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Original Research Article

Efficacy for epidural fenatnyl in single level fenestration lumbar discetomies: An randomised controlled trial

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ABSTRACT

Background: Lumbar disc prolapse is among the most frequent causes of Back pain resulting in surgery accounting for 5% of all lumbar surgeries. In this study, post operative effecgtiveness of fentanyl in lumbar disc prolapse patients is being assessed. Pateints who undergo fenestration discectomies have moderate to severe pain at surgical site, which lasts for 48 to 72 hours post surgery.

Aims and Objectives: This study would evaluate the efficacy of intra-operative epidural fentanyl infiltration on post surgical analgesia following single-level fenestration discectomy and the adverse events that occurred among the groups.

Material and Methods: 60 patients were into two groups (Group A: Control & Group B: Drug). Between November 2018 and February 2021, 30 patients in the drug group—injected with intraoperative epidural fentanyl (1 mcg/kg weight) and 30 patients in the control group with placebo. All patients were followed up for the next 3 days. VAS scoring was used to assess post-operative pain and data on time to mobilization, the requirement for rescue analgesia (50 mg IV tramadol).

Results: Group A and Group B's post-operative VAS scores at the first post-operative hour were statistically significant (value of p = 0.02). The respective times for mobilization were 19.6 and 18.4 hours.

Conclusion: A single-level discectomy patient's (p=0.02) early postoperative pain (VAS) was statistically significantly reduced after intraoperative fentanyl infiltration and there were no appreciable side effects. Although not statistically significant(p>0.05), there was a earlier time to mobilization in the test group.

1. Introduction

In the treatment of any disease, analgesia plays an important role in their management. Pain following surgery is know to be very severe often delaying or hindering the immediate rehabilitation of patients. Prior Sensitization of the central and peripheral nervous systems would result from inadequate treatment of postoperative pain after spine surgery.[1] For at least the first three to four days, most individuals suffer moderate to severe pain.[2] Adequate postoperative analgesia has been achieved with either parenteral NSAIDs ("Non-Steroidal Anti-Inflammatory Drugs") or sometimes combined with epidural local anesthetics.[3–5] Patients who have undergone lumbar fenestration discectomy can begin rehabilitation nearly soon after surgery, although post-operative pain makes it difficult for the patient to stay compliant to the post operative rehabilitation.

2. Aim and Objective

In the current study, we wanted to assess the effectiveness of intraoperative epidural fentanyl as well as its function in managing post-operative pain and side effects in patients

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undergoing single-level lumbar discectomy.

3. Materials and Methods

The Institutional Ethics Committee approval was sought and was allowed to carry out this open labelled ramdomised trail. Patients with single-level intervertebral disc prolapse who reported to the orthopedics outpatient department between Nov 2018 and October 2021 were involved in the trail. The patients were of all genders and older. In contrast, patients who had multilevel disc prolapse, pathological spine fractures, scoliosis, kyphosis, failing back syndrome, procedures requiring instruments or who did not consent were not allowed to take part in the study. Written consent was obtained and the patient's complete medical history was documented. A comprehensive physical examination and standard pre-surgical investigations were performed on the selected patients.

Simple randomization was applied to divide the patients into 2 groups, Group A consisted of controls along Group B consisted of cases. The group division was unknown to the patients or the investigator. The concerned investigator did not know the drug given by the operating surgeon. The same incison and surgical technique were used on all patients.

The controls received placebo (2 ml of 0.9%NS), in the epidural space before wound closure whereas the cases obtained an intraoperative epidural fentanyl bolus(dose: 1 mcg/kg body weight).[6] Before the start of closure or 30 minutes after the end of the procedure, each patient received an IV infusion of 1 gm of paracetamol. After a 24-hour IV infusion of 1 g of paracetamol every 8 hours. Intraoperative analgesia was decided after consulting the anesthetist.

were VAS "Visual Analogue Scale" at 4,8,12,24, & 48hrs post-surgery. The study also included additional assessments of the time it took to mobilize following surgery and to take a rescue analgesic. The study prevalence of adverse effectsrespiratory depression, pruritus as well as urine If the post-operative VAS was greater than fiveillustration.

3.1. Statistical analysis

Along with VAS scoring charts, a structured Proforma was used to gather the data. The master chart was created by coding and entering the gathered data into Microsoft Excel. For all data, descriptive statistics were performed and the results were presented as mean values and percentages. Appropriate statistical comparison tests were conducted. The unpaired t-test along with the Mann-Whitney U test had been employed to determine continuous variables. Categorical variables were determined by utilizing the Fisher Exact and Chi-Square Test. The 95 percent confidence interval indicates that the p-value is significant. The relevant tables and graphs were used to express the results as a proportion.

Table 1: Demographical parameters of the study subjects

	Control	Intrathecal fentanyl	P-value
Female	11	12	
Male	19	18	
Age (years) (mean ± SD)	46.6 ± 8.6	45.7 ± 8.1	0.68 (NS)
Total no. of levels decompressed	30	30	0.72 (NS)

*p<0.05 statistically significant

4. Results

With a standard variation of 8.6 years, the study population's average age in the placebo group was 46.6 yrs. Study participants in the drug group were 45.7 yrs old on average, with an 8.1-year standard deviation. A total of 37 males and 23 females participated in the trial; of these, 11 females (36.7 percent) and 19 males (63.3%) were allocated to the placebo group, while 12 females (40%) and 18 males (60%) were allocated to the medication group (Table 1).

In the first post-operative hour (value of p = 0.02), there was a statistically significant variation in the drug as well as the other group, with mean Pre-Op VAS scores of 5.93 and 6.03. When comparing the groups at other times, there was no statistically significant variation (Table 2).

Among the control group, 5 patients (16.7%) needed to be given a rescue medication, whereas the treatment group had 7 patients (23.3%) who needed it. Between the two groups, there was no difference in the earliest time for the rescue drug. It took six hours after surgery for both groups to need rescue drugs.

As 6 patients (20%) in the control group and 7 patients (23.3 percent) in the drug group needed catheterization (p-value greater than 0.05), the occurrence of urine retention did not considerably vary between the 2 groups. The variation between the mean time to mobilization for the drug group (18.4 hours) and the control group (19.6 hours) was not statistically significant (Table 3).

5. Discussion

The ventral and dorsal spinal roots as they exit the spinal column appear to be the main site of action for local anesthetics delivered epidurally.[6] Limiting the dosage of local anesthetic medicines injected epidurally allows for selective sensory blockade without causing motor block. These medications inhibit both motor and sensory nerve activity in a concentration-dependent action.[7,8]

This single-level, blinded, randomized trial was carried out in our hospital's orthopedic department to ascertain the effectiveness of an intraoperative Fentanyl mix with control in single-level "lumbar fenestration discectomy" procedures.

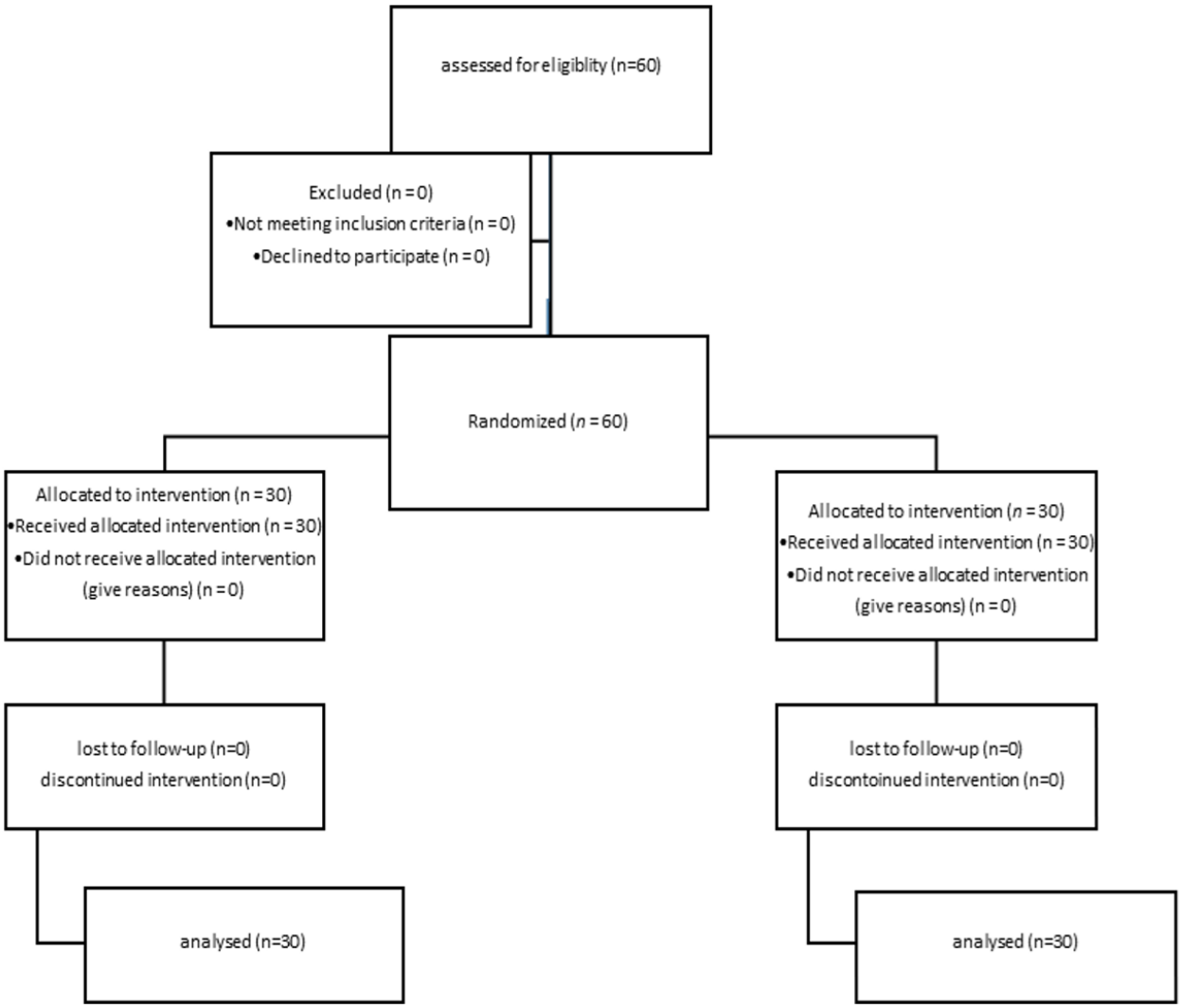

Figure 1: Consort flow diagram

Individuals in the drug "group had a mean age of 45.7 yrs, while those in the control group had a mean age of 46.6 yrs. Both groups' age distributions were similar and there was no statistically significant variation between them (p-value 0.68) in" group A, there were 11 women and 19 men patients; in group B, there were 12 women and 18 men patients. The patients' genders in the two groups have been similar and did not reach statistically significant (p-value 0.79).

disc Prolapse rates were similar in both groups and did not reach statistical significance (p-value 0.72). Both groups underwent a single-level lumbar vertebrae surgical treatment that was comparable.

The results in each group were unaffected by the co-morbidities and they were not statistically significant (p-value 0.48).

Comparable findings have been shown in Dhir P et al. and Jason H. H. Chan et al.[9] and showed that both groups' surgical procedures, which involved two or three levels of the lumbar vertebrae, were performed to a similar extent.[9]

The pre-operative VAS for the two groups was 5.93 and 6.03, respectively. In the first hour (p-value=0.02) following surgery, there was a statistically significant change. For the remaining time intervals, there was no statistically significant variation in the groups. This is explained by the brief (one to three hours) duration of action of epidural fentanyl.[10]

Similar findings were reported by Jason H. H. Chan et al. in their analysis, showing that patients who took fentanyl showed a substantial reduction in their mean pain. The fentanyl group's VAS and VAS ratings were considerably lower 2, 4, and 24 hours after surgery.[8]

Table 2: Comparing the VAS scores of the research groups at various time intervals

VAS (hour)	Study group	Mean (SD)	Mann Whitney U test	
			U statistic	P-value
Pre-Op	Placebo	5.93 (1.08)	427.5	0.73(NS)
	Drug	6.03 (1.13)		
1^{st} Post-Op	Placebo	3.60 (1.07)	299	0.02*
	Drug	3.03 (0.93)		
2^{nd} Post-Op	Placebo	3.73 (1.29)	326	0.05(NS)
	Drug	3.23 (1.36)		
4^{th} Post-Op	Placebo	3.33 (1.30)	396.5	0.41(NS)
	Drug	3.27 (1.60)		
8^{th} Post-Op	Placebo	2.50 (0.94)	446	0.95(NS)
	Drug	2.77 (1.68)		
12^{th} Post-Op	Placebo	2.20 (0.89)	365	0.19(NS)
	Drug	1.93 (1.17)		
24^{th} Post-Op	Placebo	1.53 (0.78)	433.5	0.80(NS)
	Drug	1.63 (1.00)		
36^{th} Post-Op	Placebo	1.23 (0.94)	397.5	0.40(NS)
	Drug	1.00 (0.83)		
48^{th} Post-Op	Placebo	1.10 (0.89)	372	0.21(NS)
	Drug	0.80 (0.76)		

*p<0.05 indicates significant

Table 3: Compares the groups' complications and time to mobilization

Groups variables	Control	Epidural fentanyl	P-value
	Rescue analgesia		
Yes	5 (16.7)	7 (23.3)	0.52 (NS)
No	25 (83.3)	23 (76.7)	
	Urine retraction		
Yes	6 (20)	7(23.3)	0.75 (NS)
No	24 (80)	23(76.7)	
	Time to mobilization (hours)		
	19.6	18.4	0.38(NS)

*p<0.05 indicates statistical significance

According to 2017 research by Dhir P et al. comparing the effectiveness of intrathecal morphine with control showed that patients receiving morphine at 4, 8, 12, and 24 hrs had considerably lower pain scores.

5 patients (16.7%) in the control group and 7 patients (23.3%) in the drug group in our research needed rescue drugs. There was no statistical significance between the groups, as shown by the p-value > 0.05 (0.52). There was no statistical correlation found between a certain time interval and the groups' requirement for the rescue analgesic. This is in comparison to research in Jason H et al.,[8] where patients in the intrathecal fentanyl group[9] had a considerable decrease in the usage of rescue medication. According to Efthimios Samoladas et al., the drug group did not require rescue analgesia, while the control group required rescue analgesia in around 40% of cases.[11]

According to research by Hunt C.O. et al.,(1987),[12] Varrassi et al.,(1992)[13] and Dahlgren et al.,(1997)[14] Intrathecal fentanyl prolonging the average duration of analgesia within patients decreased the need for rescue analgesics in comparison to a control group.

According to Dhir P et al., the drug group in their trial comparing the effectiveness of intrathecal morphine with a placebo required less rescue analgesia (P = 0.001) and reported greater levels of patient satisfaction.[9]

The occurrence of urinary retention didn't vary significantly between the 2 groups, with 20 percent of patients (6) in the control group and 23.3% of patients (7) in the drug group requiring catheterization (p-value greater than 0.05). Other impacts such as respiratory depression, pruritus, or sleepiness, have been absent from both groups of patients, however, hypotension was documented. The same findings were observed in Jason H et al.,[8]

The only side effect associated with the caudal epidural injection seen in the C. Sekar et al. trial was the increase in temporary postoperative urine retention.[15]

In 1985, Naulty J.S. and colleagues discovered that there was minimal pruritus and drowsiness, necessitating no therapy.[16]

According to Rutter D.V. and colleagues' 1981 study, 100μg of epidural fentanyl had a quick start but a shorter half-life, causing a noticeable drop in breathing rate and a rise in sedation. It also never needed to be treated.[17]

Significant pruritus has been reported in association with intrathecal fentanyl usage by Dahlgren et al.,[18] and Bruce-Ben David et al.[19]

After 12 hours following surgery, mobilization at our institution was delayed. The medication group experienced an average time to mobilization of 18.4 hours, whereas the control group experienced an average time of 19.6 hours. The p-value at the 95 percent confidence interval was 0.38 (>0.05); while the medication group did mobilize more quickly, the difference in time to mobilization was not statistically significant. Comparable to research by

Lowe TG, Jorgenson SS, France JC, et al. that compared intrathecal morphine with a placebo and found no variation in hospital stay in 2 groups.[20]

The lack of evidence on fentanyl's effectiveness in multilevel and instrumentation procedures was one of our study's limitations. The study did not evaluate the role that preoperative chronic pain and concurrent analgesic usage played.

6. Conclusion

An intra-operative epidural fentanyl bolus dosage of 1 mcg/kg body weight was administered prior to the "wound closure during lumbar fenestration discectomy substantially decreased early postoperative pain" with little adverse reactions and a much shorter time to mobilization. We further suggest more trials to determine the effectiveness of fentanyl in managing pain following posterior spinal instrumentation procedures in a more extensive study population.

7. Ethical Approval

This study was conducted after taking approval from the institution Ethical Review Board, RRMCH-IEC/26/2018-19.

8. Conflicts of interest

None.

9. Source of Funding

None.

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