

Settings and Design: A randomized open label parallel group prospective study was done in Psychiatry OPD.

**Methods and Material:** 75 male nicotine dependent subjects were included in the study. These patients were divided into three groups and were given the following treatment regimes: Group A (25 patients) - Bioresonance therapy; Group B (25 patients) - Sustained release Bupropion tablet and Group C (25 patients) - combination of Bioresonance therapy and Bupropion. Severity of dependence symptoms was checked with Fagerstrom Test for Nicotine Dependence (FTND) scale at baseline, after 2 weeks and then at 12 weeks in all three groups.

Statistical analysis used: Results were analysed by using chi square, Kruskal-Wallis Test. Friedman Test and Mann-Whitney Test.

**Results:** Initially at 2 weeks, treatment regimes in both Group A and Group C were more effective as compared to that in Group B (p<0.05). But at 12 weeks, treatment regimes in both Group B and Group C were more effective as compared to that in Group A (p<0.05). Least number of dropouts was seen in Group C.

**Conclusions:** Bioresonance therapy alone was not found to be effective in nicotine dependence. The only benefit of combination therapy was lesser dropouts as compared to other two regimes.

**KEYWORDS**: Nicotine dependence, Bioresonance therapy, Bupropion.

### Introduction:

Nicotine dependence is a major cause of mortality and morbidity all over the world. Worldwide there are nearly 1.2 billion users of nicotine and tobacco products.

Worldwide tobacco use causes more than 5 million deaths per year, and if smoking prevalence continues to increase in the developing world, the number of annual deaths attributable to cigarette smoking will be more than 8 million by 2030 (World Health Organization [WHO], 2009). In India, the overall prevalence of current tobacco use from the NHSDAA (National Household Survey of Drug and Alcohol Abuse) was 55.8% (Srivastava, Pal, Dwivedi, Pandey & Pande, 2004). Also, in Global Youth Tobacco Survey conducted in India, prevalence of current tobacco use among 13-15 years aged adults has increased from 13.7% in 2006 to 14.6% in 2009 (Gajalakshmi & Kanimozhi, 2010). Therefore, Smoking cessation significantly improves life expectancy, decreases morbidity, and reduces healthcare costs associated with smoking-related conditions (Asaria, Chisholm, Mathers, Ezzati & Beaglehole, 2007). There are several pharmacological interventions available to aid smoking cessation (Wu, Wilson, Dimoulas & Mills, 2006). The Food and Drug Administration (FDA) has approved seven medications for this purpose: five nicotine replacement therapies (NRT), bupropion and varenicline (Herman & Sofuoglu, 2010).

But, Blumberg et al. (1974) stated that most smokers repeatedly fail to quit because they are addicted to nicotine. Nicotine has been rated by drug addicts as the most difficult drug of all to give up. Bonese, Wainer, Fitch, Rothberg and Schuster (1974) observed that high relapse rates among drug abusers seeking treatment has made it imperative to develop new treatment options for this disease.

Alternative methods may be applied in combination with pharmacological ones because they increase the smoker's motivation to stop smoking and at the same time increase the chance to overcome the addiction in general. A number of alternative methods for nicotine dependence treatment are available like bioresonance therapy, acupuncture, laser therapy, herbalism, aromatherapy and homeopathy (Koszowski, Goniewicz & Czogała, 2005). Bioresonance therapy claims to inverses the waves of nicotine and its metabolites along with other chemicals in tobacco, electronically and introducing these inversed waves to the body to balance its nicotine waves and facilitates the excretion of nicotine and all toxic metabolites from the body. Effectiveness of the alternative methods is often disputable and the main advantage of these methods is a support effect to patient who wants to give up smoking (Koszowski, Goniewicz & Czogała, 2005). So this study was conducted to check the effect and clinical utility of bioresonance therapy in nicotine dependent disorder patients.

## Aims and Objectives:

To compare the effects and relative clinical utility of Bioresonance therapy, Bupropion and combination of Bioresonance therapy & Bupropion in the treatment of Nicotine dependent patients.

#### Methodology

STUDY DESIGN: Randomized open label parallel group prospective study was done in Psychiatry OPD.

SAMPLE: 75 male patients, age group of 18 to 60 yrs. These were further randomly assigned into three groups

In Group A (25 patients) - 2 Session of Bioresonance therapy were given at interval of 1 week.

In Group B (25 patients) – Patients received sustained-release Bupropion at 150 mg/d, which was increased to 150mg/d bid after 1 week.

In Group C (25 patients) – Patients received combination of Bioresonance therapy and Bupropion.

Measurement: Severity of Dependence symptoms was recorded by using Fagerstrom Test for Nicotine Dependence (FTND). Measurements using FTND were taken at baseline, 2 weeks and 12 weeks.

Statistics: Chi square test, Kruskal-Wallis Test, Friedman Test and Mann-Whitney Test were applied.

Criteria: Male patients in the age group of 18-60 years with current diagnosis of Nicotine dependence disorder as per DSM-5 and with no other comorbid substance abuse were included in the study. Patients with other Major mental illness or significant medical problem or Polydrug abuse were excluded.

Results: Table no. 1

99

Volume - 7	Issue - 6	June - 2017	ISSN - 2249-555X	IF: 4.894	IC Value : 79.96
------------	-----------	-------------	------------------	-----------	------------------

Group	Baseline			2 weeks				12 weeks				P value\$	
	Ν	Range	Mean ±SD	Median	Ν	Range	Mean ±SD	Median	Ν	Range	Mean $\pm$ SD	Median	]
Group A	25	5-9	$6.88 \pm 1.17$	7	25	0 - 8	$3.44 \pm 2.36$	4	23	0 - 8	$4.61\pm2.81$	6	< 0.001**
Group B	25	5-9	$6.92 \pm 1.04$	7	25	0 - 8	$4.68 \pm 1.75$	5	21	0 - 7	$3.05 \pm 2.36$	3	< 0.001**
Group C	25	5-9	$6.80\pm\!\!0.96$	7	25	0 - 8	$3.36 \pm 2.12$	4	24	0 - 7	$2.88 \pm 2.31$	3	< 0.001**
P value#	lue# 0.927NS			0.043*			0.031*						

# Kruskal-Wallis Test (Non-Parameteric) for Inter Group  $Comparison: NS: p \! > \! 0.05; Not Significant; * p \! < \! 0.05; Significant$ 

\$ Friedman Test for Intra-Group comparison; p < 0.001; Highly significant

Table 1 shows that mean FTND score in 3 groups at baseline is  $6.88 \pm$ 1.17,  $6.92 \pm 1.04$ ,  $6.80 \pm 0.96$ . So, there is no significant difference between 3 groups at baseline. After this, FTND score was recorded at 2 weeks (as bioresonance therapy claims to exert its most of action in 2 sessions). Mean score of 3 groups at 2 weeks is  $3.44 \pm 2.36$ ,  $4.68 \pm 1.75$ ,  $3.36 \pm 2.12$ . So, mean score of all the 3 groups got decreased. However, at 12 weeks, mean score of group A got increased whereas mean score of group B and C showed downward trend.

#### Table no. 2

	Baseline			2 Weeks			12 weeks		
Comparison	Mean Rank	P value	Significance	Mean Rank	P value	Significance	Mean Rank	P value	Significance
Group A	25.36	0.944	Not	21.40	0.044	Significant	26.22	0.042	Significant
Group B	25.64		Significant	29.60			18.43		
Group A	26.06	0.777	Not	25.52	0.992	Not	28.98	0.013	Significant
Group C	24.94		Significant	25.48		Significant	19.23		_
Group B	26.24	0.706	Not	30.18	0.020	Significant	23.26	0.898	Not
Group C	24.76		Significant	20.82			22.77		Significant

Multiple comparisons using Mann-Whitney Test

Table 2 shows mean score of group A at 2 weeks is significantly lower than group B. But at 12 weeks results got just opposite to that of results at 2 weeks i.e. group B mean score is significantly lower than group A at 12 weeks.

In comparison between group A and C, results are non-significant at baseline and 2 weeks.

But, mean score of group C is significantly lower than group A at 12 weeks.

In group B and C comparison, mean score of group C is significantly lower at 2 weeks. But at 12 weeks, both groups showed non-significant result.

# Table no. 3

GROUP	DROPOUT
A (25)	2(8%)
B (25)	4(16%)
C (25)	1(4%)

Table 3 shows the dropout cases are more in group B (16%) as compared to group A(8%) and C(4%).

#### **Discussion:**

Bioresonance therapy was developed by physician Franz Morell and electrical engineering technician Erich Rasche in the 1970s (Morell, 1987). The therapy claims to collect low electromagnetic oscillations of humans (endogenous bioresonance) or of bioactive substances (e.g. allergens, heavy metals, vitamins, exogenous bioresonance) by plane electrodes. After this, it inverses the waves of bioactive substance, electronically and introducing these inversed waves to the body to balance its waves and facilitates its excretion from the body. A number of clinical studies showed its effectiveness in allergies, rheumatic diseases, respiratory diseases, and various pain syndromes (Maiko, 2000; Gogoleva, 2001; Chen, 2010; Herrmann, 2011; Liu, 2013). But some studies showed negative result in treatment of above disorders (Kofler, 1996; Schöni, 1997). In this study, bioresonance therapy is applied with cigarettes/biddi/tobacco as exogenous bioactive substance, to check the effect and clinical utility of bioresonance therapy in nicotine dependent patients.

It was found that, at 2 weeks, bioresonance therapy alone and in combination with bupropion was more effective than bupropion alone. This could be due to delayed (2 weeks) onset of action of bupropion.

But at 12 weeks, bupropion alone and in combination with bioresonance therapy has been found more effective than bioresonance therapy alone. Also, bupropion in combination with bioresonance therapy has not been found more effective than bupropion alone. So bioresonance therapy alone has not been found effective in nicotine

dependence patients. But, Pihtili et al. (2014) observed that bioresonance therapy was effective in smoking cessation. This disparity in results could have been because as Pihtili et al. compared Bioresonance therapy with placebo rather than any FDA approved therapy.

So, it was concluded that alone Bioresonance therapy was not found to be effective in nicotine dependence patients. The only benefit of bioresonance therapy was that, when it was combined with other FDA approved therapies then chances of dropout were found to be decreased.

Limitations of this study were small sample size that could limit the generalizability of our findings and short time period for data collection.

#### References:

- Asaria, P., Chisholm, D., Mathers, C., Ezzati, M., Beaglehole, R. (2007). Chronic disease prevention: health effects and financial costs of strategies to reduce salt intake and control tobacco use. Lancet, 370, 2044-2053.
- Blumberg, H.H., Cohen, S.D., Dronfield, B.E., Mordecai, E.A., Roberts, J.C., Hawks, D. (1974). British opiate users: people approaching London drug treatments centres. Int 2 JAddict, 9, 1-23.
- Bonese, K., Wainer, B., Fitch, F., Rothberg, R., Schuster, C. (1974). Changes in heroin 3. self-administration by a rhesus monkey after morphine immunisation. Nature, 252, 708–710.
- Chen, T., Guo, Z.P., Zhang, Y.H., Gao, Y. (2010). Effect of MORA bioresonance therapy 4. in the treatment of Henoch-Schonlein purpura and influence on serum antioxidant Gajalakshmi, V., Kanimozhi, C.V. (2010). A survey of 24,000 students aged 13–15 years
- 5. in India: Global Youth Tobacco Survey 2006 and 2009. Tob Use Insights, 3, 23-31
- Gogoleva, E.F. (2001) New approaches to diagnosis and treatment of fibromyalgia in spinal osteochondrosis. Ter Arkh, 73, 40–45.
  Herman, A.I., Sofuoglu, M. (2010). Comparison of available treatments for tobacco addiction. Curr Psychiatry Rep, 12, 433–440. 6.
- 7.
- Herrmann, E., Galle, M. (2011). Retrospective surgery study of the therapeutic effectiveness of MORA bioresonance therapy with conventional therapy resistant patients suffering from allergies, pain and infection diseases. Eur J Integr Med, 3, 8. 237-244
- Kofler, H., Ulmer, H., Mechtler, E., Falk, M., Fritsch, P.O. (1996). Bioresonanz bei 9. Pollinose - eine vergleichende Untersuchung zur diagnostischen und therapeutischen Wertigkeit. Allergologie, 19, 114-122.
- Koszowski, B., Goniewicz, M., Czogała, J. (2005). Alternative methods of nicotine dependence treatment. Przegl Lek, 62(10), 1176-1179. 10
- Liu, L.L., Wan, K.S., Cheng, C.F., Tsai, M.H., Wu, Y.L., Wu, W.F. (2013). Effectiveness of MORA electronic homeopathic copies of remedies for allergic rhinitis: a short-term, 11. randomized, placebo-controlled PILOT study. Eur J Integr Med, 5, 119–125. Maiko, O.J., Gogoleva, E.F. (2000). Outpatient bioresonance treatment of gonarthrosis.
- 12.
- Marko, 53, 56,500, 217 (200), Ouparten birtosinne training of gona through Fra Arkh, 72,50–53. Morell, F. (1987). MORA-Therapie patienteneigene und Farblichtschwingungen Konzept und Praxis. In MORA-Therapie patienteneigene und 13 Farblichtschwingungen. Heidelberg: Haug. Pihtilia, A., Galleb, M., Cuhadarogluc, C., Kilicaslana, Z., Isseverd, H., Erkan, F., et al.
- (2014). Evidence for the Efficacy of a Bioresonance Method in Smoking Cessation: A Pilot Study. Forsch Komplementmed, 21, 239–245.Srivastava, A., Pal, H., Dwivedi, S.N., Pandey, A., Pande, J.N. (2004). National Household Survey of Drug and Alcohol Abuse in India (NHSDAA). New Delhi:
- 15. Ministry of Social Justice and Empowerment, Government of India and Regional Office of South Asia: UN Office for Drug and Crime.
- Schöni, M.H., Nikolaizik, W.H., Schöni-Affolter, F. (1997). Efficacy trial of bioresonance in children with atopic dermatitis. Int Arch Allergy Immunol, 112, 238-246
- World Health Organization. (2009). World Health Organization Report on the Global 17. Tobacco Epidemic. Geneva, Switzerland.
- Wu, P., Wilson, K., Dimoulas, P., Mills, E.J. (2006). Effectiveness of smoking cessation therapies: a systematic review and meta-analysis. BMC Public Health, 9, 300. 18.