Trends Observation during Different Medications by Subjects under EMG & GSR Biofeedback


Abstract: Tension is one of the most common problems found in people now a days. With upcoming of problem, stress level increases and headache is the most common problem faced during stress. The common headache found is tension type headache (TTH). The present study aim at studying the effect on TTH of various biofeedback technique like EMG and GSR on various mode like audio and audio visual. The experiment was conducted on 90 people out of which 78 remained till end (out of which 46 females and 32 males) these groups were randomly assigned groups like EMG, EMG+GSR, GSR, GSR+Rav and the control group (the group which was not treated with any of the therapy). The control group was only given the medication given by doctor. The session of the biofeedback therapy was conducted for over a time of 20 minutes in an isolated chamber. The therapy continues for over a period of 12 months. The results were taken after 1 month, 3 month, 6 month and 12 months. Authors have tried best to verify the hypothesis and establish the fact that which kind of therapy is more useful through comparison between both therapies in audio mode. The Study protocols have been registered with Clinical Trials Registry with ref. No. REF/2018/06/020361 of India affiliated to national institute of Medical Statistics, authoritative body of Indian Council of Medical Research. The dataset and obtained results are under process of registration. The Related project is also under process with DST-Ministry of Health to better deal with the TTH issue for public welfare.

Keywords: Stress, Meditation, Audio, Visual, SF36, EMG, GSR, Mental and physical scores, mental health, biofeedback, Analgesic Consumption, TTH, PM Prophylactic Medication, Anti-Depressants, OM- Other medication, Muscle Relaxants, Triptans, AM- Alternative Medicine.

I. INTRODUCTION

A. Biofeedback

The term “Biofeedback” is a technique which can be used to control our body function such as heart rate.

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With biofeedback we relate to our body part and receive electrical signals about them. It helps us to control our body such as reducing pain, relaxing pain. This technique is often used to improve our health.1

B. Tension Type Headache and Stress

Tension type headache is widely spread type of headache found in most of the people about 90 percent of the headache are of tension type. It is called by various names like including tension headache, muscle contraction, stress headache, ordinary headache, essential headache etc. TTH usually last for about 30 minutes to 7 days, depending on its intensity. The pain level is generally ranging from mid to moderate. It is accompanied by vomiting and nausea.2

C. Analgesic Consumption

Analgesic is also known as a pain killer it is basically a type of drug which is used to achieve pain relief (analgesia). The word analgesia itself means “the absence of the sense of pain while remaining conscious”. Analgesic drug affects our mind and nervous system in different ways. They are different from anesthetics. Which either temporarily and in some cases completely vanish the sensation. Analgesics include paracetamol, NSAIDs such as the salicylates, and opioid drugs. Nonsteroidal anti-inflammatory drugs are kinds of drug which lower the fever, reduces the pain and in case of Higher dose decrease inflammation. Some of the common drugs are aspirin, naproxen, ibuprofen. These all are available across all the countries easily. So basically, it was the group that consumed analgesic medicines to get relief from the stress and headache.

D. PM

Along with traditional headache medication there are other drugs that help to reduce headache these are antidepressants. in medical this approach is referred as prophylaxis. A analysis published in 2014 proposed that antidepressants also reduce the depression in the people suffering from hepatitis c by 40 percent. Some studies even depict that is the person is pretreated with anti-depressants there are likely less chance to have depression symptom. Even the person which take depressants after them stroke is less likely to get depression.3,4,5

E. AM- Alternative Medicines
Alternative medicine is also known as pseudo medicine or questionable medicine. Alternative medicine is claimed to have the healing effect like that of medicine which is unproven or impossible to prove and are likely to be harmful.

According to scientist a therapy is said to be unproven and not working when it does not follow the natural laws and violate it. Alternative medicine is not same as traditional medicine. alternative medicine is a bit dangerous as it does not give proper results .it is used by significant number of people, but still large amount of funding is raised by united state government. The industry of alternative medicine is highly profitable. This fact is overlooked, or we can say that hidden by media, with alternative medicine portrayed positively when compared to big pharma. The license for practicing varies based on different health care provider and different countries. Though the practice of alternative medicine is illegal, yet it is promoted by various practitioner in cancer treatment. Alternative medicine is criticized for taking advantage of the weakest members of society.

F. OM

This was the group which was called as OM (Other medication) which include muscle relaxants and use of triptans. Triptan is a drug of the family tryptamine which is used as abortive medication in the treatment of headache and migraines. This drug is effective in treating individual headache, but it is not a cure for tension type headache especially for a person suffering from migraine. They are sometime effective in disabling the tension type headache. Triptans do not relieve other kinds of pain.

Triptans are highly efficient in reducing the chances of attack in 70 to 80 percent people within 3 to 90 minutes. Triptans are not recommended to a person with skin sensitivity ,it is advisable to take triptan after twenty minutes of headache’s onset. Most of the triptan are advised not to be used during pregnancy, breastfeeding and for the patient younger 18 years; but there are triptan like sumatriptan and zolmitriptan nasal spray approved for young once like over 12. Despite the opinions of expert drug governing bodies suggest that monoamine oxidase inhibitor and FDA are contraindicated for sumatriptan, rizatriptan and zolmitriptan and with combination like ergotamine. Triptan also have some side effect, the most common is recurrence of migraine.

While a muscle relaxant is a drug that decrease muscle tone by affecting skeletal muscle. They are used to decrease muscle pain and hyperflexes. It may have following effects on our body.

- Dependency
- Allergic reactions
- Sleepiness
- Tapering off

II. RESULTS, INTERPRETATION AND DISCUSSION

A. About the Study & Analysis

The Whole Analysis is being done in Tableau software which is a data Analytics tool and gives data analysis in different visualizations and was designed by 3 Professors of Stanford university in their research work in 1996-97 and was launched in 2003. The Microsoft had also various data visualization tools but Tableau is more powerful among all. Now MS has launched Power BI as latest data visualization tool which has more features and very less cost than Tableau (one seventh). But the data integrity and facility in Tableau are more popular with 10 + years of research experience.

![Weightage Medication Score](image)

**Fig. 1 The Allotments of Average Medication Scores**

To Understand the Correlation of subjects shifting from one medication to other in the period of stipulated time of experiment (12 months here), the different medications ever been allotted the weights.

**AC i.e. Analgesics Consumption**

Combination drugs and plain analgesics (NSAIDs, other analgesics) Given as the Main Rating (second least rating as 5) (As per Figure 1.).

**No Medication**

No analgesics (Given the Highest Rating or 0 score NULL i.e. Considered as No analgesics (Given the Highest Rating or 0 score)

**PM i.e. Prophylactic medication**

Other anti-depressants etc. (given as Third Rating as 4)

**OM i.e. Other medication**

Muscle relaxants, triptans etc. (given as Fifth Rating as 1)

**AM**

Switched to Alternative Medicine (given as Fourth Rating as 2)

**NA**

Information not available which shows that particular subjects has dropped out or switched to previous medicine during the experiment so given the lowest ratings (highest Score as 8)
B. Summary of Drug Consumption

Below is the Summary of Drug Consumption of different Subjects in Different Groups (out of 6 i.e. EMGa, EMGv, EMGav, GSRa, GSRv, GSRav) (By Fig. 2)

It shows the switching of subjects from one medication to another in different groups in due course of time period of 12 months.

The readings have been observed in start of the experiment (Baseline), at 1 month, 3 months, 6 months and 12 months.

The color combination shows the intensity of the counting of total subjects (on the scale of 1 to 25) in different groups out of 6 designed over the time period of 12 months.

The total 820 subjects were analyzed and their medication details group wise, time period wise are as below which shows that subjects in EMGav=135, GSRv=145, EMGa=130, EMGv=130, GSRa=135, GSRav=140 were measured.

If we see the AC—Analgesic Consumption, it is a clear demarcation that Biofeedback Therapy has been extremely fruitful in reduction of Analgesic in subjects.

The baseline data for Total 132 subjects EMGav=17, GSRv=23, EMGa=23, EMGv=25, GSRa=23, GSRav=21 were measured which was reduced to total 37 which as EMGav=9, GSRv=5, EMGa=6, EMGv=4, GSRa=7, GSRav=6 in 12 months of time period.

Many subjects have been also reduced from PM zone to other lighter zones of medicine consumption due to benefits of therapies.

In PM criteria the initial baseline data was total 19 initially EMGav=4, GSRv=5, EMGa=3, EMGv=1, GSRa=1, GSRav=5 were measured which was decreased to total 4 which as EMGav=0, GSRv=0, EMGa=2, EMGv=2, GSRa=0, GSRav=0 were measured.

Also its sure that, in OM criteria the initial baseline data was total 7 initially EMGav=3, GSRv=1, EMGa=1, EMGv=1, GSRa=0, GSRav=1 were measured which was increased to total 31 which as EMGav=6, GSRv=6, EMGa=6, EMGv=4, GSRa=3, GSRav=6 were measured. It is clearly understood that these subjects have shifted from AC Zone to OM Zone which were lighter medicines.

It is obvious that subjects were shifted to AM—Alternative medicine and No Medicine Zone due to benefits of Biofeedback Methods.

In No Medication the criteria for baseline was total 5 initially EMGav=3, GSRv=0, EMGa=0, EMGv=0, GSRa=2, GSRav=0 were measured which was increased to total 36 which as EMGav=4, GSRv=5, EMGa=6, EMGv=10, GSRa=6, GSRav=5 were measured in the completion of experimental period.

If we check the effect of Biofeedback therapy in the longer range that any subjects have left the medications permanently and completely shifted to Alternate Therapy and Medications. Which is a clear indication of the success of the applied therapies in stipulated time period and proves the high social impact on the long-term subject health, monetary benefits, avoidance of side effects due to Analgesic consumptions and slow but steady effect of alternate therapies.

Fig. 3(a) Trend Observed During Medication in EMGa Mode (Separate)

In Alternate Medication the criteria for baseline was total 1 initially EMGav=0, GSRv=0, EMGa=0, EMGv=1, GSRa=0, GSRav=0 were measured which was increased to total 7 which as EMGav=2, GSRv=0, EMGa=1, EMGv=2, GSRa=0, GSRav=2 were measured in the completion of experimental period. Also, in study of NA criteria where we have studied the dropouts of the different therapy subjects.
Initially NA Criteria for baseline was total 3 initially EMGav=1, GSRv=2, EMGa=0, EMGv=0, GSRa=0, GSRav=0 were measured which was increased to total 48 at the end of the study which as EMGav=6, GSRv=13, EMGa=6, EMGv=5, GSRa=10, GSRav=8 were measured in the completion of experimental period.

The above facts are clear Indicator that EMGav and GSRv has a neck to neck competition in effectiveness on the subjects. Seeing the NA criteria to show the dropouts, the EMGav has clear cut better impact over GSRv methodology.

C. Trend Observed During Medication in different Modes of EMG Biofeedback Therapy

Trend Observed During Medications (all types of Medications individually) and Trend Observed (Drug Groups Combined and Alternative Medications, No Medications and Dropouts-NA)

a) EMGa Mode

The trend observed during the study with the number of subjects moving from one medication bucket to other has been drawn to visualize the effectiveness of techniques.

In the EMGa subject group, during baseline period 100% of subject were on medication out of which all subjects were on Analgesic consumption. After the 1 month of therapy period 22.22% increase in count of subject has been observed who stopped taking the medicines. Also 22.22% drop is observed in the analgesic consumption patient. With the passage of time it has been observed that alternative medicine (AM) consumptions has been started and increased but also the trends of decreasing the analgesic consumption continues during the therapy with some minor fluctuations. Few subjects left the therapy in between when they gain the health and analgesic consumption is no more required for them. (By Fig. 3)

As the gap between the feedback duration increases the rate of improvement of subject of shifting from Analgesic to alternate or other or no medication has been reduced. Even the gap seems to be resulted in de motivation due to which for few types of medication negative rate has also been observed.

After 3 months and 6 months 33.33% improvements were recorded in no. of subjects shifting from AC zone to No Medication Zone. The Movement from AC zone to drop Outs were counted as total in One Month were 0, in 3 months 3, in 6 months 3 and 12 months 6 were measured in the therapy.

Overall during EMGa therapy time 33.33% of subject has been either moved from AC to optional medication or stopped taking medicines.

b) EMGv Mode

The trend observed during the study with the number of subjects moving from one medication bucket to other has been drawn to visualize the effectiveness of techniques.

In the EMGv subject group, during baseline period 100% of subject were on medication out of which all 100% were on Analgesic consumption. After the 1 month of therapy period 11.11% increase in count of subject has been observed who stopped taking the medicines. Also 22.22% drop is observed in the analgesic consumption patient. With the passage of time it has been observed that alternative medicine (AM) consumptions has been started and increased but also the trends of decreasing the analgesic consumption continues during the therapy with some minor fluctuations. Few subjects left the therapy in between when they gain the health and analgesic consumption is no more required for them. (By Fig. 3)

As the gap between the feedback duration increases the rate of improvement of subject of shifting from Analgesic to alternate or other or no medication has been reduced. Even the gap seems to be resulted in de motivation due to which for few types of medication negative rate has also been observed.
c) EMGav Mode

The trend observed during the study with the number of subjects moving from one medication bucket to other has been drawn to visualize the effectiveness of techniques. In the EMGav subject group, during baseline period 88.88% of subject were on medication out of which all these were on Analgesic consumption. After the 1 month of therapy period 23.07% increase in count of subject has been observed who stopped taking the medicines. Also 16.66% drop is observed in the analgesic consumption patient. With the passes of time it has been observed that alternative medicine (AM) consumptions has been started and increased but also the trends of decreasing the analgesic consumption continues during the therapy with some minor fluctuations. Few subjects left the therapy in between when they gain the health and analgesic consumption is no more required for them. (By Fig. 5)

As the gap between the feedback duration increases the rate of improvement of subject of shifting from Analgesic to alternate or other or no medication has been reduced. Even the gap seems to be resulted in de motivation due to which for few types of medication negative rate has also been observed.

After 3 months 32% and after 6 months 40.9% the improvements were recorded in no. of subjects shifting from AC zone to No Medication Zone.

The Movement from AC zone to drop Outs were counted as total in One Month were 2, in 3 months 8, in 6 months 9 and 12 months 10 were measured in the therapy.

Overall during EMGav therapy time 40% of subject has been either moved from AC to optional medication or stopped taking medicines.

D. Trend Observed During Medication in different Modes of GSR Biofeedback Therapy

Trend Observed During Medications (all types of educations individually) and Then Observed (Drug Groups Combined and Alternative Medications, No Medications and Dropouts-NA)

a) GSRa Mode

The trend observed during the study with the number of subjects moving from one medication bucket to other has been drawn to visualize the effectiveness of techniques.

In the EMGav subject group, during baseline period 88.88% of subject were on medication out of which all these were on Analgesic consumption. After the 1 month of therapy period 23.07% increase in count of subject has been observed who stopped taking the medicines. Also 16.66% drop is observed in the analgesic consumption patient. With the passes of time it has been observed that alternative medicine (AM) consumptions has been started and increased but also the trends of decreasing the analgesic consumption continues during the therapy with some minor fluctuations. Few subjects left the therapy in between when they gain the health and analgesic consumption is no more required for them. (By Fig. 5)

As the gap between the feedback duration increases the rate of improvement of subject of shifting from Analgesic to alternate or other or no medication has been reduced. Even the gap seems to be resulted in de motivation due to which for few types of medication negative rate has also been observed.

After 3 months 21.73% and after 6 months 27.27% the improvements were recorded in no. of subjects shifting from AC zone to No Medication Zone.

The Movement from AC zone to drop Outs were counted as total in One Month were 1, in 3 months 4, in 6 months 5 and 12 months 6 were measured in the therapy.

Overall during EMGav therapy time 28.57% of subject has been either moved from AC to optional medication or stopped taking medicines.
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The trend observed during the study with the number of subjects moving from one medication bucket to other has been drawn to visualize the effectiveness of techniques.

In the GSRa subject group, during baseline period 92.3% of subject were on medication out of which 88.46% were on Analgesic consumption. After the 1 month of therapy period 19.23% increase in count of subject has been observed who stopped taking the medicines. Also 26.08% drop is observed in the analgesic consumption patient. With the passes of time it has been observed that alternative medicine (AM) consumptions has been started and increased but also the trends of decreasing the analgesic consumption continues during the therapy with some minor fluctuations. Few subjects left the therapy in between when they gain the health and analgesic consumption is no more required for them. (By Fig. 6)

As the gap between the feedback duration increases the rate of improvement of subject of shifting from Analgesic to alternate or other or no medication has been reduced. Even the gap seems to be resulted in de motivation due to which for few types of medication negative rate has also been observed.

After 3 months 20% and after 6 months 36.84% the improvements were recorded in no. of subjects shifting from AC zone to No Medication Zone.

The Movement from AC zone to drop Outs were counted as total in One Month were 0, in 3 months 1, in 6 months 5 and 12 months 10 were measured in the therapy.

Overall during GSRa therapy time 37.5% of subject has been either moved from AC to optional medication or stopped taking medicines.

b) GSRv Mode

The trend observed during the study with the number of subjects moving from one medication bucket to other has been drawn to visualize the effectiveness of techniques.

In the GSRv subject group, during baseline period 100% of subject were on medication out of which 79.31% were on Analgesic consumption. After the 1 month of therapy period 22.22% increase in count of subject has been observed who stopped taking the medicines. Also 43.47% drop is observed in the analgesic consumption patient. With the passes of time it has been observed that alternative medicine (AM) consumptions has been started and increased but also the trends of decreasing the analgesic consumption continues during the therapy with some minor fluctuations. Few subjects left the therapy in between when they gain the health and analgesic consumption is no more required for them. (By Fig. 7)

As the gap between the feedback duration increases the rate of improvement of subject of shifting from Analgesic to alternate or other or no medication has been reduced. Even the gap seems to be resulted in de motivation due to which for few types of medication negative rate has also been observed.

After 3 months 44% and after 6 months 37.5% the improvements were recorded in no. of subjects shifting from AC zone to No Medication Zone.

The Movement from AC zone to drop Outs were counted as total in One Month were 2, in 3 months 4, in 6 months 5 and 12 months 13 were measured in the therapy.

Overall during GSRv therapy time 31.25% of subject has been either moved from AC to optional medication or stopped taking medicines.

c) GSRav Mode
The trend observed during the study with the number of subjects moving from one medication bucket to other has been drawn to visualize the effectiveness of techniques.

In the GSRav subject group, during baseline period 100% of subject were on medication out of which all of them were on Analgesic consumption. After the 1 month of therapy period 11.11% increase in count of subject has been observed who stopped taking the medicines. Also 7.4% drop is observed in the analgesic consumption patient. With the passes of time it has been observed that alternative medicine (AM) consumptions has been started and increased but also the trends of decreasing the analgesic consumption continues during the therapy with some minor fluctuations. Few subjects left the therapy in between when they gain the health and analgesic consumption is no more required for them. (By Fig. 8)

As the gap between the feedback duration increases the rate of improvement of subject of shifting from Analgesic to alternating or other or no medication has been reduced. Even the gap seems to be resulted in de motivation due to which for few types of medication negative rate has also been observed.

After 3 months 25% and after 6 months 30.43% the improvements were recorded in no. of subjects shifting from AC zone to No Medication Zone.

The Movement from AC zone to drop Outs were counted as total in One Month were 0 , in 3 months 3, in 6 months 4 and 12 months 8 were measured in the therapy.

Overall during GSRav therapy time 26.31% of subject has been either moved from AC to optional medication or stopped taking medicines.

**III. NOVELTY IN OUR WORK**

In present scenario the problem of stress has emerged out to be as a big problem. Each person belonging to any class and society is now some and how affected by the problem of stress and thus face TTH. 13,14 Our research work is unique on its own which aim at reducing the headache level. Based on results it was seen the transfer of people from one group to other. These type to research is really helpful for society seeing the increasing number of sufferings, 15,16,17,18

**IV. FUTURE SCOPE, LIMITATIONS AND POSSIBLE APPLICATIONS**

The study was conducted by our researcher on the limited number of people. The study in the future may be conducted on various type of people residing in various regions.

This TTH depends on various factors like age, gender, climate, region etc. The effect of biofeedback in future can be seen on people of different age, gender of various countries. The study is also affected by the various factors like education and mental status. The biofeedback therapy is very useful their effects can also be seen on various other health related problem. Although the biofeedback is very useful yet the cost to afford this therapy is still not in reach of common people. Efforts can be made in making this therapy accessible for every class of people whether high or low. 19,20

Various healthcare devices can be made which once attached or worn by the patient can take the readings of various parameters, so the effect of biofeedback can easily be studied. These devices will not only help the researcher but will help the doctors in providing best healthcare facilities to the patient. Devices like these have been made and some better are yet to be launched in the market. The further research work may be conducted taking help of these devices. 21,22,23,24

**V. CONCLUSIONS**

It was seen that with the starting of the experiment the we had 96 people in AC group in the 1st month, which get reduced to 69 in the 3rd month, 57 in 6th month and 37 in the 12th month.

On seeing the results of Am group there was 1 single person in the 1st month, and in the 3rd month,4 in 6th month and 7 in the 12th month. The number of persons kept on increasing in this group.

In no medication group there were 14 people in the 1st month,17 in the 3rd month 22 in the month,31 in the 12th month. Here the number of people increased with increase in time.

In PM group there were 22 people in the 1st month, 14 in the 3rd month,8 in the 6th month, 4 in the 12th month. Here the people decreased with increased in time.

While in NA group there were 3 people in the 1st month, 17 in 3rd month, 27 in 6th month and 48 in the 12th month. 25,26,27,28

The Overall Scenario shows a clear picture that EMGv has the best performance in terms of analgesic consumption dropouts and benefits to the subjects in biofeedback therapy in the period of stipulated time of 12 months in the cure of Chronic TTH.

Overall during EMGv therapy time 40% of subject has been either moved from AC to optional medication or stopped taking medicines.

Also, in overall scenario, EMG therapy is showing better performance over the GSR therapy.
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