

“A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF 90 mg DULOXETINE IN POSTOPERATIVE PAIN RELIEF IN PATIENTS IN UNDERGOING SPINE SURGERY ”

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ABSTRACT:AIMS AND OBJECTIVES: To evaluate the efficacy of duloxetine in different doses in postoperative pain relief in patients undergoing lumbar spine surgery.. **MATERIAL AND METHOD:** : 60 patients of ASA grade I & II of either sex scheduled for lumbar spine surgery under general anaesthesia were divided into 2 groups (n=30 each) randomly. Group D (n=30) Patients who received a 90 mg duloxetine 1 hour before surgery and another tablet the following morning. Group ‘P’(n=30) Patients who received a placebo tablet 1 hour before surgery and again the following morning. Pulse rate, blood pressure, respiratory rate and severity of pain on NRS scale was noted at 0 hr, 4 hr, 8 hr, 12 hr, 16 hr, 20 hr, 24 hr, 28 hr, 32 hr and 48 hr after surgery. And the presence or absence of adverse effects, such as headache, nausea, vomiting, dizziness, and drowsiness were noted. **RESULT:** Analysis revealed that time for first analgesic requirement was significantly longer with oral Duloxetine 90 mg than with placebo. Pre-emptive oral Duloxetine 90 mg decreases the severity of pain postoperatively but not significantly as compared to placebo in patients posted for lumbar spine surgery under general anaesthesia. Oral Duloxetine 90 mg had no significant effect on cardiovascular and respiratory parameters. Patients receiving duloxetine had higher incidence of nausea, vomiting. **CONCLUSION:** that time for first analgesic requirement was significantly longer with oral Duloxetine 90 mg than placebo.

KEYWORDS: Duloxetine , lumbar spine surgery, post operative analgesia

INTRODUCTION: Lumbar Spine surgeries are almost elective by nature. Some Commonly performed spinal surgeries are laminectomies, discectomies, spinal fusions, scoliosis corrections, and spinal tumour excision.

spinal surgeries often leads to extensive dissection of subcutaneous tissues, bones, and ligaments and thus result in a considerable degree of post operative pain(1) . Pain is one of the most important cause of postoperative morbidity.

Failure to adequate management of postoperative pain can have combined bunch of numerous undesirable sensory, emotional experiences, which are often associated with autonomic hyperactivity ,reduced mobility, endocrine metabolic, psychological and behavioural responses

Sufficient pain management is important to prevent negative outcomes(2) . Breakthrough development in the knowledge of molecular mechanism have led to the evolution of multimodal analgesia and new pharmaceutical products to treat postoperative pain(2) ..

Recently, antidepressants such as duloxetine, a selective serotonin and norepinephrine reuptake inhibitor(SSNRI), have accomplished pain relief in persistent and chronic pain⁸.

In addition it can improve post operative quality of recovery through mood improvement that can be helpful in the post operative period.

MATERIAL AND METHODS:

60 patients of ASA grade I & II of either sex scheduled for lumbar spine surgery under general anaesthesia. 60 patients who fulfilled the eligibility criteria were chosen, explained about the procedure and written consent was taken. Patients were classified randomly into 2 groups (30 patients in each group).

Group D (n=30) Patients who received a 90 mg duloxetine 1 hour before surgery and another tablet the following morning.

Group 'P'(n=30) Patients who received a placebo tablet 1 hour before surgery and again the following morning.

Pulse rate, blood pressure, respiratory rate and severity of pain on NRS scale(0-10 numaric pain rating scale) was noted at 0 hr, 4 hr, 8 hr, 12 hr, 16 hr, 20 hr, 24 hr, 28 hr, 32 hr and 48 hr after surgery. And the presence or absence of adverse effects, such as headache, nausea, vomiting, dizziness, and drowsiness were noted.

RESULT AND ANALYSIS :

Table: SHOWING DEMOGRAPHIC PROFILE OF PATIENTS IN TWO GROUPS

S.no.	Parameters	Group D		Group P		p value
		Mean	±SD	Mean	±SD	
1.	Age (yrs)	42.33	10.97	47.5	11.43	0.127#
2.	Weight (kgs)	65.25	7.24	65.78	5.84	0.425#
3.	Sex (M:F)	18:12		22:8		

Table 1 showing demographic profile of patients in three groups according to age, weight and sex.

Statistical analysis of Mean \pm SD of Age and Weight of the groups were comparable in both groups and statistically insignificant ($p>0.05$).

Table 2 : Duration (min) of surgery (Mean \pm SD)

Duration of surgery	Group D	Group P
Minutes (Mean \pm SD)	135.50 \pm 41.07	119.0 \pm 28.35

There was no statistically significant difference in duration of surgery in these two groups ($p>0.05$)

Table 3 : Time for Rescue Analgesia (TRA)

Parameter	Group D	Group P
TRA (mins)	116.50 \pm 14.90	40.62 \pm 7.94

Above table showing statistical analysis of Time for Rescue Analgesia in these two groups ($p>0.05$)

Table 4 : comparison of pulse rate at various time intervals

SN	Time Hrs	Group D Mean(\pm SD)	Group P Mean(\pm SD)	P value
1	Pre-op	85.95 \pm 5.738	85.05 \pm 6.854	
2	PO-0	90.95 \pm 11.545	99.65 \pm 6.200	$p> 0.05$
3	PO-4	87.13 \pm 8.486	86.48 \pm 4.873	$p> 0.05$
4	PO-8	86.88 \pm 7.845	87.55 \pm 5.315	$p> 0.05$
5	PO-12	87.75 \pm 9.410	86.35 \pm 5.903	$p> 0.05$
6	PO-16	87.25 \pm 7.928	86.40 \pm 3.350	$p> 0.05$
7	PO-20	85.78 \pm 7.468	86.75 \pm 2.12	$p> 0.05$
8	PO-24	85.75 \pm 9.870	87.20 \pm 5.431	$p> 0.05$
9	PO-28	84.15 \pm 7.651	83.95 \pm 3.088	$p> 0.05$
10	PO-32	83.48 \pm 8.171	84.88 \pm 2.989	$p> 0.05$
11	PO-048	86.33 \pm 10.511	86.40 \pm 4.733	$p> 0.05$

Above table showing statistical analysis of pulse rate at different post operative time intervals in comparison to preoperative pulse rate. No statistical significant difference was seen.

Table 5 : comparison of Mean Blood Pressure (MBP) at various time intervals

SN	Time Hrs	Group D Mean(\pm SD)	Group P Mean(\pm SD)	P value
1	Pre-op	93.68 \pm 5.722	94.60 \pm 8.189	$p> 0.05$
2	PO-0	98.67 \pm 5.44	106.07 \pm 4.98	$p> 0.05$

3	PO-4	96.03±4.02	96.70±3.11	p> 0.05
4	PO-8	94.78±6.09	95.05±3.97	p> 0.05
5	PO-12	94.44±3.60	94.78±3.79	p> 0.05
6	PO-16	94.18±3.49	94.77±2.72	p> 0.05
7	PO-20	93.82±3.06	94.55±2.67	p> 0.05
8	PO-24	93.57±5.01	94.12±4.01	p> 0.05
9	PO-28	92.96±3.93	93.76±2.97	p> 0.05
10	PO-32	91.71±3.56	93.02±2.80	p> 0.05
11	PO-048	94.57±4.72	95.02±3.93	p> 0.05

Above table showin statistical analysis of mean blood pressure at different post operative time intervals.. No significant difference was seen.

Table 6 : Mean Numeric Rating Scale (NRS) score at different time interval

SN	Time Hrs	Group D Mean(±SD)	Group P Mean(±SD)	P value
1	PO-0	2.2±0.648	3.23±0.891	p> 0.05
2	PO-4	2.6±0.496	2.43±0.931	p> 0.05
3	PO-8	3.50±0.599	3.80±0.883	p> 0.05
4	PO-12	2.50±0.877	2.80±1.018	p> 0.05
5	PO-16	2.80±0.564	2.93±0.944	p> 0.05
6	PO-20	2.58±0.549	2.58±1.059	p> 0.05
7	PO-24	1.80±0.687	2.00±0.716	p> 0.05
8	PO-28	2.10±0.304	2.10±0.841	p> 0.05
9	PO-32	2.00±0.226	2.13±0.853	p> 0.05
10	PO-048	2.10±0.632	2.20±0.758	p> 0.05

Above table showing statistical analysis of post operative NRS Score at different time interval in the three groups. No significant difference is seen at different point of time postoperatively in both group.

Table 7 SHOWING COMPLICATIONS IN ALL TWO GROUPS

Complications	Group D		Group P	
	N	%	N	%
Nausea	5	12.5%	3	7.5%
Vomiting	5	12.5%	3	7.5%
drowsiness	5	12.5%	0	-
Shivring	4	10%	4	10%

Incidence of post operative nausea & vomiting and drowsiness were higher in group D.

Discussion

Our study assessed the effect of short-term administration of duloxetine in different doses on acute postoperative pain in patients undergoing lumbar spine surgery under general anesthesia.

DEMOGRAPHIC DATA:

In our study there is even distribution of age, weight and sex in both groups. (Table-1) and we find that it was statistically insignificant.

DURATION OF SURGERY As shown in table 2 the mean \pm SD of duration of surgeries (min) in group D, and P were 135.50 ± 41.07 and 119.0 ± 28.35 minutes respectively. These values were statistically insignificant.

DURATION OF RESCUE ANALGESIA As shown in table 3 the mean \pm SD of duration of surgeries (min) in group D, and P were 116.50 ± 14.90 , and 40.62 ± 7.94 minutes respectively. These values were statistically significant.

Our study in accordance with Attia JZ et al (3), Kassim DY et al (4), Nasr DA et al (5), Govil N et al (6), Lierz P et al (7) and Srivastava S et al (8).

HAEMODYNAMICS

Perioperative pulse rate and mean blood pressure in group Duloxetine 90mg, and Placebo is shown in table no.4 & 5. On comparing the statistics of postoperative pulse rate at different time intervals in comparison to preoperative pulse rate, statistically significant difference was found at 1st postoperatively that may be due to emergence from general anaesthesia. No significant difference was seen at 4th, 8th, 12th, 16th, 20th, 24th, 28th, 32nd and 48th postoperative hours. Our study in accordance with Kassim DY et al (4).

ADVERSE EFFECTS: As regard of postoperative adverse effect in the study, all cases of two groups were haemodynamically stable and study showed incidence of postoperative nausea & vomiting and drowsiness were higher in duloxetine 90 mg when compared to group Placebo. Our study in accordance with Saoud A et al (9), Kassim DY et al (4) and Nasr DA et al (10).

CONCLUSION

Analysis revealed that time for first analgesic requirement was significantly longer with oral Duloxetine 90 mg than with placebo. Pre-emptive oral Duloxetine 90 mg decreases the severity of pain postoperatively but not significantly as compared to placebo in patients posted for lumbar spine surgery under general anaesthesia. Oral Duloxetine 90 mg had no significant effect on cardiovascular and respiratory parameters. Patients receiving duloxetine had higher incidence of nausea, vomiting.

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