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A RANDOMIZED CONTROL TRIAL ON EFFICACY OF ANALGESIC EFFECT OF 5% DEXTROSE CAUDAL EPIDURAL INJECTION FOR NON-SPECIFIC CHRONIC LOW BACK PAIN

Orthopaedics

Dr. Nitin Pandey Associate Professor, SMS Medical College, Jaipur.

Dr. Priyanka Nayak* MD PM&R, SMS Medical College, Jaipur. *Corresponding Author

Dr Vijendra Gahnolia MS Orthopaedics, JLN Medical college, Ajmer.

ABSTRACT

Background: Low back pain (LBP) is a major health issue that causes more disability and global burden than any other conditions. It is one of the most common musculoskeletal disorders. Chronic low back pain (CLBP) is defined as a pain that persists for more than 3 months, or longer than the expected healing period. It is associated with increased medical expenditure, work absence, and loss of quality of life. This study aims to ascertain efficacy of 5% dextrose (D5W) in chronic non-specific low back pain.

Material and Methods: This study is conducted on patient suffering from chronic low back pain presenting in Department of PM&R, SMS Hospital, Jaipur. It is a Single blind randomized control trial study. We include 34 patients of non-specific chronic LBP in each group as sample size which is further enhanced and rounded off to 40 patients in each group as final sample size expecting 10% attrition/drop out.

Results: We found that mean age of our study group is 49 years. This is female dominant study with 56.25% patients. Dextrose participants reported greater Numerical Rating scale pain score change at baseline (6.4 vs 6.25 points, p=0.59), but there is significant reduction of mean NRS pain score at 1st week (4.9 vs 5.4 points, p=01), 2nd week (4 vs 5.45 points, p=0.0001), 3rd week (3.15 vs 5.32 points, p=0.<0.0001), 1st month (2.95 vs 5.32 points, p=<0.0001), 2nd month (2.9 vs 5.32 points, p=<0.0001) and 3rd month (2.82 vs 5.32 points, p=<0.0001).

CONCLUSION: Serial caudal epidural injection of D5W resulted in consistent post injection analgesia and clinically significant improvement in pain through 3 months among participants with non-specific CLBP. Patients with CLBP can be treated effectively by using 5% dextrose.

KEYWORDS

Chronic low back pain, Caudal epidural injection, Efficacy of 5% dextrose

INTRODUCTION

Low back pain (LBP) is a major health issue that causes more disability and global burden than any other conditions.[1] It is one of the most common musculoskeletal disorders and it is estimated that approximately 60% to 80% of adults will experience LBP at some point in their lives. Low back pain (LBP) has become an increasing problem around the world.[2] It is increasing as a result of an ageing and expanding world population.[2]

In low-income and middle-income countries, disability and costs from low back pain will rise in the future, especially where health systems are delicate and cannot cope with this increasing burden.[3] Globally, in 2016, low back pain contributed 57.6 million [95% uncertainty interval (UI) 40.8–75.9 million (7.2%, 6.0–8.3)] of total years lived with disability (YLDs). [4]

Guidelines recommend the non-pharmacological and non-invasive management.[5] These include the provision of advice to stay active and the use of patient education and exercise therapy.[5] Guidelines regularly recommend the use of physical exercise for non-specific LBP.[6] Guidelines endorse the cautious use of imaging, of medication, and of surgery.[7] A risk stratification tool is recommended in the National Institute for Health and Care Excellence (NICE) guidelines[6] , so that treatments can be co-ordinated to each risk subgroup.[7] Chronic low back pain (CLBP) is defined as a pain that persists for more than 3 months, or longer than the expected healing period. It is associated with increased medical expenditure, work absence, and loss of quality of life.[8,9] While the effect of low levels of physical activity on pain and disability is becoming clear, the possible effect on postural control outcomes has received less attention to date. A sedentary behaviour may inadvertently cause reduced neuromuscular efficiency[10], increased skeletal muscles atrophy, and diminished muscle strength.[11] This reduction of physical activity and the associated muscle weakening of the lower limbs might have significant negative consequences on postural control and functional performance[12,13], and could contribute to back pain. In fact, poor neuromuscular control has been identified as an important risk factor in the development of NSCLB.[14]

Conventional therapies are often ineffective and some are known to have unacceptable adverse outcomes. For example, prescription opioids often used for CLBP have been identified as contributing to an "opioid epidemic.[15]" Among the treatment options that have been assessed for CLBP are caudal epidural injection of anti-inflammatories, analgesics and anesthetics[16], and interventional procedures not involving injection.[17] Effectiveness of each, however, is suboptimal.[18] The identification of safe and effective therapy for CLBP is a public health priority.[19] Dextrose in 12.5–25% concentration injection at entheses and intra-articular joint spaces for chronic musculoskeletal pain (prolotherapy) has been reported to reduce pain and improve function in a variety of conditions.[20,21] A multifactorial mechanism has been proposed, including a direct sensorineural effect.[22] The main reason of low back pain is mechanic pathologies especially overuse, ligament sprains, muscle problems or disc herniation.[23] Dextrose prolotherapy is a cheap and effective complementary treatment method to decrease pain for various musculoskeletal system disorders including low back pain. Prolotherapy is a nonsurgical regenerative injection technique that introduces small amounts of an irritant solution to the site of painful and degenerated tendon insertions (entheses), joints, ligaments, and in adjacent joint spaces during several treatment sessions to promote growth of normal cells and tissues.[24] Dextrose injections in 5–20% concentration have been used to treat superficial peripheral sensory nerves associated with chronic pain in uncontrolled[25] and controlled studies.[26] Dextrose 5–10% has also been safely injected into the epidural or intrathecal space to control epidural injectate placement.[27] Caudal epidural administration of corticosteroids is one of the commonly used interventions in managing chronic low back pain. Caudal epidural steroid injections are indicated in patients with chronic low back pain who have failed to respond to conservative modalities of treatments. A recent single-injection double-blind study comparing the short-term analgesic effect of epidural 5% dextrose (D5W) with that of saline reported a safe and significant analgesic effect of D5W that endured for over 48 h.[28] However, whether additional serial D5W injections would result in repeated short-term and enduring long-term pain diminution, and whether it has a concomitant effect on disability are not known. This study aim to ascertain efficacy of 5% dextrose (D5W) in chronic non-specific low back pain.

MATERIAL AND METHOD

This study is conducted on patient suffering from chronic low back pain presenting in Department of PM&R, SMS Hospital, Jaipur. It is a Single blind randomized control trial study. We include 34 patients of non-specific chronic LBP in each group as sample size which is further enhanced and rounded off to 40 patients in each group as final sample size expecting 10% attrition/drop out.

INCLUSION CRITERIA:
People of both sexes with chronic low back pain (>3 month) of age group 40-60 years. Failure of one or more non-injection therapy. Willing for inclusion and furnishing written informed consent.

EXCLUSION CRITERIA:
Known hypersensitivity to agents. Local or systemic infection. Local malignancy. Bleeding diathesis. Congestive heart failure. Uncontrolled diabetes mellitus. Progressive weakness are excluded.

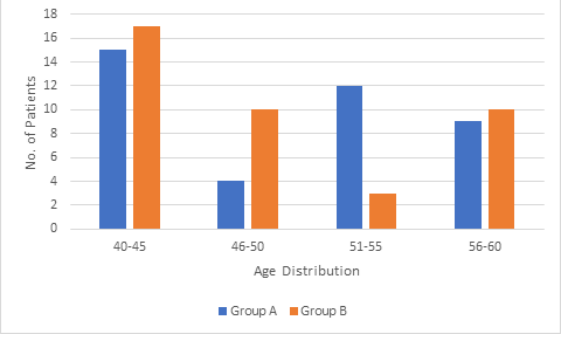
STATISTICALANALYSIS:
Qualitative data will be expressed with percentage and proportions. Quantitative data will be expressed with mean and standard deviation. The difference in mean will be inferred using 't'- test & ANOVA test as and when required. P- value of <0.05 will be considered statistically significant

RESULT

Table 1: Distribution according to age.

Age Distribution	No. Of Patients	Percentage
40-45	32	40
46-50	14	17.5
51-55	15	18.75
56-60	19	23.75
Total	80	100
Mean ± Sd	49±7.16	

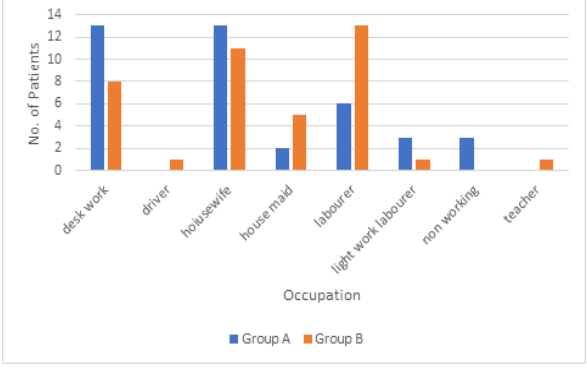
Mean age for group A is 49.7 years and mean age for group B is 48.3 years. There is no-significant difference between two group as p value is 0.38.



Graph 1: Distribution according to age

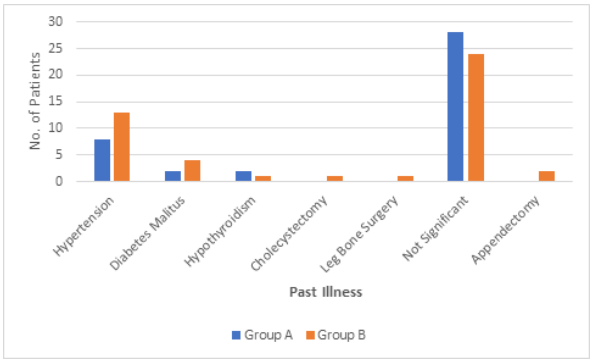
Table 2: Distribution according to gender

Gender Distribution	Group A		Group B		P-value
	No. of Patients	Percentage	No. of Patients	Percentage	
Female	20	50	25	62.5	0.25
Male	20	50	15	37.5	
Total	40		40		



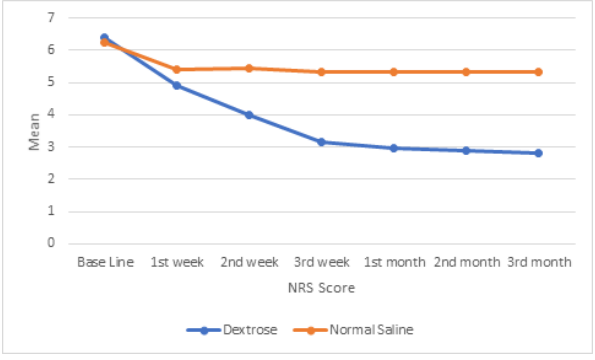
Graph 2: Distribution according to Occupation

In our study, 70% patients did not possess any past illness in group A and in 60% patients in group B (graph 3). 20% in group A and 32.5% patients in group B are hypertensive. 5% in group A and 10% in group B are diabetic patients. There is no significant difference between these group as p value is >0.05.



Graph 3: Distribution according to past-illness

We calculated mean NRS score for both the groups at baseline, at 1st week, at 2nd week, at 3rd week, at 1st month, at 2nd month and at 3rd month. At baseline mean NRS score for group A is 6.4 and for group B is 6.25, similarly at 1st week the score is 4 for group A and 5.4 for group B. There is no significant difference between these two groups as p-value is >0.05. We observe that there is continuous declination in mean NRS score in group A but in group B the mean NRS score is not decreasing much. There is significant difference between these group as p-value is <0.05 (Graph 4).



Graph 4: Distribution according to NRS score.

DISCUSSION

Epidural steroid injections are one of the most commonly performed invention for the treatment of low back pain. It has shown to reduce inflammation by inhabiting either synthesis or release of number of pro-inflammatory mediator. Various approaches have been described, out of which interlaminar & caudal are the most common. Both these approaches are useful in delivering the steroids near the problem site in low back pain patients which is usually L4-5 & L5 S1. For achieving such affectivity, various studies have evaluated the role of epidural steroid injections in low back ache with and without fluoroscopy. The use of fluoroscopy confirms the needle placement thereby improving drug delivery to appropriate site; thus reducing complications.[29-34]

In our study majority (40%) of patients are in age group 40-45 years followed by 23.75% in 56-60 years age group. Mean age for group A is 49.7 years and mean age for group B is 48.3 years. There is no-significant difference between two group as p value is 0.38. 56.25% patients are female and 43.75% patients are male. Maniquis-Smigel L et al[28] found that the study sample was middle aged (54 ± 10.7 years) and 31% female. Moshrif A et al[35] found that the mean age of his study group was 42.56 and 43.39 years in group A and B respectively. The female to male ratio was the same in both groups (2.8:1). In our study we calculated mean NRS score for both the groups at baseline, at 1st week, at 2nd week, at 3rd week, at 1st month, at 2nd month and at 3rd month. At baseline mean NRS score for group A is 6.4 and for group B is 6.25, similarly at 1st week the score is 4 for group A and 5.4 for group B. There is no significant difference between these two groups as p-value is >0.05. We observe that there is continuous declination in mean NRS score in group A but in group B the mean NRS score is not decreasing much. There is significant difference between these group as p-value is <0.05. Maniquis-Smigel L et al[28] found that pain improvement in the dextrose group at 15 minutes, 2 and 4 hours exceeded twice the minimal important change for pain improvement in low back pain as measured by NRS for pain.[36] These results suggest a short-term

analgesic effect of dextrose for CLBP with radiation to buttock or leg. Dextrose appears safe; 5% - 10% dextrose has been used to alter the spread of epidural anaesthesia (A Previous studies including dextrose in the injectate did not assess for an analgesic effect attributable specifically to dextrose. These findings suggest for the first time that 5% dextrose injected in the caudal space may confer a pain-specific neurogenic effect at the dorsal root level. The selection of 10 mL volume as the dose of 5% dextrose was based on the authors' clinical experience. It is unclear if this is optimal for all patients, as the dermatomal pain level for each patient is not the same 11-14, 25-31) and has not been associated with complications. Given an analgesic effect in participants with pain at and above the iliac crest level, which is supplied by T12-L1, this suggests that the 10 mL volume introduced vertically at the sacral cornua level[37] was sufficient to allow cephalad flow of dextrose. Injection of larger volumes of 5% dextrose and radiographic confirmation of the extent of rostral movement of dye merit additional study.

CONCLUSION

Patients with low back can be treated effectively by using 5% dextrose prolotherapy. Since the rehabilitation clinics are so busy and patients have to get an appointment sometimes longing for months for receiving physical medicine program, we can prefer only prolotherapy as an effective treatment method for low back pain. Serial caudal epidural D5W injection in the absence of anaesthetic, resulted in consistent post injection analgesia and clinically improvement in pain through 3 months for most participants. The consistent pattern post injection analgesia suggests a potential sensorineural effect of D5W in caudal space.

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