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Pulsed Electromagnetic Field Treatment as a Non-Pharmacological, Non-Invasive Treatment for Chronic Back Pain: Promising Results from a Randomized Controlled Trial and Review of Literature

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Abstract

Objective : Comparison of Pulsed electromagnetic field (PEMF) therapy via Quantron Resonance System (QRS), QRS® 101 to oral pain medications in Chronic Back Pain (CBP).

Methods: CBP patients were randomly divided into two groups, Group P (n=30): 15 sessions of 30 minutes of PEMF (40 mT) over 3 weeks with oral pain medications; Group M (n=30): sham PEMF of similar duration with oral pain medications.

The primary outcome was comparison of Pain Numeric Rating Scale (NRS). Secondary outcomes were comparison of Pain Quality Assessment Scale (PQAS), Modified Oswestry Disability Index (ODI) and Wong-Baker Faces Pain Rating Scale- (WBFS), Pain Location Score (PLS); noted at baseline, at completion of 5,10 and 15 sessions and follow up at 1,2, 3 weeks, then monthly for 3 months.

Results

Pain NRS, PQAS, Modified ODI, WBFS were significantly less in the PEMF group ($p < 0.05$) at all time frames. PLS was statistically significant lesser in the PEMF group at all time frames after ten sessions ($p < 0.05$).

Conclusion

15 sessions of 30 minutes per day of PEMF (40 mT) QRS® 101 treatment in three weeks may significantly alleviate CBP compared to oral medications.

Keywords: *Pulsed electromagnetic field; lumbar pain; chronic back pain; PEMF; PEMF QRS® 101; pain management.*

Introduction

Chronic Back Pain (CBP) is a significant healthcare burden that affects millions of people globally with an incidence of 65% of disability globally.[1] CBP can significantly impact an individual's quality of life, leading to decreased work productivity, increased absenteeism, impaired physical and social functioning which can lead to psychological distress, including depression, anxiety, and decreased self-esteem. [2,3]

Treatment of CBP requires a comprehensive approach that includes a combination of physical therapy, medication, and lifestyle modifications.[4] However, despite

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advances in medical treatments, many individuals continue to experience persistent pain and disability, leading to significant healthcare costs and societal burden. [1,4]

Pulsed electromagnetic field (PEMF), a new non-invasive treatment involves the generation of electromagnetic pulses that create a pulsating energy field when applied to the body and produces anti-inflammatory and bone-healing effects by decreasing the production of free radicals and stimulating osteoblasts by creating minute electromagnetic currents in the applied body area which increases calcium inflow yielding dense bones and was previously shown to be effective in CBP of various etiologies. [5-7]

PEMF treatment is available via different types of equipment's, most of which is now either obsolete or is cumbersome to use. [8-17] [Table 1] Available literature has not explored the long term effects of PEMF treatment on chronic back pain. PEMF treatment via QRS® 101 system is available as a full body gel mattress has not been previously investigated for CBP.

Hypothesis of the present study was that PEMF QRS® 101 treatment will significantly decrease Pain Numerical Rating Scale (Pain NRS) compared to oral medical management in CBP.

Primary objective was comparison of Pain NRS between patients of CBP treated with PEMF QRS® 101 to oral pain medications. Secondary objectives were comparison of PQAS, disability and quality of life by Modified Oswestry Disability Index (ODI) and Wong-Baker Faces Pain Rating Scale- (WBFS). Pain Location Score (PLS) was also compared. Follow up was for 3 months.

Materials and Methods

Study Design

The present study is a prospective, randomized, controlled trial. Ethical approval was obtained from the institutional review board at Ethics Sub Committee, All India Institute of Medical Sciences (AIIMS), New Delhi (Ref. No.: IEC-275/0705.2021, RP-12/2021). The study followed the Guidelines of Declaration of Helsinki on the conduct of human research and after informed written consent was scheduled to carry out in the Pain clinic of the Department of Anaesthesiology, Critical Care and Pain Medicine at All India Institute of Medical Sciences, New Delhi, between September 2021 to August 2024. This trial is prospectively registered at Clinical Trials Registry-India (CTRI). (CTRI/2021/06/034194).

Inclusion criteria for the study were chronic back pain patients secondary to any etiology, 18-80 years of age with no prior epidurals or any surgical interventions related their back pain within the past three months prior to the study. Exclusion criteria was patients with serious medical illness or co-morbidities, pregnancy and conditions which might affect the compliance, and/ or the assessment of symptoms or previous participation in a clinical trial within the last 30 days. After informed written consent, participants were randomly divided into the allocated group with computer-generated randomization method. No participant withdrew from the study.

After randomization, patients were recruited to either of the two groups. Group P (n=30): CBP patients given PEMF with oral pain medications and Group M (n=30): CBP patients given sham PEMF with oral pain medications. (Figure 1) Patients were asked to lie down on the QRS® - 101 gel mattress, with the effected level of vertebrae over the middle of the mattress. A total of 15 sessions with each session of 30 minutes duration was given over a three-week period (Mon-Fri) using the maximum field-level setting on the PEMF device (Bmax = 40 microTesla). All sessions were given in the Pain OPD clinic under standard American society of anesthesiologists (ASA) monitoring. In group M, similar protocol was followed but QRS® - 101 system was not activated. Patient and assessment research officer were blinded. All parameters were noted at baseline and thereafter at completion of 5,10 and 15 sessions with follow up at end of 1 week, 2 weeks and 3 weeks of treatment and thereafter every month for 3 months (12 weeks).

Sample Size Calculation

The sample size was calculated based on the mean difference in pain intensity (1.52) and standard deviations reported in the intervention and control groups by Elshiwi et al., in 2019. Keeping the alpha error as 0.05 and the power of the study at 90%, the sample size calculated using the effect size reported in the previous study with 1:1 allocation in the control and intervention groups was n = 28 in each group. The sample size was calculated using G*Power – Ver. 3.1 (Statistical Power Analysis tool; University of Dusseldorf).

Statistical Analysis

All data were tested for normality of distribution using the 'D'Agostino & Pearson test'. The summary statistics of normally distributed outcome variables are represented as Mean ± SD and those not falling into a normal distribution are represented as Median (25^{th} percentile – 75^{th} percentile). Baseline continuous and categorical variables were compared between the two groups respectively using the unpaired t test/Mann-Whitney test and Chi-

squared/Fisher's exact test as appropriate. Two-way ANOVA with mixed-model effects was used to analyze the effects of intervention on all outcome variables across time points of assessment in the intervention and control groups also evaluating any possible interactions between the intervention and time of assessment. 'Šídák's multiple comparisons test', was used to compare the outcome variables between the intervention and control groups across the time points of assessment. All statistical analyses were done using GraphPad Prism (Version 10.1.1; GraphPad Software, Boston).

Results

Both groups were comparable in demographics, duration of illness, site of Pain (Table 2).

In intergroup analysis, baseline Pain NRS was comparable between the groups (p> 0.99) (Table 3) The intervention group showed a decline in NRS in response to the PEMF (Group P) while the group on medical drugs (Group M) didn't show any significant change. The overall trend observed in the data of NRS was statistically significant for the effect of time (p <0.0001), intervention (p <0.0001) and the interaction between intervention and the time point of assessment (p <0.0001). On comparing NRS scores between the two groups across the time points of assessment, it was noticed that the Mean NRS scores were significantly lower in the intervention group after 5 sessions (p <0.006), 10 sessions (p <0.0001) and 15 sessions (p <0.0001) of PEMF treatment and at follow-ups 1month (p <0.0001), 2 months (p <0.0001)and 3 months (p <0.0001). (Table 3, Figure 2)

Rescue oral pain medications were completely stopped or were reduced in dosage in 22 patients in Group P while all 30 patients continued ongoing oral pain medications with same or increased dosage in Group M.

Baseline PQAS between both groups was comparable (p>0.99). (Table 4) Group P showed a decline in PQAS in response to the PEMF treatment while Group M didn't show any significant change. The overall trend observed in the data of PQAS was statistically significant for the effect of time (p <0.0001), intervention (p <0.0001) and the interaction between intervention and the time point of assessment (p <0.0001). On comparing PQAS scores between the two groups across the time points of assessment, it was noticed that the Median PQAS scores were significantly lower in the intervention group after 5 sessions (P<0.027), 10 sessions (p <0.0001) and 15 sessions (p <0.0001) of PEMF and at follow-ups 1, 2 and 3 months (p <0.0001, p <0.0001, p <0.0001) respectively. (Table 4, Figure 3)

Baseline Modified ODI was comparable between both groups (p > 0.98). (Table 5) The intervention group showed a decline in ODI scores in response to the PEMF (Group P) while the group on medical drugs (Group M) didn't show any significant change. The overall trend observed in the data of ODI was statistically significant for the effect of time (p <0.0001), intervention (p <0.0001) and the interaction between intervention and the time point of assessment (p <0.0001). (Table 5, Figure 4) On comparing NRS scores between the two groups across the time points of assessment, it was noticed that the Mean NRS scores were significantly lower in the intervention group after 5 sessions (p <0.004), 10 sessions (p <0.0001) and 15 sessions (p <0.0001) of PEMF treatment and at follow-ups 1month (p <0.0001), 2 months (p <0.0001)and 3 months (p <0.0001). (Table 5, Figure 4)

Baseline WFBS between both groups was comparable (p>0.87). (Table 6) Group P showed a decline in WBFS in response to the PEMF treatment while Group M didn't show any significant change. The overall trend observed in the data of WBFS was statistically significant for the effect of time (p <0.0001), intervention (p <0.0001) and the interaction between intervention and the time point of assessment (p <0.0001). (Table 6, Figure 5) On comparing WBFS scores between the two groups across the time points of assessment, it was noticed that the Median WBFS scores were significantly lower in the intervention group after 5 sessions (P<0.001), 10 sessions (p <0.0001) and 15 sessions (p <0.0001) of PEMF and at follow-ups 1, 2 and 3 months (p <0.0001, p <0.0001, p <0.0001) respectively. (Table 6, Figure 5)

Total locations of Pain were graded as PLS. Each site of Pain was graded as a single point with one point each allocated to Pain location at lower back, Pain location at upper back, radiating Pain to left lower limb /radiating Pain to right lower limb, upper back (cervical), left shoulder and right shoulder. Considering the inclusion of 7 anatomical locations, a maximum score of 7 was awarded for PLS. Baseline PLS was comparable between the groups (p> 0.99) (Table 7) The intervention group (Group P) did not show an immediate decline in PLS in response to PEMF when compared to Group M. The overall trend observed in the data of PLS was statistically significant for the effect of time (p <0.0001), intervention (p =0.0149) and the interaction between intervention and the time point of assessment (p <0.0001). On comparing PLS scores between the two groups across the time points of assessment, it was noticed that the Mean PLS scores were not statistically significantly between the groups after 5 sessions (p >0.99) and 10 sessions (p >0.25) (Table 7, Figure 6). However, a

statistically significant difference was observed after 15 sessions (p =0.002) of PEMF treatment and was sustained at follow-ups 1month (p =0.0008), 2 months (p =0.001) and 3 months (p =0.002). (Table 7, Figure 6)

Table 1. Analysis of comparative studies of PEMF to medical management/therapeutic exercises

Author/Year	PEMF Device	Etiology	No. of pts/ Power of Study	Durtn of Rx/FU	Session details (Time/sessions x wk or d/total duratn)	PEMF details	Parameters studied	Results
Lee et al./ 2006	CR- 3000 System	CLBP	36/ 80%	3 wks/ 7 wks	15 min/3/3 wks	1-50 hz 1.3-2.1 tesla	PAIN NRS/ Revised ODI	PEMF better
Harden et al/ 2007	TEMF	CLBP	40/ Nil	2 wks/ 6 wks	30 min 6/2 wks	15 millitesla	VAS; MPQ-SF; BDI; STAI; QPDI; Physical performance tests	Comparable
Omar et al./ 2012	Not mentioned	DLRP	40/ Nil	3 wks/Nil	20 min/ 7/3 wks	N/A	VAS/ ODI/ SSEP	PEMF better
Oke et al./ 2013	Empulse	Back Pain	16/ Nil	5–9 days/ N.R.	120 min/d (5-9 days)		PAIN NRS; MFAS	PEMF better
Park et al./ 2014	NUGA-MRT-II	Lumbar myalgia	38/ 80%	2 wks/ 3 wks	10 min/3/ 2 wks	N/A	VASB/ VASP/ ODI/ SF-36/ EQ-5D/ BDI/ RMDQ	PEMF better
Elshiwi et al/ 2015	TEMF Automatic PMT Quattro Pro	Non-specific LBP	50/ 85%	4 wks/Nil	20 min/3/4wks	50 hz 20 G	VAS/ODI	PEMF better
Kramer at al/ 2015	Recovery Rx	Acute LBA	40/ 80% Pilot study	1wk/ 4 wks	Continuous for 7 days	0.003 milli Tesla	ODI/ PAIN NRS/ Patient Specific Functional Scale/ Level of Function	Comparable
Abdelhalim et al/ 2019	CR- 3000 system	Non specific LBP	42/ 80% Pilot study	1 mth/Nil	NM/3/4 wks/	5-10 hz	NRS/M-OSW/ Modified Schober test/ HRQOL	PEMF better
Alzayed et al/ 2019	BEMER	CLBP	42/ 90%	13 wks	20 min/ 3-5/3 mths	35 microTesla	NRS/ Roland Morris disability questionnaire	Control
Kyle et al/ 2021	BEMER	LBP	40/ N/A	3 wks	8min-16min-20min/5/3wks	N/A	VAS/ODI/ SF12 Heath survey	Comparable

Sr. No.=Serial number; No. of pts=number of patients; Duran of Rx/FU= duration of treatment/follow up; wk or d/total duratn= week or day/ total duration; TEMF= Therapeutic Electromagnetic Fields; BEMER= Bio Electro Magnetic Energy Regulation; CLBP= chronic lower back Pain; DLRP= Discogenic Lumbar Radiculopathy; LBA= Lower Back Ache; LBP= Lower Back Pain; wks= weeks; N/A = Not Applicable; N.R.= Not Recorded; mth= Month; d = Day; PAIN NRS = Numeric Pain Rating Scale; ODI = Oswestry Disability Index; VAS – visual analogue scale; VASB – visual analogue scale for discomfort for low back Pain; VASP – visual analogue scale for Pain intensity; SF-36 – Short-Form 36; EQ-5D – EuroQol-5 Dimension (Korean adapted); BDI – Beck's Depression Inventory (Korean

adapted); RMDQ – Roland-Morris Disability Questionnaire (Korean adapted); MPQ-SF – McGill Pain Questionnaire – Short Form; BDI – Beck Depression Inventory; STAI – State-Trait Anxiety Inventory; QPDI – Quebec Pain and Disability Index; SSEP= Somato Sensory Evoked Potential; MFAS= Modified Functional Activity Scale; Health–Related Quality of Life (HRQOL), Modified Oswestry LBP Disability Score (M-OSW).

Table 2. Demographics and baseline disease parameters between both groups

Demographic Data	Group P (n=30)	Group M (n=30)	p-value
Age	41+-13.55	38.86+-12.53	0.52
Males	8	11	0.29
Females	22	19	0.29
Duration of illness in years	4.23+-3.30	5.2+-4.52	0.48
Lower back Pain	30	29	0.5
Upper back Pain	9	8	0.5
Left leg	20	17	0.298
Right leg	17	17	0.603
Cervical Pain	1	5	0.097
Left shoulder Pain	5	4	0.5
Right shoulder Pain	4	3	0.5

PEMF= Pulsed Electromagnetic Frequency; Pain NRS =numerical Pain rating scale; Group P = PEMF group; Group M = Medical drugs; *p < 0.05, statistically significant.

Table 3. Comparison of Pain NRS between both groups at different time intervals: Intergroup Analysis

	Group P (n=30)	Group M (n=30)	p-value
Time of assessment	**Mean +- SD**	**Mean +- SD**	
Baseline Pain NRS	7.15+-0.92	7.1+-0.88	>0.999
After 5 sessions	5.85+-1.47	7.1+-0.88	0.006**
After 10 sessions	4.85+-1.63	7.07+-1.10	<0.0001****
After 15 sessions	3.81+-2.12	7.28+-1.11	<0.0001****
F/U after 1 month	3.68+-2.02	7.55+-0.97	<0.0001****
F/U after 2 months	3.66+-2.01	7.55+-0.90	<0.0001****
F/U after 3 months	3.91+-2.02	7.55+-0.89	<0.0001****

PEMF= Pulsed Electromagnetic Frequency; Pain NRS = Pain numerical rating scale; Group P = PEMF group; Group M = Medical drugs; F/U = Follow up, *p < 0.05, statistically significant

Table 4. Comparison of PQAS between both groups at different time intervals: Intergroup Analysis

	Group P (n=30)	Group M (n=30)	p-value
Time of assessment	**Median (min-max)**	**Median (min-max)**	
Baseline PQAS	52.5 (40-73)	55 (44.25-64.25)	>0.999
After 5 sessions	41.5 (33.25-53.25)	55 (44.25-63.5)	0.027*
After 10 sessions	32.25 (26-42)	55 (44.25-63.5)	<0.0001****
After 15 sessions	24.5 (19-36.25)	55 (45 -65.5)	<0.0001****
F/U after 1 month	23.5 (16-37)	56 (45 -66)	<0.0001****
F/U after 2 months	23.5 (16-35.5)	56 (45.5 -66)	<0.0001****
F/U after 3 months	24 (17-39.25)	56 (45.5 -65.75)	<0.0001****

PEMF= Pulsed Electromagnetic Frequency; PQAS =Pain Quality Assessment Scale; Group P = PEMF group; Group M = Medical drugs; F/U = Follow up, *p < 0.05, statistically significant.

Table 5. Comparison of ODI between both groups at different time intervals: Intergroup Analysis

Time of assessment	Group P (n=30) Mean +- SD	Group M (n=30) Mean +- SD	p-value
Baseline ODI	36.3+-6.20	37.6+-5.37	0.983
After 5 sessions	31.7 +-7.79	37.6+-5.37	0.004**
After 10 sessions	26.27+-7.25	37.2+-6.26	<0.0001****
After 15 sessions	23.9+-7.70	37.8+-5.96	<0.0001****
F/U after 1 month	23.47+-7.73	38.33+-5.49	<0.0001****
F/U after 2 months	23.7+-7.68	38.33+-5.49	<0.0001****
F/U after 3 months	23.93+-7.4	38.4+-5.55	<0.0001****

PEMF= Pulsed Electromagnetic Frequency; ODI =Modified Oswestry Low Back Pain Disability Index; Group P = PEMF group; Group M = Medical drugs; F/U = Follow up., *p < 0.05, statistically significant.

Table 6. Comparison of WBFS between both groups at different time intervals: Intergroup Analysis

Time of assessment	Group P (n=30) Median (min-max)	Group M (n=30) Median (min-max)	p-value
Baseline WBFS	4(3.75-4)	4(4-4)	0.874
After 5 sessions	4(3-4)	4(4-4)	0.001**
After 10 sessions	3(2-3)	4(4-4)	<0.0001****
After 15 sessions	2.5(2-3)	4(4-4)	<0.0001****
F/U after 1 month	2.5(2-3)	4(4-4)	<0.0001****
F/U after 2 months	2.5(2-3)	4(4-4)	<0.0001****
F/U after 3 months	3(2-3)	4(4-4)	<0.0001****

Group P=PEMF= Pulsed Electromagnetic Frequency; WBFS =Wong Baker Faces Scale; Group P = PEMF group; Group M = Medical drugs; F/U = Follow up., *p < 0.05, statistically significant.

Table 7. Comparison of PLS between both groups at different time intervals: Intergroup Analysis

Time of assessment	Group P (n=30) Mean +- SD	Group M (n=30) Mean +- SD	p-value
Baseline Pain Location Score	2.9+-1.39	2.73+-1.38	0.998
After 5 sessions	2.7+-1.31	2.73+-1.38	>0.999
After 10 sessions	2.06+- 1.11	2.73+-1.38	0.250
After 15 sessions	1.6+- 0.81	2.76+-1.47	<0.002**
F/U after 1 month	1.5+- 0.77	2.76+-1.47	<0.0008***
F/U after 2 months	1.6+- 0.85	2.8+-1.44	<0.0017**
F/U after 3 months	1.63+- 0.88	2.8+-1.44	<0.0025**

PEMF= Pulsed Electromagnetic Frequency; PLS= Pain Location Score; Group P = PEMF group; Group M = Medical drugs; F/U = Follow up., *p < 0.05, statistically significant, ** P<0.00

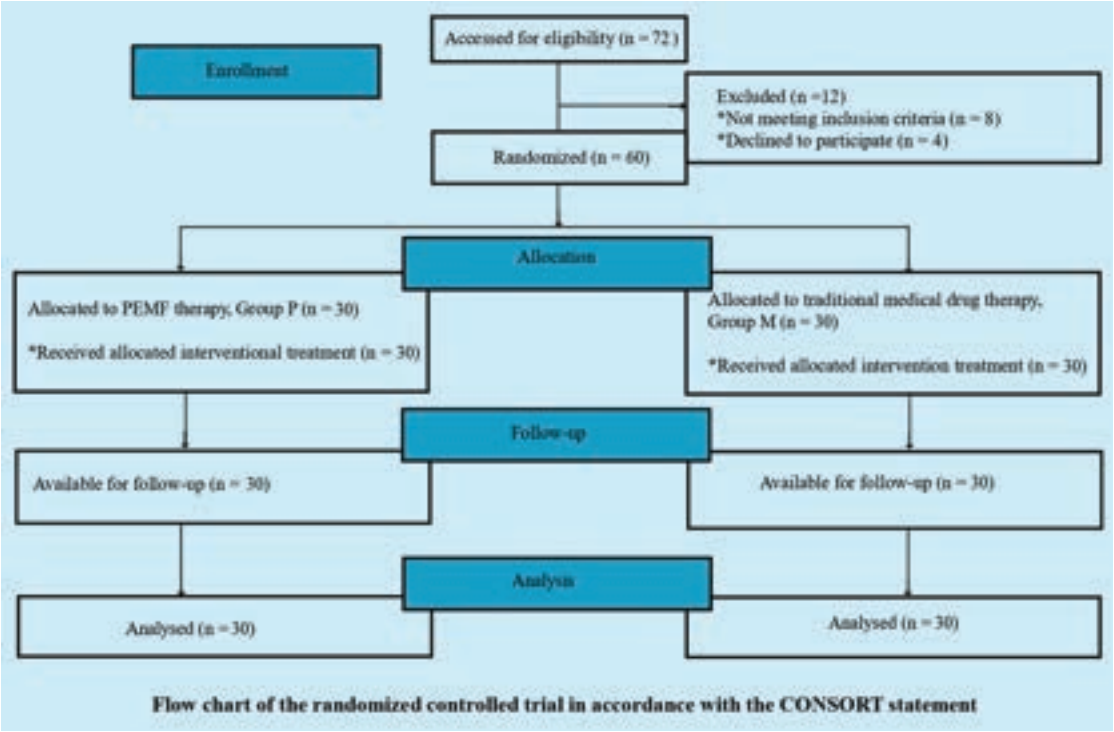

Figure 1: CONSORT statement

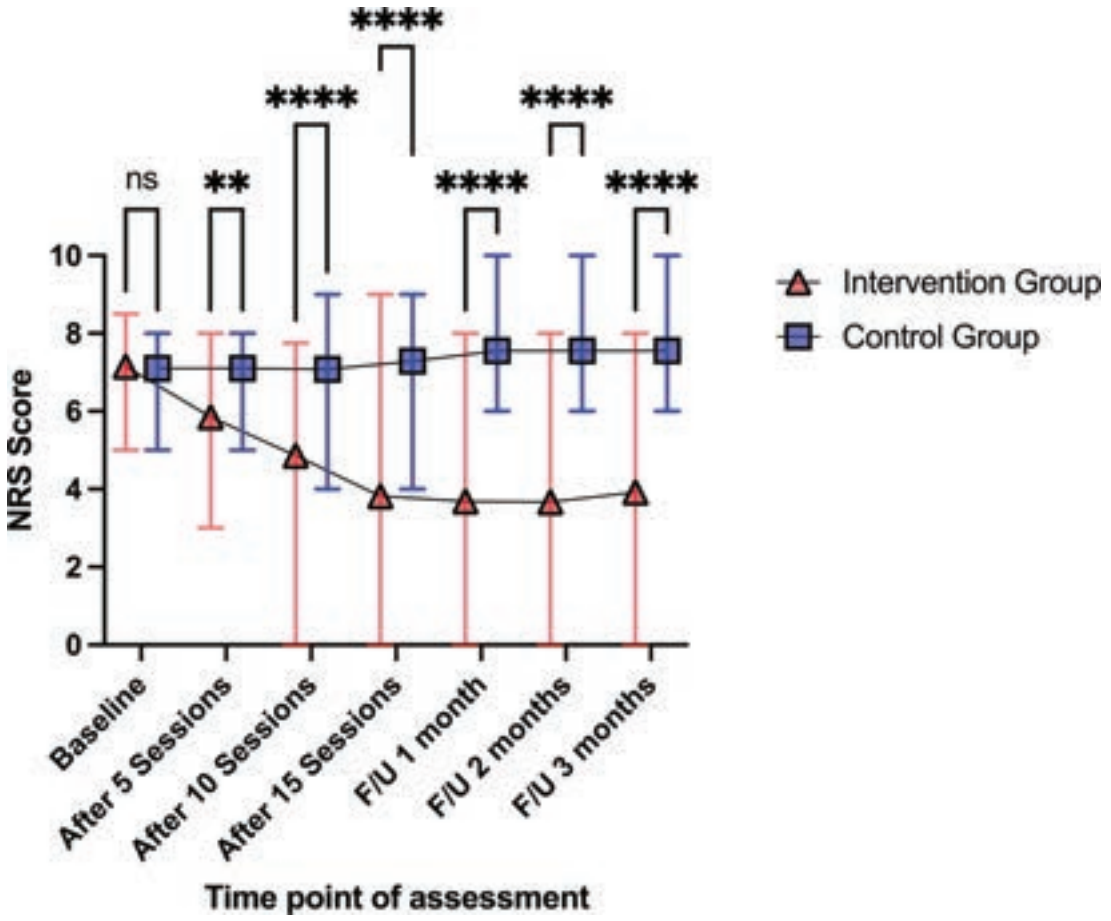

Figure 2: Comparison of NRS at different time intervals between both groups

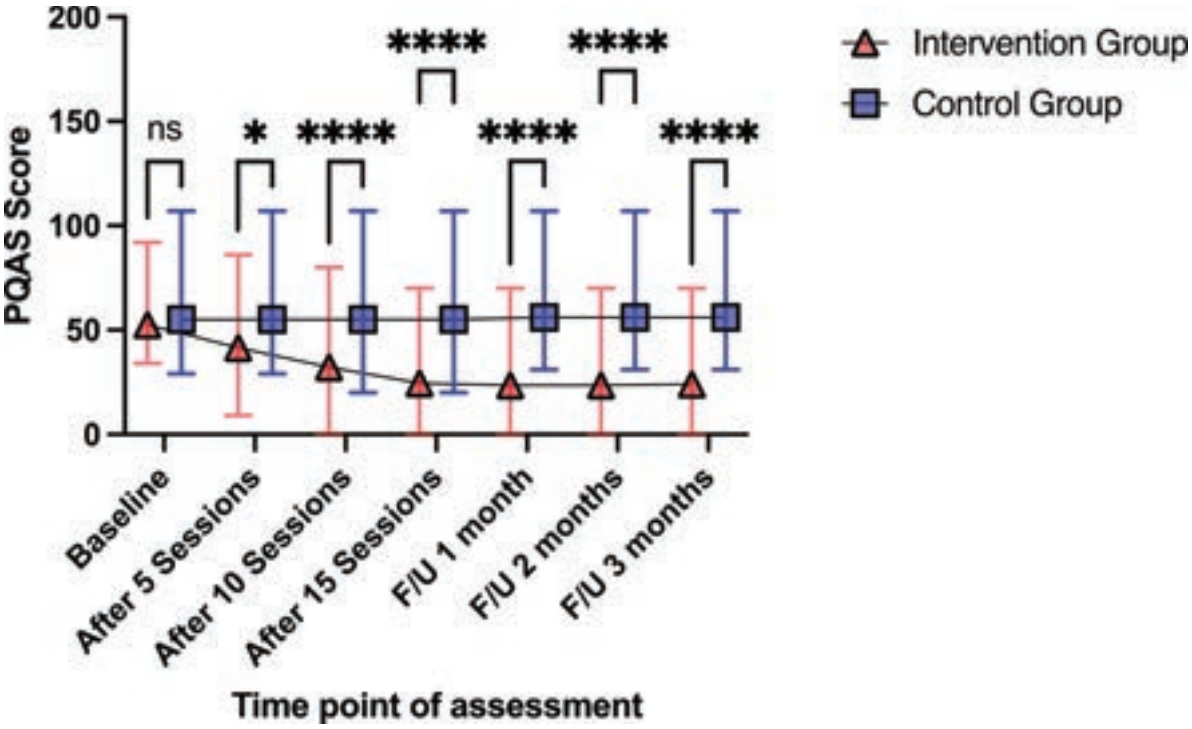

Figure 3: Comparison of PQAS score at different time intervals between both groups

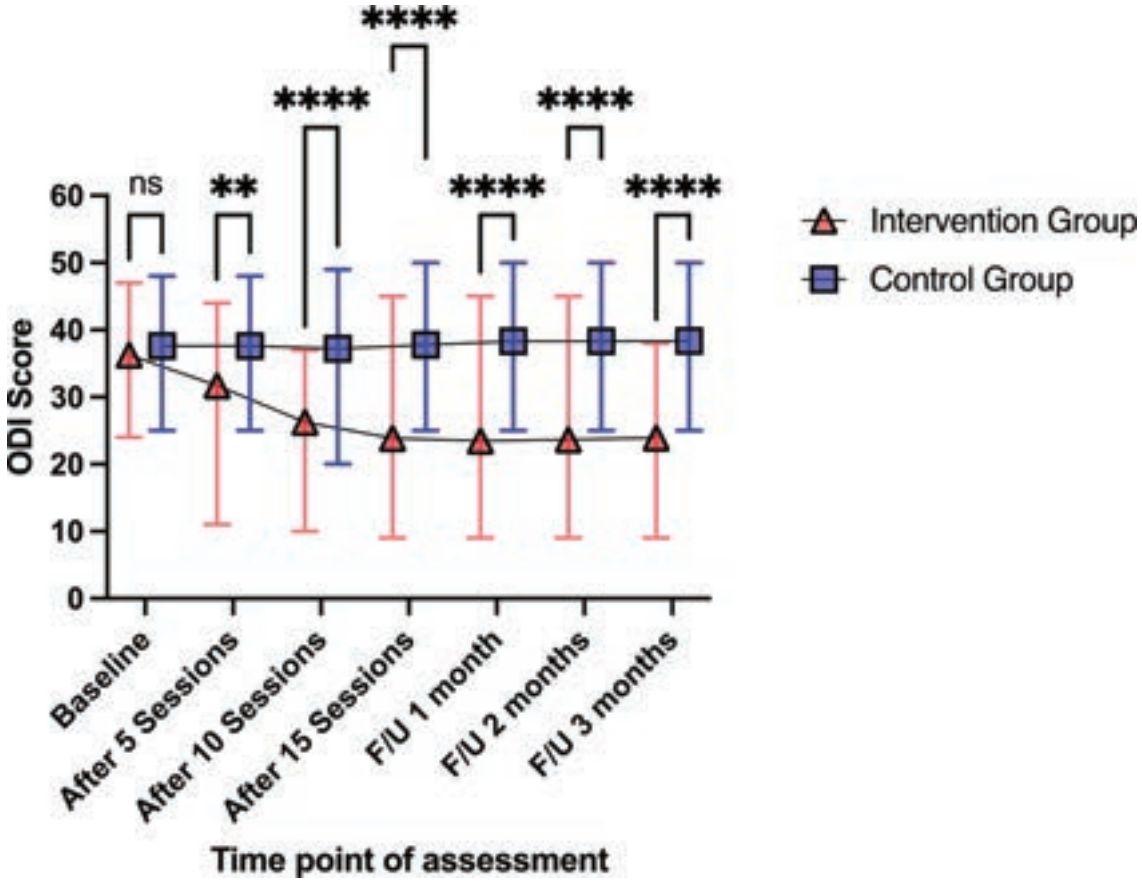

Figure 4: Comparison of ODI at different time intervals between both groups

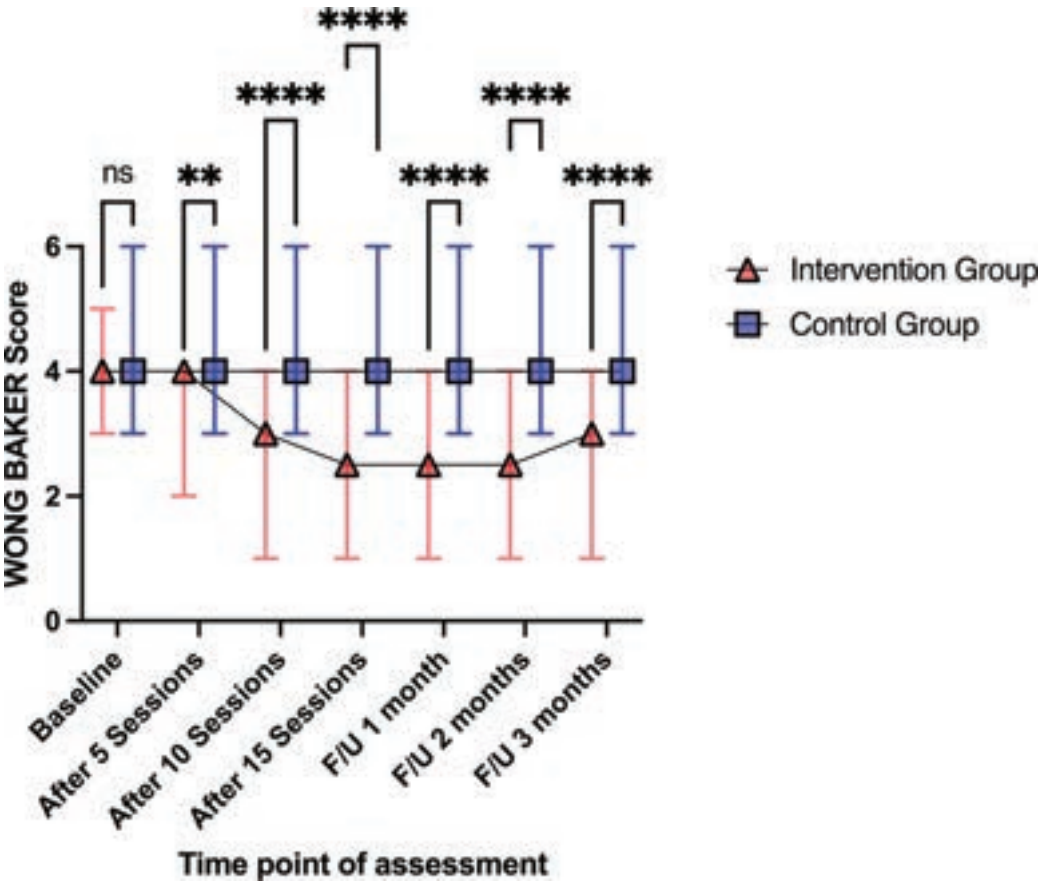

Figure 5: Comparison of WONG BAKER score at different time intervals between both groups

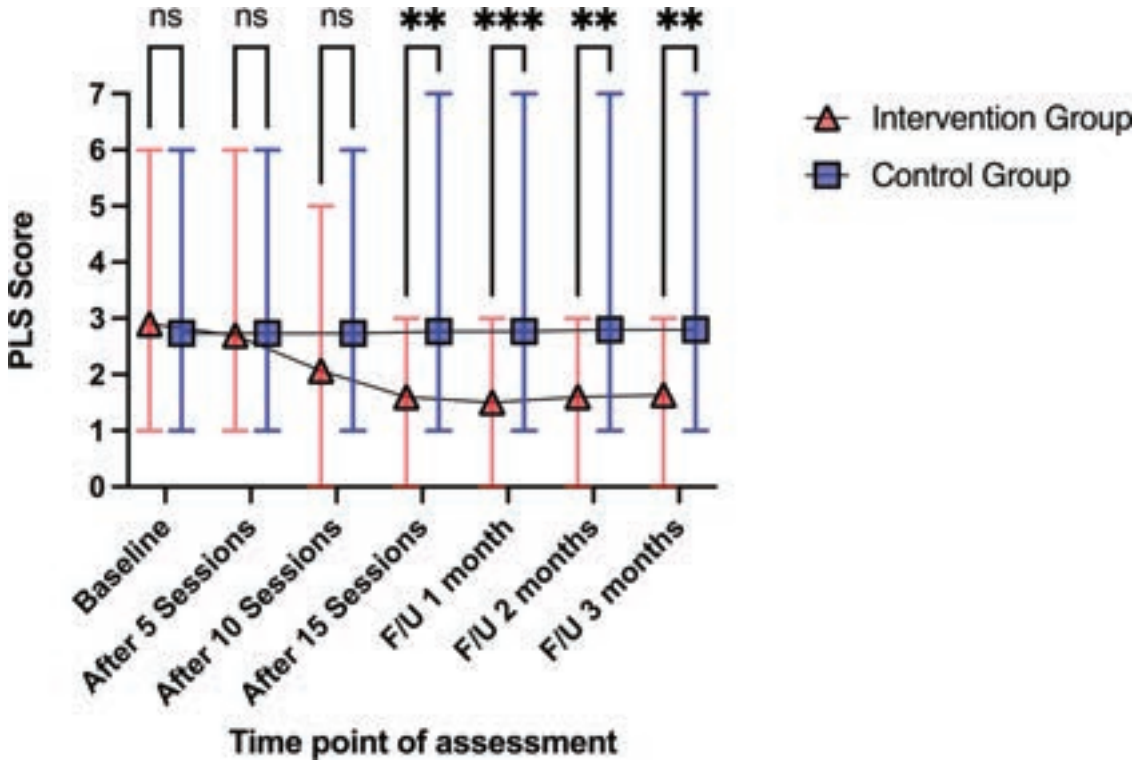

Figure 6: Comparison of PLS score at different time intervals between both groups

Discussion

Present study reveals that PEMF QRS® 101 treatment leads to significant improvement in quantitative index (Pain NRS) and qualitative index (PQAS, ODI, WBFS) of CBP after 5 sessions of intervention while PLS scores showed improvement only after 15 sessions of treatment. However, the improvement was well sustained for all the parameters until 3 months of follow up.

In the current study, in the medical treatment group, it is intriguing to observe that there was minimal deviation in the parameters of Pain NRS, PQAS, MODI, WBFS and PLS at baseline and at all follow ups .This finding suggests favourable effects of PEMF QRS® 101 and ceiling effect of oral pain medications given over prolonged period of time in CBP patients.

It is also interesting to note that PEMF intervention has an additive effect with time which is reflected by the trends in the graph (Figure 2) and has a clinically and statistically significant mean difference of >3.5 in NRS values from baseline to after completion of 15 sessions. The mean differences in values of other parameters of disability and pain quality are also highly clinically significant. These effects are sustained over a prolonged period of time as noted in follow ups done up to a long follow-up of 3 months in the present study. Another interesting finding from the study is that PLS showed greater latency in response. This could be due to the cumulative effect of PEMF resulting in the complete remission of pain from a particular site/region.

CBP is a common and morbid disease. The lifetime prevalence of low back pain is reported to be higher in older (80-84 yrs) and female populations. The global disability adjusted life years (DALYs) of LBP increased by 47% from 1990-2019. [1,2] International guidelines recommend a multidisciplinary approach at an early stage in the event of CBP owing to the various aspects of Pain genesis.[4]

There are several approaches to manage CBP, depending on the underlying etiology and individual patient conditions. Some of the existing proven treatments include physical therapy like exercises and stretches, medications like non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and opioids, injections like epidural steroid injections and nerve blocks, surgery and complementary and alternative therapies like acupuncture, chiropractic adjustments, massage etc. [4]

PEMF is a non-invasive treatment that uses electromagnetic fields to stimulate the body's tissues and promote healing. This field can penetrate deep into tissues and cells, affecting various physiological processes. The mechanism of action of PEMF is not yet fully understood, but several hypotheses have been proposed. One theory suggests that PEMF therapy works by modulating the activity of cells, particularly in the mitochondria which enhances the production of adenosine triphosphate (ATP) to improve cellular metabolism and enhanced tissue repair and regeneration. [18] Another proposed mechanism is the effect of PEMF on calcium ions. Calcium plays a vital role in cellular signalling and is involved in numerous cellular processes. PEMF therapy is also suggested to influence calcium ion channels, leading to changes in intracellular calcium concentrations. These changes can affect cell signalling pathways and promote tissue healing. A critical role of Sirtuin 1 (SIRT1)-dependent autophagy signalling pathway in extra cellular matrix (ECM) protection and thereby in the establishing the therapeutic effect of PEMF on intervertebral disc (IVD) degeneration. [19] Furthermore, PEMF has been shown to have anti-inflammatory effects by reducing the production of pro-inflammatory cytokines, such as tumour necrosis factor-alpha (TNF-α) and interleukin-1 beta (IL-1β).[20] PEMF has been shown to enhance blood circulation, including microcirculation, which can provide oxygen, nutrients, and other essential factors for tissue repair and thus alleviating CBP. [18-20]

PEMF is available in many forms like localized, full body, transcranial, Magnetic Resonance Therapy (MRT). In recent years, PEMF therapy, in different forms of delivery and equipment have been used for CBP. [18] [8-22] Effect of PEMF on CBP has previously been studied. (Table 1) On literature search in pubmed, 10 RCTs describe comparison different types of PEMF to medical management in CBP. The published data is not similar in methodology to the present study in duration of treatment, type of PEMF equipment, PEMF parameters (frequency, pulse rate and width, magnetic flux density), number of sessions and time of sessions with no or short follow up. (Table 1) Most of the equipment is now obsolete or is cumbersome. Moreover, long term effect of treatment beyond 7 weeks is not investigated previously. [15-26] A recent study concluded full body PEMF comparable to medical management after 13 weeks of treatment. This is in contrast to the present study which showed significant improvement in most CBP parameters after 5 sessions. This could be because of duration of treatment in the present study to be 30 minutes compared to 20 minutes in the above-mentioned study. Moreover, the equipment used in both these studies is different which might have affected the results.[17]

There is no previous published data of QRS ® 101 on CBP. In the present study, PEMF QRS® system was found effective in both quantitative and qualitative parameters of CBP when compared to oral pain medication of CBP. This also has translational potential as QRS ® 101 system is cheaper than BEMER in India (another full body gel mattress form of PEMF), easy to operate, portable and user friendly for both patient and operator. As it doesn't require major expertise, with minimal training treatment may be offered in centers and hospitals short on medical specialists where the treatment may be executed even by nurses. As it is portable, it can be easily carried from one part of the hospital to another and thus immobile patients suffering from CBP at various beds or wards may benefit with a single equipment. Patients of CBP may carry the light gel mattress, if they afford to purchase their personal QRS® mattress, even while travelling. It also has the potential to decrease the dosages of oral pain medications and its side effects and may prevent recurrences of CBP and also avoid or delay invasive methods of treatment.

Limitation of the present study is that physiotherapy and physical exercises were not standardized in both groups though these were practiced by the patients. The PLS score which was used in the present study is a newly devised score and needs further validation in future studies.

To conclude, PEMF QRS® 101 system with oral pain medications seems to be superior to oral pain medications alone in CBP after at least 5 sessions of 30 minutes each given over three weeks and the effect sustains for at least three months. We propose further trials to assess effect of the modality for more than three months.

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Author Contributions Study conception and design—JP. Data acquisition- JP, NS, BG, RP. Data analysis and final interpretation —NS, JP, DC. Study administration—NS, JP. Manuscript Writing—NS, JP, DC. All authors read and approved the final manuscript.

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Competing interests: None declared

Ethics declaration: The study followed the Guidelines of Declaration of Helsinki on the conduct of human research and after informed written consent is scheduled to carry out in the Pain clinic of the Department of Anaesthesiology, Critical Care and Pain Medicine at All India Institute of Medical Sciences, New Delhi, between September 2021 to August 2024.

Patient consent Informed written patient onset form is taken from every patient.

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