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COMPARATIVE STUDY TO ASSESS THE ROLE OF CONSERVATIVE MEASURES AND STELLATE GANGLION BLOCK IN CASE CRPS – I OF UPPER EXTREMITY.

Medical Science

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ABSTRACT

Objective – To compare the results of treatment by conservative measures and stellate ganglion block in complex regional pain syndrome I of upper extremity.

Material & methods – Institutional ethical committee permission was taken before the start of the study. Patients of CRPS – I of upper extremity were included in the study after getting their informed consent. Patients were randomly divided into two groups. Both the groups received conservative measures, whereas group I received gabapentin, group II received stellate ganglion blocks for three consecutive weeks.

Discussion & Conclusion – CRPS I of upper extremity mostly affects females who do manual job. It requires a multidisciplinary approach to effectively treat this syndrome. Both conservative management including oral gabapentin and invasive treatment i.e. stellate ganglion block are beneficial in treatment of this disease. Stellate ganglion block gives a better result than oral gabapentin in treatment of CRPS I of upper extremity.

KEYWORDS

Complex regional pain syndrome I, Brief Michigan hand questionnaire, VAS.

INTRODUCTION

Complex regional pain syndrome (CRPS) type I, formerly known as reflex sympathetic dystrophy (RDS) and CRPS type II, formerly known as causalgia are debilitating pain syndromes that have been recognized for more than a century. Despite the long history of these disorders, the natural course and pathophysiology of CRPS types I and II are elusive, and hence, their therapies remain controversial. It is an inflammatory and neuropathic pain disorder principally characterized by involvement of the autonomic nervous system. Severe cases of CRPS may lead to marked limitation of function and even amputation of the affected limb. A five year follow up study of CRPS patients of upper extremity in the Netherlands indicates that 26% of patients had to change their job, and 30% of patients had to stop work for more than a year[(1)].

Epidemiological data regarding CRPS in general population are limited. Sandroni reported an incidence of 5.46 new cases of CRPS I per 100,000 annually[(2)]. A large study using current international association for the study of pain (IASP) diagnostic criteria reported an annual incidence as high as 25.2 new cases per 100,000 annually[(3)].

CRPS is usually linked to a history of trauma, immobilization or a procedure such as venipuncture or surgery. Fracture and sprains appear to be the most common events triggering CRPS. There is no correlation between the severity of the initial trauma and the ensuing painful syndrome. CRPS appear to be more common in upper extremities, is more common in females, and is most likely to occur in the 50-70 year age range[(2,3)].

The international association for the study of pain (IASP) proposed dividing CRPS into types I and II with type II being characterized also by injury to a peripheral nerve. CRPS remains one of the most enigmatic and difficult to treat of all the pain condition. Although clinical characterizations started to appear in the literature in the late 1800s[(4)], a definitive pathophysiology remains to be determined. This has resulted in the relative lack of clinical progress to date. CRPS is a very challenging condition to successfully manage. The patient presentation often changes over time, and the natural history is variable and poorly understood. Evidence for efficacy of various treatment modalities is scarce and has developed slowly. The only treatment methodology that can have a reasonable chance of successfully bridging the varied presentation and mechanisms of disease and the profound gaps in treatment evidence is a systematic and orderly interdisciplinary approach.

This study is to compare the results of treatment by conservative and invasive measure (stellate ganglion block) in patients of CRPS type I of the upper extremities.

MATERIAL AND METHODS

The study was conducted in the department of Physical Medicine and Rehabilitation in Sambhunath pandit (SNP) hospital Kolkata during the period From July 2012 to December 2013. The institutional ethical committee clearance was obtained. This was Prospective (cohort) randomized analytical study. Randomization done after recruitment of study by computer generated random number list for allotment. The cases were selected from patients irrespective of their gender, age and occupation. Patients with clinical feature of CRPS I, attending the OPD/IPD of Physical Medicine and Rehabilitation (PMR) department in our hospital were selected. Total 60 patients were selected according to the inclusion and exclusion criteria, but 54 patients completed the study. Total four visits (one initial then three follow up visits at 6, 12, 18 weeks) of patients considered.

Inclusion criteria

1) Patients of complex regional pain syndrome - I of upper limbs.
2) Patients of both sexes of age group 18 years and above.
3) Patients who had given written consent to enter into the treatment procedure.
4) Adequate communication ability to cope with the verbal rating score for pain and function.

Exclusion criteria

1) Unable to give consent.
2) CRPS II.
3) Patients with Diabetes.
4) Patients with severe cardiological or neurological problems.
5) History of malignancy.
6) Peripheral vascular disease.
7) Peripheral neuropathy.
8) Anticoagulant therapy.
9) Bleeding diathesis and Active infection of the injection site

Study tools
1) Brief Michigan hand outcome questionnaire (B MHQ)
2) Visual analogue scale (VAS)

Assessment
This study was conducted over a period of one and a half years. Ethical committee clearance was taken after the study protocol and patients examination preform has been prepared. Patients were assessed on first visit (V1) and after initial assessment the patients were recruited into two groups (group – I/II) randomly and allotted different for each group. All patients were recruited and assessed by a single doctor and also all the intervention were performed by single doctor according to standardized protocol. Assessment of all patients was repeated on second , third and fourth visits (V2, V3, V4) by the same doctor. Some baseline investigation performed (X-Ray of involved limb, Routine blood examination, Blood Sugar – F/PP, Bleeding and clotting time) to all patients.

Treatment
Group I :
1) Gabapentine (upto 900 mg/day)
2) Paraffin bath (for 15 days after initial visit)
3) Use of compressive stockings.
4) Massage.
5) Limb elevation.
6) Rang of motion exercises
7) NSAIDS (Ibuprofen) on SOS basis

Group II:
1) Stellate Ganglion block.
2) Paraffin bath (for 15 days)
3) Use of compressive stockings.
4) Massage.
5) Limb elevation.
6) Range of motion exercises.
7) NSAIDS (Ibuprofen) SOS

Stellate ganglion block :
Patients in group II were given stellate ganglion block under fluoroscopic guidance with a mixture of 1ml of triamcinolone (40mg) and 5 ml of 0.5% lignocaine. Each injection of local anesthetic was preceded by the administration of 2ml of iohexol 300 to ascertain proper needle placement as well as adequate vertical and caudal spread of the injection. Paratracheal approach was followed for stellate ganglion block and full aseptic technique was followed. The block was given on a weekly basis for three consecutive weeks after the first visits.

RESULTS AND ANALYSIS
Out of 60 patients enrolled, only 54 patients completed this study and they were included in statistical analysis. The available data were analyzed using software statistical package for social sciences version 20 (SPSS 20, SPSS Inc, Chicago II, USA).

Continuous variables like age, VAS, brief MHQ score are expressed as mean ± standard deviation(SD) and compared across the two group using unpaired t- test.

Over time comparisons in Brief MHQ score and VAS for two groups separately have been done using paired t test. Categorical variables like sex and occupation are expressed as number of patients and percentage of patients and compared across the two groups using Pearson's chi square test for independence of attributes. A level of 5% has been taken i.e. if any P value is less than 0.05, it has been considered significant.

Age Distribution
In our study the youngest patient was 38 yrs old and oldest was aged 66 yrs. Maximum patients were in the age group of 50-59 years. Least number of patients were found in the age group 30-39. Mean of patients in group I was 52.35 years with standard deviation being 6.25. Mean age of patients in group II was 51.61 with a standard deviation of 8.27. Unpaired t test showed that there was no significant difference between the mean of age of patients in two groups (P = 0.714) showing that the two group were age matched.

Table 1 : age distribution in two groups In years

	Group I	Group II		
	Mean ± std. deviation	Mean ± std. deviation	P value	significance
Age	52.35 ± 6.25	51.61 ± 8.27	0.714	Not significant

Gender distribution:
Our study had 39 female and 15 male patients showing the predominance of complex regional pain syndrome I in females. The ratio of female to male in our study is 2.6 : 1. The percentage of female patients in group I is 73.1% and in group II is 71.4%. the percentage of male patients in group I and group II is 26.9 and 28.6% respectively. Overall females formed 72.2% subjects of the study and male were only 27.8% of all enrolled subjects.

On comparing the number of male and female patients in the two groups by Chi square test the P value was 0.893 (p>0.05), there was significant difference in the gender distribution of patients in the two groups. So the groups were matched.

Table -2 : Distribution of patients in study groups according to gender.

	Group I	Group II	Total	P Value	significance
Female	19	20	39	0.893	Not significant
	73.1%	71.4%	72.2%		
Male	7	8	15		
	26.9%	28.6%	27.8%		
Total	26	28	54		
	100%	100%	100%		

Occupation :
Table – 3: Percentage of people employed in different professions.

		Group		Total	P Value	Significance
		Group I	Group II			
Occupation	COOK	1	2	3	0.792	Not Significant
		3.8%	7.1%	5.6%		
	CPT	1	0	1		
		3.8%	0.0%	1.9%		
	ELC	0	1	1		
		0.0%	3.6%	1.9%		
	FRM	1	2	3		
		3.8%	7.1%	5.6%		
	HM	10	7	17		
		38.5%	25.0%	31.5%		
	HWF	2	5	7		
		7.7%	17.9%	13.0%		
	MSN	1	0	1		
		3.8%	0.0%	1.9%		
	NUR	1	2	3		
		3.8%	7.1%	5.6%		
	OFC	2	2	4		
		7.7%	7.1%	7.4%		
	PLC	1	1	2		
		3.8%	3.6%	3.7%		
	PTR	1	0	1		
		3.8%	0.0%	1.9%		
	RET	1	1	2		
		3.8%	3.6%	3.7%		
	SG	1	2	3		
		3.8%	7.1%	5.6%		
	SW	2	1	3		
		7.7%	3.6%	5.6%		
	TLR	0	2	2		
		0.0%	7.1%	3.7%		
	WTR	1	0	1		
		3.8%	0.0%	1.9%		
Total	26	28	54			
	100%	100%	100%			

HM : House maid, HWF : House wife, FRM : Farmer, SG : Security guard, OFC : Office, PTR : Porter, CPT : Carpenter, NUR : Nurse, PLC : Police, RET : Retired.

Maximum number of patients (31.5%) in our study are house maids whose work demands prolonged manual labor and extensive use of their upper extremeties. House wives from the second most common group affected by complex regional pain syndrome.

Descriptive statistics :-

Brief Michigan hand questionnaire (BMHQ)

Table – 4 : Improvement in BMHQ score throughout the study.

	Group			
	Group I	Group II		
	Mean Std. deviation	Mean ± Std. deviation	P Value	Significance
BMHQ 1	30 1.55	30.79 ± 2.28	0.143	Not Significant
BMHQ 2	35.35 ± 4.96	38.18 ± 4.16	0.028	Significant
BMHQ 3	35.85 ± 4.96	40.11 ± 5.39	0.004	Significant
BMHQ 4	36.35 ± 5.43	42.21 ± 5.78	0.001	Significant
INTRAGROUP P VALUE				
BMHQ 1 vs. BMHQ 2	<0.001	<0.001		
BMHQ 1 vs. BMHQ 3	<0.001	<0.001		
BMHQ 1 vs. BMHQ 4	<0.001	<0.001		
BMHQ 2 vs. BMHQ 3	0.035	<0.001		
BMHQ 3 vs. BMHQ 4	0.020	<0.001		

The BMHQ score showed significant improvement from initial visit at the beginning of treatment to the fourth visit in group I ($p<0.001$). The BMHQ score similarly showed significant improvement from first visit at the beginning of treatment to the fourth visit ($p<0.001$) in group II. The rate of improvement in BMHQ score was maximum between the first and second visit in both the groups.

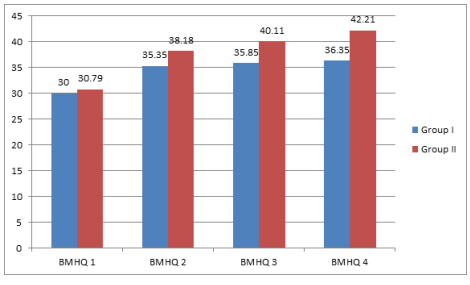

Figure -1: Change in BMHQ score in two groups following treatment.

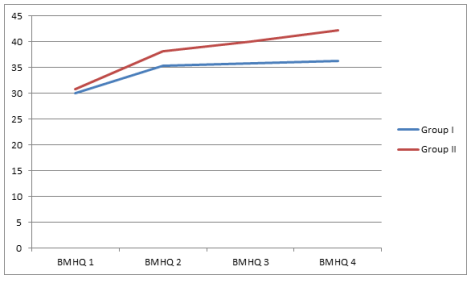

Figure – 2: Rate of improvement in BMHQ score through the study.

Visual analogue scale (VAS) –

Table – 5 : Improvement in VAS score throughout the study.

	Group			
	Group I	Group II		
	Mean Std. deviation	Mean ± Std. deviation	P Value	Significance
VAS 1	8.5±0.99	8.61 ± 1.13	0.714	Not Significant
VAS 2	6.54 ± 1.42	5.18 ± 1.09	<0.00	Significant
VAS 3	5.77 ± 1.82	4.21 ± 1.5	0.001	Significant
VAS 4	5.12 ± 2.18	3.5 ± 1.71	0.004	Significant
INTRAGROUP P VALUE				
VAS 1 vs. VAS 2	<0.001	<0.001		
VAS 1 vs. VAS 3	<0.001	<0.001		
VAS 1 vs. VAS 4	<0.001	<0.001		
VAS 2 vs. VAS 3	<0.001	<0.001		
VAS 2 vs. VAS 4	<0.001	<0.001		

The VAS score showed significant improvement from initial visit at the beginning of treatment to the fourth visit in group I ($p<0.001$). The VAS score similarly showed significant improvement from first visit at the beginning of treatment to the fourth visit ($p<0.001$) in group II. The rate of improvement in VAS score was maximum between the first and second visit in both the groups.

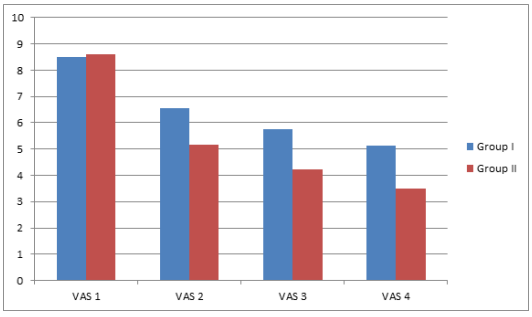

Figure -3: Change in VAS score in two groups following treatment

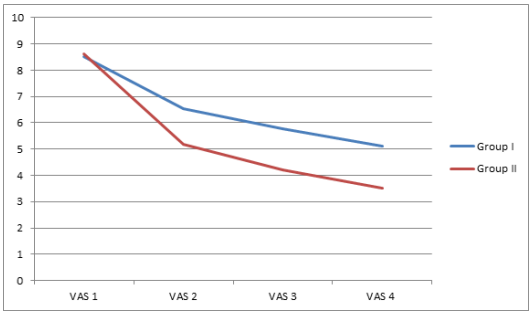

Figure- 4: Rate of improvement in VAS score through the study.

DISCUSSION

In our study the mean age of patients in two groups was not significantly different ($p>0.05$) so the two groups were comparable with respect to age of patients. The mean age of patients in group I was 52.35 years (with a standard deviation of 6.25) and the mean age of patients in group II was 51.61 years (with standard deviation of 8.27). These findings corroborate with the findings of study done by de MosM et al[3] where the mean age of patients was 52.7 years. Though these author found that the major age group affected by CRPS was that of elderly i.e. 61-70 years of age, our results found the age of majority of patients affected by CRPS I was between 30-55 years. This finding is mirrored in study by Sharma A, Agarwal S et al [5] who conducted a web based epidemiological survey and found that the major group affected by CRPS was in between 25-55 years of age.

There was no significant difference in the distribution of patients according to their gender in both the groups. Females formed the major group of patients in our study. 72.2 % patients in our study were female whereas the percentage of males in our study came out to be 27.8%. The literature shows abundant studies with similar findings. The female : male ratio in our study was 2.6:1. This ratio confirms the finding of Allen and Associates[6] (female : male = 2.3 : 1) Ochoa et al [7] 1994 (female : male = 1.6 : 1), Veldman et al [8] (female :male = 3:1).

This study found house maids were affected by CRPS of upper limbs among all occupations. The study conducted by Allen et al [6] showed the major group of patients of CRPS to be restaurant workers. Higher incidence among these groups probably due to the amount of manual work associated with such jobs.

At the beginning of study both the groups were comparable with respect to VAS and BMHQ score ($p>0.05$) of the patients included in them which were used to measure reduction in pain and improvement in hand function.

In our study patients patients in group I were treated by a multidisciplinary approach which included physical exercise, pain control using Ibuprofen, oedema control measures, occupational therapy, wax bath and gabapentine. The patients were evaluated at each visit and their functional improvement and pain reduction recorded in term of brief Michigan hand Questionnaire (BMHQ) score and visual analogue scale (VAS) respectively.

Subsequent data showed that in group I there was significant improvement in BMHQ score in follow up visits i.e. ($p<0.05$). The final BMHQ score on comparing with the initial BMHQ score showed significant improvement ($p<0.001$). Though there was definite improvement in BMHQ score throughout the study period, the rate of improvement in BMHQ score reduced as the time of study increased i.e. the improvement in BMHQ score was more in between initial visit and second visit in comparison to that in between second visit and third visit.

This is consistent with the study of Mellick GA et al [9] whose study showed the benefit of gabapentin in patients suffering from complex regional pain syndrome. In contrary to this study, the study by vusse et al[10] did not show significant improvement in hand function in CRPS patients treated with gabapentin. This difference may in part be explained by the fact that the multidisciplinary treatment approach which we adopted was not used by vusse et al in their study.

Similarly the patients in this group I showed considerable reduction in pain which was significant at the end of study period ($p<0.001$) as in improvement in hand function, though there was definite improvement in VAS score throughout the study period, the rate of improvement in VAS score reduced as the time of study increased i.e. the improvement in VAS score was more in between initial visit and second visit in comparison to that in between second visit and third visit. This finding is reflected in the study by Mellick GA et al [11] as well as in the study by Vusse et al[10] who found considerable relief in pain in patients of CRPS treatment with gabapentine.

Patients in group II were also treated by a multi disciplinary approach which included physical exercise, pain control using Ibuprofen, oedema control measures, occupational therapy, wax bath and stellate ganglion block in place of oral gabapentine. The patients were evaluated at each visit and their functional improvement and pain reduction recorded in term of brief Michigan Hand Questionnaire (BMHQ) score and visual analogue scale (VAS) respectively.

Subsequent data showed that in group II there was significant improvement in BMHQ score in follow up visits i.e. ($p <0.05$). The final BMHQ score on comparing with the initial BMHQ score showed significant improvement ($p<0.001$).Though there was definite improvement in BMHQ score throughout the study period, the rate of improvement in BMHQ score reduced as the time of study increased i.e. the improvement in BMHQ score was more in between initial visit and second visit in comparison to that in between second visit and third visit.

Similarly the patients in this group II showed considerable reduction in pain which was significant at the end of study period ($p<0.001$) as in improvement in hand function, though there was definite improvement in VAS score throughout the study period, the rate of improvement in VAS score reduced as the time of study increased i.e. the improvement in VAS score was more in between initial visit and second visit in comparison to that in between second visit and third visit.

These finding are consistent with the finding obtain by willam E Ackerman et al[12] in their study as well as the study done by Istemi Yucei et al[13] where stellate ganglion block was found effective in improving function as well as in reduction of pain in cases of CRPS of upper extremity.

On analyzing the results obtained at the end of study period in both the groups and on comparing the effect of treatment in both these groups, we find that though both the group showed significant improvement in hand function and significant reduction in pain at the end of study period ($p<0.05$) the overall improvement was more significant in the group II where patients underwent stellate ganglion block ($p <0.001$).

CONCLUSION

1) Complex regional pain syndrome is more common in females.
2) The mean age of CRPS patients is 52 years.
3) House maids form the predominant group of patients suffering from CRPS I of the upper extremeties.
4) Multidisciplinary approach is beneficial in effective management of CRPS.
5) Both treatment approaches using oral gabapentin as well as stellate ganglion block give good result with respect to improvement in hand function and reduction in pain.
6) Stellate ganglion block gives better result in improving hand function and in reduction of pain in patients of complex regional pain syndrome I of the upper extremities.

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