Original Article

"Low back pain response after application of interferential therapy alone and in combination with aceclofenac+paracetamol, tramadol+paracetamol: A prospective, comparative, clinical study"

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Abstract

Aims and Objectives: To determine efficacy of analgesia of Analgesic drugs + Interferential Therapy (IFT) or without IFT. **Material and Methods:** The 80 eligible patients (30 male, 50 female) of acute and chronic low back pain were assigned to 5 groups (Grp), i.e., Grp A, B, C, D and E. The Orthopedician prescribed tablet Xenodol (Aceclofenac 100mg + Paracetamol 500mg 1 BD for 7 days) for Grp A, tablet Patrol (Tramadol 37.5mg + Paracetamol 325mg) 1 BD for 7 days) for Grp B, IFT 25 - 100Hz application at lumbar region for 15 min daily for 7 days for Grp C, tablet Xenodol of same dose with IFT 25 - 100Hz application for 7 days for Grp D and tablet Patrol of same dose with IFT 25 - 100Hz application for 7 days for Grp E patients. Eligible patients pain were assessed twice, i.e., pre-treatment and post-treatment, by SF-LF-MPQ (Short Form-Long Form McGill Pain Questionnaire's Rating Index. **Results:** The post-treatment mean ± SD was 1.3 ± 0.9, 1.4 ± 1.5, 1.6 ± 0.85, 1 ± 0.73, 0.93 ± 1.16for Grp A, B, C, D and E respectively, while the pre-treatment pain intensity score mean ± SD was 1.9 ± 0.5, 2.4 ± 1.1, 2.13 ± 0.8, 2.25 ± 0.9, 2.25 ± 1.1 for Grp A,B,C,D,E respectively. The differences was statistically significant, i.e. ($P < 0.05$) 0.03856, 0.03601, 0.0002027, 0.002136 of Grp A, B, D, E respectively and insignificant, i.e. ($P > 0.05$) was 0.06603 for Grp C. **Conclusion:** Tablet Xenodol (Aceclofenac + Paracetamol) and tablet Patrol (Tramadol + Paracetamol)alone showed efficacy in pain reduction, while when the tablets Xenodol and tablet Patrol of same doses given with IFT 25 - 100Hz application at lumbar regionin Grp D and Grp E the pain reduction was highly significant than the medication alone groups, i.e., for Grp A, B, C.

Key words: Aceclofenac+paracetamol, interferential therapy (IFT), low-back pain (LBP), McGill pain questionnaires, tramadol+paracetamol

INTRODUCTION

Low Back Pain is highest prevalence in the aged 45 to 65 years.[1] The 60 to 80% world population experienced LBP.[2] There is multiple non-surgical LBP treatment modalities available like: e.g. Counseling and education, rest, medication, braces, passive modalities, spinal manipulation, injection, exercise and stretching, proper lifting technique. Acetaminophen and other non-steroidal anti-inflammatory drugs are commonly used for the treatment of LBP.[3]

Electrical stimulation has widespread clinical use for pain relief. The 90-130Hz frequencies stimulate the pain gate mechanisms and mask the pain symptoms, while stimulation with lower frequencies (2-5Hz) can be used to activate the opioid mechanisms to providing a degree of pain relief. It is possibility that relief of pain may be achieved by stimulation of the reticular formation at frequencies of 10-25Hz or by blocking C fiber transmission at >50Hz. Thus, Electrotherapy (Electro Physical Agents) has been possible used in clinical practice appropriately to relief pain, the evidence supports its effectiveness.[4]

So, IFT W-30, Range 1 to 250 Hz, manufactured by 'HMS Medical System' Chennai, electrical stimulator used in present study for comparison of analgesic efficacy of IFT (25 – 100Hz) + tab.

Xenodol (Aceclofenac+Paracetamol), IFT (25-100 Hz) + tab. Patrol (Tramadol +Paracetamol) and IFT (25-100Hz) alone in another group for the present study.

MATERIALS AND METHODS

After approval of the present study from the Institutional Clinical Ethics Committee, total 80 assigned patients (30 male and 50 female) segregated in five groups by using lottery method and prescribed the study therapy [Table 1]. The study was prospective, clinical study. The duration of the study was 7 days dated from 2nd July 2013 to 9th July 2013 with 7 days follow-up. Study Centre was: Out-patient Orthopedics and Physiotherapy and Pharmacology Department, DSMCH (Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur, Tamilnadu, India. Sample Selection Criteria: Inclusion Criteria: The patients, who complained acute or chronic low-back pain, No history of taking analgesics in the previous one month and male and female of ages between 30 to 60 years with LBP, were included in the study. Exclusion Criteria: If any patient does not come under inclusion criteria, post-operative patients, patients who suffered from peptic ulcers, congestive heart failure, liver and renal impairment, multiple injuries with bony fractured patients, pain due to any cause; except related to acute or chronic low-back pain, unwilling to participate in the study patients; excluded from the study. If patients absconded from the study excluded too but, that shown as dropout in percent (%) during calculation.

The study drugs provided from the DSMCH Pharmacy and Department of Physiotherapy applied IFT 25-100 Hz for 15 min daily over lumbar region in Grp C, D and in Grp E patients for seven days. The IFT specification used for the study was W-30, Range 1-250 Hz, manufactured by 'HMS Medical System' Chennai, electrical stimulator. We assessed pain intensities grade, i.e., (0...No Pain, 1....Mild, 2....Discomforting, 3.....Distressing, 4..... Horrible, 5.....Excruciating)by Short Form-Long Form McGill Pain Questionnaire[5] (SF-LF-MPQ). We noted the Pain intensities twice, first (Baseline pain/pre-treatment), i.e., at the time of registration of the patients and second (post-treatment), after end of seven days of the therapy.

Statistical calculation

After obtaining the data, we calculated the values, like percent, Mean, Standard Error, Standard Deviation, Dropout Rate from the study (in percent) and *P*-value by applying various statistical formulas, like' paired t-test', Kruskalwallis test (ANOVA) through online/offline free software, i.e., www.openepi.com.

RESULTS

The baseline pain intensity (mean) was 1.9, 2.44, 2.13, 2.25, 2.25 for Grp A, B, C, D, E treated patients respectively and post-treatment was 1.3, 1.4, 1.57,1, 0.93 of Grp A, B, C, D, E treated patients respectively [Tables 2,3 and Figure 1]. Thus, after 7th day of medication, pain reduction mean was 39.3, 53.3, 23.2, 61.9, 61.7% of Grp A, B, C, D, E patients respectively [Tables 2,3 and Figure 2].

After 7days, i.e., post-treatment, the 4 patients had 100% and 3 patients had 50% pain relief of Grp A, the 7 had 100% and 2 had

Table 1: Therapy for the Study Groups

Grp A	Grp B	Grp C	Grp D	Grp E
Tablet Xenodol (Aceclofenac 100 mg+Paracetamol 500 mg) 1 BD daily for 7 days	Tablet Patrol (Tramadol 37.5 mg+Paracetamol 325 mg) 1 BD daily for 7 days	IFT 25-100 Hz Electrical Stimulator application, 15 min, at Lumbar region daily for 7 days	Tablet Xenodol 1 BD + IFT Application daily at lumbar region for 7 days	Tablet Patrol 1BD + IFT Application daily at lumbar region for 7 days

Table 2: Pain mean, SD, SE Pre-treatment and Post-treatment of all five groups

Groups	Therapy given	1st day pain intensity (Mean)	7th day pain intensity (Mean)	1st day pain intensity (SD)	7th day pain intensity (SD)	1st day pain intensity (SE)	7th day pain intensity (SE)	1st day pain intensity (%)	7th day pain intensity reduction (%)	Dropout rate (%)
Grp A	Tablet Xenodol (Aceclofenac 100 mg+Paracetamol 500 mg) 1BD daily for 7 days	1.9	1.3	0.5	0.9	0.13	0.25	100	39.3	12.50
Grp B	Tablet Patrol (Tramadol 37.5 mg+Paracetamol 325 mg) 1 BD daily for 7 days	2.4	1.4	1.1	1.5	0.3	0.4	100	53.3	6.25
Grp C	IFT 25-100 Hz Electrical Stimulator application, 15 minutes, at Lumbar region daily for 7 days	2.13	1.6	0.81	0.85	0.20	0.21	100	23.2	12.50
Grp D	Tablet Xenodol 1BD + IFT Application daily for 7 days	2.25	1	0.93	0.73	0.5	0.25	100	61.9	12.50
Grp E	Tablet Patrol 1BD + IFT Application daily for 7 days	2.25	0.93	1.1	1.16	0.27	0.29	100	61.7	6.25

50% pain reduction of Grp B, the 1, 4, 1 patients reported 100%, 50%, 25% pain reduction respectively of Grp C, the 4, 2, 6, 1, patients had 100%, 66.7%, 50%, 33.3%, pain reduction respectively of Grp D, the 7, 4, 1, patients pain reduction was 100%, 50%, 25% respectively of Grp E [Table 3 and Figure 3].

The no reduction of pain intensity after 7 days of medication of Grp A, B, C, D, E was 7, 6, 8, 1, 3 patients respectively [Table 4].The 2, 1, 2, 2, 1 patients,(i.e., dropout rate 12.50, 6.25, 12.50, 12.50, 6.25%) had not reported (reason unknown) after 7 days of the medication of Grp A, B, C, D, E respectively [Table 3 and Figure 4].

The Statistical analysis done by applying paired t-tests and Kruskalwallis test (ANOVA) through using Online/offline Free Software, eg.www.openepi.com .Between the groups Pain intensities was reduced highly significantly ($P = 0.00001$) [Table 4].

The differences of pain reduction was statistically significant, i.e. ($P < 0.05$) 0.03856, 0.03601, 0.0002027, 0.002136 of Grp A, B, D,

Table 3: No. of patients who reported the Pain reduction in percent after the treatment

Groups	Age year Mean and (SD) of the patients	No. of Patients	No. of Male	No. of Female	After 7th day of medication number of patients get reduced pain intensity						Not reported patients
					↓100 (%)	↓66.7 (%)	↓50 (%)	↓33.3 (%)	↓25 (%)	↓0 (%)	
Grp A	41.75±11.67 (SD)	16	8	8	4	—	3	—	—	7	2
Grp B	43.63±11.77(SD)	16	4	12	7	—	2	—	—	6	1
Grp C	49.31±7.32 (SD)	16	7	9	1	—	4	—	1	8	2
Grp D	43.25 ±7.72 (SD)	16	6	10	4	2	6	1	—	1	2
Grp E	46.38±10.99 (SD)	16	5	11	7	—	4	—	1	3	1

Table 4: Statistical calculations done by using online free software, eg.www.openepi.com analysis of variance (ANOVA)

Input Data

Group	N (count)	Mean	Std. Dev.
GrpA:1st day	16	1.9	0.5
GrpA:7th day	16	1.3	0.99
GrpB:1st day	16	2.44	1.09
GrpB:7th day	16	1.4	1.55
GrpC:1st day	16	2.13	0.81
GrpC:7th day	16	1.57	0.85
GrpD:1st day	16	2.25	0.93
GrpD:7th day	16	1	0.73
GrpE:1st day	16	2.25	1.06
GrpE:7th day	16	0.93	1.16

ANOVA Table

Source of variation	Sum of squares	d.f	Mean square	F statistics	*P*-value[1]
Between Groups	43.5906	9	4.8434	4.8115	0.0000119713
Within Groups	150.995	150	1.00663		
Total	194.585	159			

	Chi square	d.f	*P*-value[1]
Test for equality of variance	22.4211	9	0.0076361

		95% CI of individual sample mean		95% CI assuming equal variance	
Group	Mean	Lower limit	Upper limit	Lower limit	Upper limit
GrpA:1st day	1.9	1.63357	2.16643	1.36538	2.43462
GrpA:7th day	1.3	0.772468	1.82753	0.765376	1.83462
GrpB:1st day	2.44	1.85918	3.02082	1.90538	2.97462
GrpB:7th day	1.4	0.574066	2.22593	0.865376	1.93462
GrpC:1st day	2.13	1.69838	2.56162	1.59538	2.66462
GrpC:7th day	1.57	1.11707	2.02293	1.03538	2.10462
GrpD:1st day	2.25	1.75444	2.74556	1.71538	2.78462
GrpD:7th day	1	0.611012	1.38899	0.465376	1.53462
GrpE:1st day	2.25	1.68517	2.81483	1.71538	2.78462
GrpE:7th day	0.93	0.311882	1.54812	0.395376	1.46462

P-value (two-tailed).

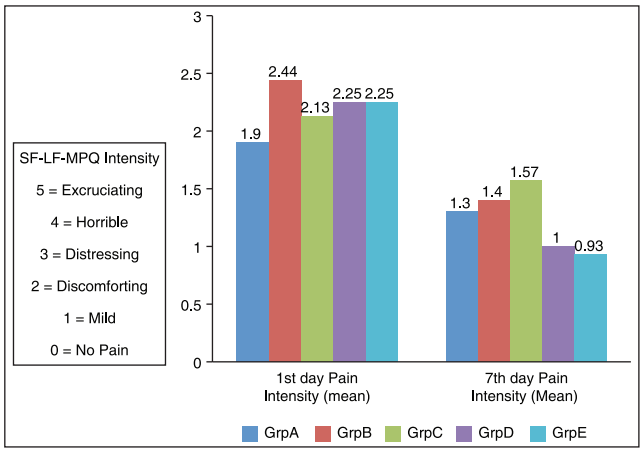

Figure 1: Intensity of Pain (mean) Before and after medication

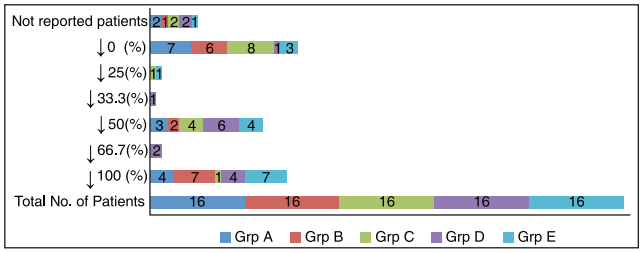

Figure 3: Number of patients reported to reduction of pain Intensity (Percent)

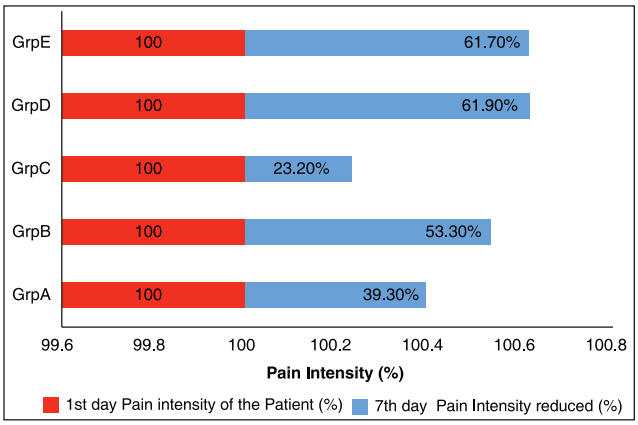

Figure 2: Intensity of Pain Reduction after medication (Percent)

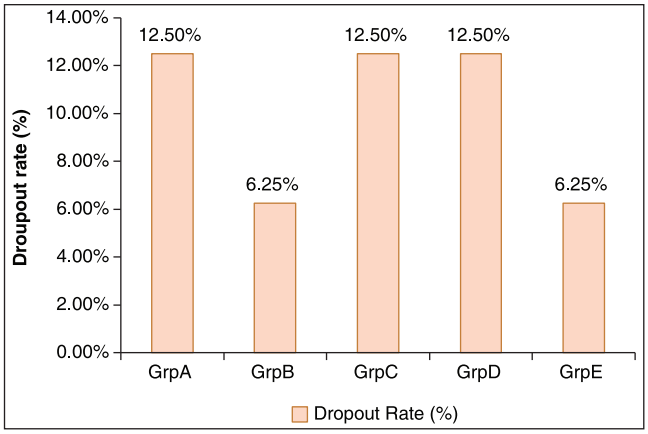

Figure 4: Number of patients not reported at end of the study (Dropout Rate %)

E respectively and insignificant, i.e. ($P > 0.05$) was 0.06603 for Grp C. So, comparatively pain reduction response was highly significant for the Group D ($P = 0.0002027$) than the GrpE ($P = 0.002136$) [Table 5].

The probability of pain reduction among Grp A (versus)Vs. D, Grp A Vs. E, Grp B Vs. D, Grp B Vs. E, Grp C Vs. D, Grp C Vs. E had 0.000175027, 0.00112602, 0.00117219, 0.00246735, 0.000432019, 0.00111177 respectively. Thus, it was indicating that the probability of the pain reduction was highly significant in Group D Vs. Group C ($P = 0.00043$), and Group D Vs. Group A ($P = 0.00017$) [Table 6].

DISCUSSION

Schug SA. 2006 reported in his study that, combination of analgesics acting by various mechanisms offer increased efficacy due to synergism/additive analgesic effects. So, the appropriate combinations when given increased analgesic efficacy and decreased adverse effects could be expected in comparison with either treatment alone.[6] Aceclofenac is a proven effective NSAID, which is cox-2 selective, good GI tolerability and safer for cardiovascular system compared to other selective cox-2 inhibitors.[7] Paracetamol has been considered as highly effective, i.e., first line drug for acute low back pain in all reviewed guidelines. Paracetamol is a good analgesic, antipyretic drug with weak anti-inflammatory effect.[8] Tramadol is a centrally acting opioid analgesic produces analgesic effect that begins within one hour of its administration and reaches a peak in 2 to 3 hours. Though, the oral opioids are effective in acute low back pain like sciatica, but it is not advisable for long term use. Thus, opioid should be considered a second- or third-line analgesic drug for a short period.[9] Every living cell has a membrane potential (of about -70 mV), if the membrane potential changes, it influences the movement of ions. The energy in the membrane (and other organelles of course) offers the potential to change the behaviour of the cell – one of the fundamental tenets of electrotherapy – and therefore make a difference to the behaviour of cells and tissues. Thus, Electrotherapy has a place within clinical practice.[10-12] So, in the present study, the pain reduction response was highly significant for Aceclofenac 100 mg + Paracetamol 500 mg + IFT treated Grp D ($P = 0.0002027$) and Tramadol 37.5 mg + Paracetamol 325 mg + IFT treated Grp E ($P = 0.002136$) than compared to Group A, B, C treated medication, but among Group D and E, the pain reduction was more in Group D than the Group E.

LIMITATIONS

This present study data has helped only viewing analgesic effectiveness of the Aceclofenac100 mg + Paracetamol 500 mg, Tramadol 37.5 mg + Paracetamol 325 mg, Interferential therapy alone and combination with this study drugs.

Table 5: Applied Paired t-test of each Grp: Before Vs. After medication. through using online/offline free software, eg. www.openepi.com

Grps	Before and after therapy	No. of patients	Pain intensity (Mean)	S.D.	Result	*t* statistics	df	*P*-value[1]	Mean difference	Lower limit	Upper limit
Grp A	1st Day	16	1.9	0.5	Equal variance	2.16392	30	0.03856	0.6	0.0337328	1.16627
	7th Day	16	1.3	0.99							
Grp B	1st Day	16	2.44	1.09	Equal variance	2.19538	30	0.03601	1.04	0.0725362	2.00746
	7th Day	16	1.4	1.55							
Grp C	1st Day	16	2.13	0.81	Equal variance	1.90778	30	0.06603	0.56	0.039474	1.15947
	7th Day	16	1.57	0.85							
Grp D	1st Day	16	2.25	0.93	Equal variance	4.2291	30	0.0002027	1.25	0.646366	1.85363
	7th Day	16	1	0.73							
Grp E	1st Day	16	2.25	1.06	Equal variance	3.36013	30	0.002136	1.32	0.517714	2.12229
	7th Day	16	0.93	1.16							

Table 6: Comparison of pain intensities among different groups and its probability by applying ANOVA test, through using online/offline free software, i.e. www.openepi.com

Grps	Before and after therapy	No. of patients	Pain intensity (Mean)	S. D.	Source of variation	sum of squares	df	Mean square	*F* statistics	*P*-value
Grp A Vs. Grp D	1st Day	16	1.9	0.5	Between Groups	15.39,	3,	5.13,	7.80852,	0.000175027
	7th Day	16	1.3	0.99	Test for equality of variance	Chi square, 7.3049,	df 3 ,		*P*0.0627892	
	1st Day	16	2.25	0.93						
	7th Day	16	1	0.73						
Grp A Vs. Grp E	1st Day	16	1.9	0.5	Between Groups	16.8208,	3,	5.60693,	6.0627,	0.00112602
	7th Day	16	1.3	0.99	Test for equality of variance	Chi square, 9.93037,	df 3,		*P*0.0191674	
	1st Day	16	2.25	1.06						
	7th Day	16	0.93	1.16						
Grp B Vs. Grp D	1st Day	16	2.44	1.09	Between Groups	22.5452,	3,	7.51507,	6.02603,	0.00117219
	7th Day	16	1.4	1.55	Test for equality of variance	Chi square, 8.88783,	df 3,		*P*0.03082	
	1st Day	16	2.25	0.93						
	7th Day	16	1	0.73						
Grp B Vs. Grp E	1st Day	16	2.44	1.09	Between Groups	24.3344,	3,	8.11147,	5.35428,	0.00246735
	7th Day	16	1.4	1.55	Test for equality of variance	Chi square, 2.90851,	df 3,		*P*0.405948	
	1st Day	16	2.25	1.06						
	7th Day	16	0.93	1.16						
Grp C Vs. Grp D	1st Day	16	2.13	0.81	Between Groups	15.8188,	3,	5.27293,	6.94927,	0.000432019
	7th Day	16	1.57	0.85	Test for equality of variance	Chi square, 2.26455,	df 3,		*P*0.519346	
	1st Day	16	2.25	1.06						
	7th Day	16	1	0.73						
Grp C Vs. Grp E	1st Day	16	2.13	0.81	Between Groups	17.5296,	3,	5.8432,	6.07433,	0.00111177
	7th Day	16	1.57	0.85	Test for equality of variance	Chi square, 2.59683,	df 3,		*P*0.458046	
	1st Day	16	2.25	1.06						
	7th Day	16	0.93	1.16						

CONCLUSION

According to the finding and within the limitation of the present study, the combination of IFT (25-100 Hz) application 15 min at Lumbar region daily for 7 days + Tablet (Aceclofenac 100 mg + Paracetamol 500 mg) 1BD daily for 7 days is good combination as an analgesics, than, the Tablet (Aceclofenac 100 mg + Paracetamol 500 mg) alone. The combination of IFT application + Tablet (Tramadol 37.5 mg + Paracetamol 325 mg) 1 BD daily for 7 days is good combination analgesics, than, the Tablet (Tramadol 37.5 mg + Paracetamol 325 mg) alone. But, the IFT + (Aceclofenac 100 mg + Paracetamol 500 mg) therapy relieved pain much better, than IFT + (Tramadol 37.5 mg + Paracetamol 325 mg). So, Tramadol 37.5 mg + Paracetamol 325 mg + IFT (25-100 Hz) should be given 2nd or 3rd preference (van Tulder MW, 2006 also reported that tramadol should be 2nd or 3rd line drug)[9] than the (Aceclofenac 100 mg + Paracetamol 500 mg) + IFT. The Group A, B, C measures can also be used for the relief the pain, but the analgesic response was lesser than the group D, E measures application.

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