# Progressive Muscle Relaxation in Hyperemesis Gravidarum

### <sup>1</sup>Sushil Gawande, <sup>2</sup>Madhuri Vaidya, <sup>3</sup>Rahul Tadke, <sup>4</sup>Vivek Kirpekar, <sup>5</sup>Sudhir Bhave

<sup>1</sup>Assistant Professor, Department of Psychiatry, NKP Salve Institute of Medical Sciences and Lata Mangeskar Hospital Nagpur, Maharashtra, India

<sup>2</sup>Assistant Professor, Department of Obstetrics and Gynecology, NKP Salve Institute of Medical Sciences and Lata Mangeskar Hospital Nagpur, Maharashtra, India

<sup>3</sup>Assistant Professor, Department of Psychiatry, NKP Salve Institute of Medical Sciences and Lata Mangeskar Hospital Nagpur, Maharashtra, India

<sup>4</sup>Professor, Department of Psychiatry, NKP Salve Institute of Medical Sciences and Lata Mangeskar Hospital, Nagpur, Maharashtra, India
<sup>5</sup>Professor and Head, Department of Psychiatry, NKP Salve Institute of Medical Sciences and Lata Mangeskar Hospital Nagpur, Maharashtra, India

**Correspondence:** Sushil Gawande, Assistant Professor, Department of Psychiatry, NKP Salve Institute of Medical Sciences and Lata Mangeskar Hospital, Digdoh Hills, Hingana Road, Nagpur-440019, Maharashtra, India, Phone: 07104236291 09322013915, e-mail: sushil.gawande@rediffmail.com

#### ABSTRACT

Aims: To assess the role of progressive muscle relaxation in the management of hyperemesis gravidarum.

*Methods*: This is a prospective, randomized, observer blind and comparative study. Around 30 pregnant women admitted for the treatment of hyperemesis gravidarum were enrolled and randomized into experimental and control groups. Each group was of 15 patients. Experimental group patients received pharmacotherapy with daily progressive muscle relaxation for 2 weeks, while patients in control group received only pharmacotherapy.

*Results*: (1) Significantly high number of patients required three or more drugs in control group as compared to experimental group, (2) experimental group patients achieved complete response within 2.73 days  $\pm$  SD, while control group patients achieved complete response within 4 days  $\pm$  SD, (3) none of the patients in experimental group had recurrence within 2 weeks of observation period, while 13% patients in control group had recurrence after complete response, (4) on clinical global improvement scale, patients in experimental group achieved better improvement.

*Conclusions*: Progressive muscle relaxation is effective in hyperemesis gravidarum and when combined with antiemetics, it reduces the number of antiemetics required to treat hyperemesis gravidarum. Patients also show early response to treatment, less recurrence and better improvement when combined with antiemetics.

Keywords: Progressive muscle relaxation, Hyperemesis gravidarum, Antiemetics.

## INTRODUCTION

Hyperemesis gravidarum (HG) occurs in 0.3 to 2% of pregnant women; although population with significantly higher rates have been reported. In clinical practice, HG is identified by unexplained intractable vomiting and dehydration. For the purposes of investigation, a confirmatory criterion of weight loss, usually more than 5% of prepregnancy weight, is used.<sup>1</sup>

Although, there is conflicting information, several lines of evidence point toward a role of human chorionic gonadotropin and estradiol in HG.<sup>1</sup> Numerous psychoanalytic theories identified that women are rejecting the father of the baby, being ambivalent about the pregnancy, rejecting their own feminity, being either too dependent on their mothers or conversely not dependent enough. Buckwalter and Simpson reviewed these studies and concluded that there is little support for the concept of HG is caused by particular psychological state.<sup>2</sup> In some instances, social and psychological factors contribute to the illness.<sup>3</sup>

As HG is often resistant to conservative treatments, alternative modalities are sometimes used, such as acupressure and ginger root. Both modalities received equivocal support.<sup>4,5</sup> There is evidence that behavioral approaches, such as relaxation

and hypnosis/distracting therapy can diminish nausea and vomiting associated with hyperemesis gravidarum.<sup>6</sup> Relaxation produces physiological effects opposite to those of anxiety: Slow heart rate, increase peripheral blood flow and neuromuscular stability. A variety of relaxation methods have been developed. Most of the methods use progressive muscle relaxation developed by psychiatrist Edmund Jacobson. Patients relax major muscle groups in a fixed order, beginning with the small muscle groups of the feet and working cephalad. Some clinicians use hypnosis or tape recorded exercise to allow patients to practice relaxation on their own. Muscle tension, respiration rate, heart rate, blood pressure and skin conductance decreases during relaxation. Finger temperature and blood flow to the finger increase. Relaxation increases respiratory heart rate variability, an index of parasympathetic tone.<sup>7</sup>

Thus, this study was undertaken to assess the role of progressive muscle relaxation in the management of hyperemesis gravidarum.

### **METHODS**

The study started after written permission from Institutional Ethics Committee. Around 30 pregnant women admitted for



the management of hyperemesis gravidarum during first trimester (which is diagnosed based on severe vomiting, dehydration, acidosis and hypokalemia) in obstetric ward were included after their written informed consent. Patients with psychogenic vomiting, multiple pregnancy, molar pregnancy and pregnancy more than 12 weeks of gestation were excluded. Eligible subjects were grouped randomly in experimental and control group. Treating obstetricians were blind toward these group distribution and psychiatric interventions. Each group comprised of 15 patients. Sociodemographic and obstetric history were taken for using semistructured proforma. Experimental group patients received pharmacotherapy along with daily progressive muscle relaxation for 2 weeks, while patients in control group received only pharmacotherapy. Progressive muscle relaxation sessions were given by psychiatrist in psychiatric OPD. In the session, individual patient was advised to lie in a supine position on a comfortable bed in a well-ventilated silent room. Therapist explained the procedure of progressive muscle relaxation and guided the patient to perform relaxation technique. The protocol followed was common to all patients. In all sessions, procedure was characterized by asking patient to tense the feet muscles slowly, holding it for sometime, experiencing the tension in the muscles and then relaxing it gradually. Patients were asked to progress in the same manner with calf muscles, thigh muscles, gluteal muscles, abdominal muscles, chest muscles, hand muscles, forearms, shoulders, neck muscles, facial muscles, and then forehead muscles. The procedure was associated with instructions by therapist at each step. Each session was taken for 20 minutes. Control group did not receive any psychiatric interventions, though they were being called to psychiatric OPD; to maintain the blinding in the treating obstetrician.

Though pharmacotherapy for hyperemesis gravidarum is not an objective, we formulated the protocol to use same drug to initiate treatment, and to add next drug in the same order if necessary. Obstetrician used the drugs in the order of Doxylamine succinate, Ondansetron, Metoclopramide and Promethazine. All the patients were first treated with

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Doxylamine succinate. Next drug was added as per the above order in nonresponders. Complete response to drug is defined as no vomiting in 24 hours. The patients with complete response were then continued with the same drugs for 48 hours. Patients without complete response were treated by adding next antiemetic as per above order. Dosages were Doxylamine succinate 10 mg BD or TDS, Ondansetron 8 mg BD or TDS, Metoclopramide 10 mg BD or TDS and Promethazine 25 mg BD or TDS. Dosing of these drugs was based on the clinical condition of the patient.

Patients in both the groups were observed for 2 weeks on following parameters; number of drugs required for the control of vomiting, number of days required for complete response, number of patients with recurrence after complete response, and clinical global improvement at the end of 2 weeks of interventions.

### **Statistical Analysis**

This study was designed to allow preliminary examination of the role of progressive muscle relaxation in the management of hyperemesis gravidarum. Therefore, formal sample size is not calculated for the study.

Patient data were analyzed on an intent to treat basis. Number of drugs required for the treatment and recurrence of hyperemesis gravidarum were expressed in number and percentage. Comparison between two groups was done using Fisher's exact test or Chi-square test as appropriate. Protocolspecified response of the treatment and CGI score were expressed in mean and standard deviation, and compared between two groups using unpaired t-test. p-value  $\leq 0.05$  is considered statistically significant.

### **RESULTS AND DISCUSSION**

### **Sociodemographic Profile**

The sociodemographic profile of the patients is given in Table 1.

As our hospital is a public hospital and located in the rural area, all patients belonged to lower and lower middle classes.

Table 1	Sociodemographic profile of the patients						
	Experimental group			Control group			
Sr. no.	Age (yrs)	Education (std)	Family structure	Age (yrs)	Education (std)	Family structure	
1	26	10	Joint	20	8	Joint	
2	25	12	Nuclear	22	11	Joint	
3	22	10	Joint	20	6	Joint	
4	24	11	Joint	24	7	Joint	
5	26	8	Joint	23	10	Joint	
6	20	11	Nuclear	21	12	Joint	
7	28	12	Joint	30	11	Joint	
8	20	Graduate	Joint	21	12	Nuclear	
9	22	11	Nuclear	20	11	Joint	
10	23	12	Joint	26	Graduate	Nuclear	
11	28	Graduate	Joint	22	10	Joint	
12	22	6	Joint	26	8	Joint	
13	25	10	Joint	28	12	Joint	
14	24	11	Nuclear	22	10	Joint	
15	25	12	Joint	24	12	Joint	
Mean ± SD	24 ± 2.5	11	Joint–73% Nuclear–26%	23.26 ± 3.05	10.33	Joint-86.66% Nuclear-13.33%	

Average age of patients in experimental group was 24 years while average age of patients in control group was 23 years. Majority of the patients had completed 10th standard. Most of the patients in experimental group (73%) and control group (86%) belonged to joint families. The sociodemographic profile was similar in both the groups.

## **Obstetric History**

Obstetric history of the patients is given in Table 2. In both groups, majority of women (> 80 %) were primigravidae with no history of abortion and had 10 weeks of pregnancy.

Obstetric parameters were comparable in both the groups.

	Experimental group			Control group			
Sr. no.	Primigravida (P)/ multipara (M)	Weeks of gestation	History of abortion	Primigravida (P)/ multipara (M)	Weeks of gestation	History of abortion	
1	Р	10	No	Р	8	No	
2	M	8	No	Р	10	No	
3	Р	9	No	Р	9	No	
4	Р	9	No	Р	11	No	
5	Р	10	No	Р	12	No	
6	Р	12	Yes	Μ	10	No	
7	Р	11	No	Μ	10	No	
8	Р	12	No	Р	8	No	
9	Р	12	No	Р	9	No	
10	Р	9	No	Р	10	No	
11	M	10	No	Р	11	No	
12	Р	11	No	Р	12	No	
13	Р	12	Yes	Р	10	Yes	
14	Р	10	No	М	11	No	
15	Р	8	No	Р	12	No	
Avg.	P-86.66% M-13.33%	10.2 ± 1.42	No-86.66% Yes-13.33%	P-80% M-20%	10.2 ± 1.32	No–93.33% Yes–6.66%	

### **Comparison between Experimental and Control Group**

		Experimental g	roup			Contr	ol group	
Sr. no.	А	В	С	D	A	В	С	D
	No. of drugs required	Complete response (days)	Recurrence	CGI score	No. of drugs required	Complete response (days)	Recurrence	CGI score
1 2 3 4 5 6 7 8 9 10 11 12 13	D,O,M (3) D,O,M(3) D,O,M(3) D,O (2) D,O (2) D,O,M D,O,M D,O,M D,O D,O D,O D,O D,O D,O D,O,M D,O,M	2 2 3 3 3 2 2 3 3 3 3 3 3 3 3	- - - - - - - - - - - - -	1 1 2 2 2 1 1 1 2 2 1 1 1	D,O,M (3) D,O,M (3) D,O,M (3) D,O,M (3) D,O,M (3) D,O,M D,O,M D,O,M D,O D,O,M,P D,O,M,P D,O,M,P D,O,M,P	4 2 5 6 7 3 4 5 2 4 5 3 3 3	- - + - - - - - -	2 2 3 2 3 1 1 1 2 2 2 2
14 15	D,O,M D,O,M	3 3	-	2 2	D,O,M D,O,M,P	3 No improvement	-	2 4
Avg.	6.66% (1) - 4 60% (9) - 3 33.3% (5) - 2 Mean ± SD - 2.73 ± 0.59	Mean ± SD – 2.73 ± 0.46 days	No recurrence	8 (53%) – 1 7 (47%) – 2 Mean score – 1.46 ± 0.52	27% (4) - 460% (9) - 313.3% (2) - 2Mean ± SD -3.13 ± 0.64	Mean ± SD – 4 ± 1.47 days	2 (13%)	8 (53%) – 2 4 (26.67%) – 2 2 (13.33%) – 3 1 (6.67%) – 4 Mean score – 2 ± 0.85

D – Doxylmine succinate; O – Ondansetron; M – Metoclopramide; P – Promethazine; clinical global improvement at the end of 2 weeks (CGI): 1 – very much improved; 2 – much improved; 3 – minimally improved; 4 – no change; 5 – minimally worse; 6 – much worse; 7 – very much worse

# Number of Drugs required for the Control of Vomiting

Experimental group $(n = 15)$	Control group $(n = 15)$
6.66% (1) required 4 drugs	27% (4) required 4 drugs
60% (9) required 3 drugs 33.3% (5) required 2 drugs 66.6% (10) required 3 or more drugs	60% (9) required 3 drugs 13.3% (2) required 2 drugs 86.6% (13) required 3 or more drugs
p-value* 0.39 (NS)	

\*Fisher exact test is applied; NS - not significant

Patients in experimental group required lesser number of drugs as compared to control group. This finding is not statistically significant.

### Number of Days required for Complete Response

<i>Experimental group</i> $(n = 15)$	Control group $(n = 15)$
$Mean-2.73\pm0.46$	Mean $-4 \pm 1.47$

### **Group Statistics**

Groups	Ν	Mean		Standard error mean
Complete Experimental	15	2.7333	0.45774	0.11819
response Control	15	4.6667	2.94392	0.76012

\*Unpaired t-test is applied; S - significant

Experimental group patients achieved complete response within 2.73 days, whereas control group patients achieved complete response within 4 days. The difference was significant. It means patients showed significant response following 2 to 3 sessions of progressive muscle relaxation along with antiemetics, though the possibility of other factors influencing this improvement cannot be ruled out.

### Number of Patients with Recurrence

Experimental group $(n = 15)$	Control group $(n = 15)$
0 (0%)	2(13%)
p-value* 0.48 (NS)	

\*Fisher exact test is applied; NS - not significant

Two patients in control group showed recurrence in next week after cessation of therapy. No recurrence was seen in experimental group. The rate of recurrence was comparable in both the groups.

### Clinical Global Improvement

Experimental group	Control group
8 (53%) – very much improved 7 (47%) – much improved	4 (26.67%) – very much improved 8 (53%) – much improved 3 (20%) – minimal improvement

### **Group Statistics**

	Groups	Ν	Mean	Standard deviation	Standard error mean
CGI	Experi- mental	15	1.4667	0.51640	0.13333
	Control	15	2.0000	0.84515	0.21822

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\*Unpaired t-test is applied; S - significant

Three patients in control group showed minimum improvement, whereas all the patients in experimental group showed much improvement. The rate of improvement was comparable in both the groups.

CGI score who significantly low in patients was received progressive muscle relaxation as compared to control group. Mean CGI score in experiment group was  $1.47 \pm 0.52$ , while mean CGI score in control group  $2.00 \pm 0.85$ .

### DISCUSSION

Progressive muscle relaxation is one of the most commonly used behavioral technique in anxiety, psychosomatic and depressive disorders. In variety of medical illnesses, like hyperemesis gravidarum, psychological stress acts as a precipitating or aggravating factor. Hyperemesis, during pregnancy, induces a state of apprehension among mothers. Anxiety about the well-being of baby and mother, physical discomfort and repeated hospital admissions give rise to significant psychological stress. There are very few systemic research studies available to validate the role of progressive muscle relaxation in hyperemesis gravidarum.

In this study, patients in the experimental group required significantly lesser number of antiemetics and showed significantly early response to treatment. Though, there are no equivalent studies to compare, but in a study conducted by Fuchs K et al, out of 138 women who participated in hypnotic treatment, 88% stopped vomiting completely after 1 to 3 hypnosis sessions.<sup>8</sup> In this study, patient achieved complete response within  $2.73 \pm 0.46$  days (mean) following two to three sessions of progressive muscle relaxation. It is difficult to assume that progressive muscle relaxation will show physiological effect in such a short-span. This effect could be perceived because of psychological support by the patients in experimental group. Tolerance to nausea, which leads to vomiting, varies with individual and psychological support by doctors may affect this. Positive assistance with psychological and social support is beneficial.9

The rate of recurrence was comparable in both the groups. None of the patient wished to terminate the pregnancy because of hyperemesis. Sometimes poor responders for treatment do opt for the termination as observed in the study of Fuchs K et al, where out of 160 women, 22 (13.7%) refused hypnotherapy and four of whom elected for early termination of their pregnancies.<sup>8</sup>

As seen in the results, mean CGI score is significantly low in patients received progressive muscle relaxation. Patient perceived better improvement when treatment was accompanied with progressive muscle relaxation. Interpretation of this data lacks significance because of small sample size. Perception of improvement could be related to doctor-patient relationship and feeling of being cared by doctor. It is difficult to differentiate the effect of psychological support from the effect of progressive muscle relaxation, at least during the initial sessions. This is a limitation of this study along with the small sample size.

## CONCLUSIONS

Progressive muscle relaxation is effective in hyperemesis gravidarum, and when combined with antiemetics, it reduces the number of antiemetics required to treat hyperemesis gravidarum. Patients also show significant early response, better improvement and less recurrence when antiemetics are given along with progressive muscle relaxation. This can be used as an effective modality of treatment in hyperemesis gravidarum in combination with pharmacotherapy. Large scale multicentric trial should be undertaken to substantiate these findings.

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