient with medical illness treated with systemic steroids medication.

Sample size estimation

Based on our first objective to assess the efficacy of intradiscal steroid injection in patient with discogenic backpain before and at 6 months post injection using visual analog scale .Sample was calculated using ps software and Alpha= level of significance= 0.05 and Power of study= 0.8 . Sd of mean disability change = 16.87 (Khot et al., 2004[2])Detectable difference= 6 ,n = 64 + 10% for drop out rate= 70.

From the previous study by Knot et al 2004[2], standard deviation of mean of disability changes was 16.87 and stated that based on Type I error probability (α) of 0.05, power of study of 0.8 and detectable difference was 6.

For first objective outcome of intradiscal steroid injection after 6 months based on pain score (Visual Analog Score) sample was calculated as much 70 patient .For second objective to see outcome of injection steroid based on disability score(Oswestry disability Score) we use the same sample as much 70 sample. For last our objective to see correlation between change of disability score and changes in pain score with Adam's classification .We will measure the correlation in the same sample with first and second objective.

Sampling method and subject recruitment

- **Sampling Method**

  All eligible (fulfilled the inclusion & exclusion criteria) will be selected

  Patient selection based on inclusion and exclusion criteria.

- **Subject recruitment**

  Patient selection based on inclusion and exclusion criteria in orthopaedic clinic to fulfill the objective of the study.

  Magnetic Resonance Imaging assessment for severity and exclude other pathology that cause lower backpain.

  Completion of data collection sheet for demographic data and assessment of clinical symptoms by Oswestry Disability Index and Visual Analogue Scale questionnaires must be done before injection and within six months post injection.

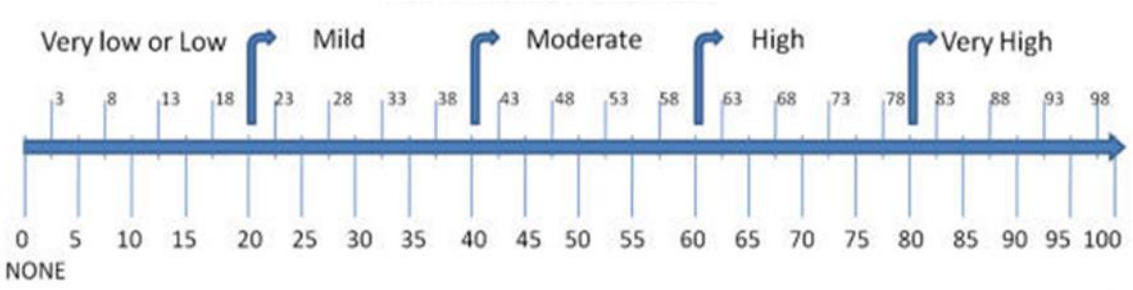
Research tool

1. **Oswestry Disability Index (ODI)**

A self-completed questionnaire by the patient that examines perceived levels of disability in 10 everyday activities of daily living to assign a subjective score of level of function. The test is considered the 'gold standard' of low back functional outcome tools (Fairbank et al 2000[7]) and Minimal Clinical Important Difference of 6 points shows sensitivity of 91% and specificity of 83% (Firtz et al 2001[8]).

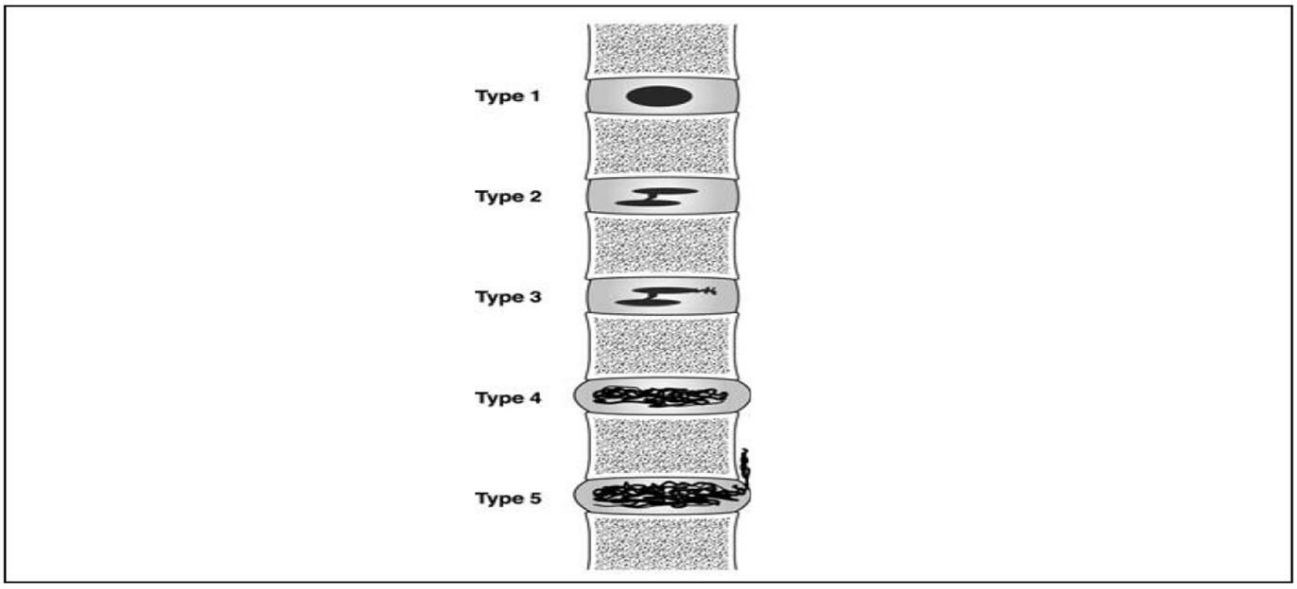
2. **Visual Analogue Scale (VAS)**

The overall current low back and leg pain intensity is assessed by a self-administered Visual Analogue Scale (VAS) (range 0-100 mm) in a sitting position during study visits. The visual analogue scale is considered to be a valid, reliable, and easily understood tool for pain assessment (Langley et al 1985[9]). Reliability and repeatability of the VAS is good as can be seen by correlation coefficients ranging from 0.97 to 0.99 as stated by Bijur et al. 2001 and Gallagher et al. 2002. VAS has greater sensitivity to change because of more levels to detect a slight change in pain compared to Numerical Rating Scale or Verbal Rating Scale (Jamison et al. 2002[11]).



Visual Analogue Scale (VAS)

3. Adam's grading/classification



Disc Degeneration as revelated by discograms - Adam's Classification.

This classification measure during intraoperative before injecting the steroid ,the dics will color/stained by contrast injected into dics and the morphology will document in operative notes.

Data collection method

Data collection sheet will be used to collect the data for further analysis. Data will collected from patient folder from record department. All data for pain score and disability index score will document based on result in patient folder. Data for pre injection and at 6 months post injection every patient inlvolved will be document based on documentation in folder.

All data from from folder for pain score (VAS) and Oswestry Disability Index (ODI) will be collect by primary investigator based on retained documentation in patient folder.

Data analysis

Data will be entered and analysed using SPSS version 24. Descriptive statistics will be used to summarise the socio-demographic characteristics of subjects. Numerical data will be presented as mean or median based on their normality distribution:

Expected Results

We will discuss on demographic characteristic of the patients whose coming with discogenic backpain.

Clinical characteristics of the study subjects with discogenic backpain (n=70)

Age	Mean (Std Dev.)
Male/Female	Percentages
Body Mass Index	Mean (Std Dev.)
Oswestry Disability Index	Mean (Std Dev.)
Visual Analogue Scale	Mean (Std Dev.)

For first objective to see the efficacy out intradisca steroid injection pre and post 6 months injection .the pain score based on Visual Analog Score(VAS) taken and documented .the efficacy based on visual analog score will be compare pre and post injection by paired T test.The result will expected as below.

	Pain Score pre injection	Pain score Post injection 6 moths	T stat	P value
Mean(SD)				

Paired t test

For second objective we want to compare the disability score based on Oswestry Disability Index pre injection and post 6 month intradiscal steroid injection in discogenic backpain patient. We will using paired T test to see the efficacy of intradiscal steroid injection. The result will be expected as below.

	Oswestry disability Score pre injection	Oswertry disability score Post injection 6 moths	T stat	P value
Mean(SD)				

Paired t test

For third objective, we want to see correlation between the efficacy of the intradiscals steroid injection with the mophorlogy of affected dics based on intraoperative finding using contrast Adam classification .First we want to see correlation the Adam classification with the pain score (Visual Analog Score) .We also will correlate the Adam classification with our the disabily score Oswestry Disability index.

1. Correlation Adam classification and efficacy of intradiscal steroid injection based on Visual Analog Score.

	Change in pain score	
	R	P value
Adam classification/discogram		

2. Correlation between Adam classification and change of disability score/efficacy of intradiscal steroid injection based on Oswestry disability Index.