Utility of passiflora incarnata homoeopathic mother tincture in general anxiety disorder: A pilot study

Dr. Basavaraj S Adi and Dr. Siva Rami Reddy E

Abstract
A pilot study in utility of passiflora incarnata tincture in General Anxiety Disorder. General anxiety disorder is the most common anxiety disorder but is generally less severe than panic disorder. The study was performed on 30 out patients diagnosed with General Anxiety Disorder using DSM IV criteria. Patients were allocated in a random fashion. Passiflora tincture 20 drops per day at bed time up to six month. The results suggest that passiflora incarnata tincture is an effective drug for the management of generalized anxiety disorder and the low incidence of impaired of job performance with passiflora compared to other drugs is an advantage.

Methodology: A Pilot Study was carried out on Bhartish Homoeopathic Medical College, Hospital and Research Center, Belgaum, Karnataka. The study was selected 30 patients based on purposive sampling method, 30 diagnosed cases were considered. Data collected were analyzed and inferred with T test used to calculate.

Result: The overall response of the treatment with the help of Passiflora Incarnata 7% not improved, 37% improved and 56% patients in General Anxiety Disorder.

Conclusion: Homoeopathic Mother Tincture Passiflora Incarnata very effective in treating General Anxiety Disorder. There was no side effect during the study/treatment.

Keywords: General anxiety disorder, passiflora homoeopathic mother tincture, outcome

1. Introduction
General anxiety disorder (GAD) is a syndrome of ongoing anxiety and worry about many events or feelings that the patient generally recognizes as extreme and inappropriate (DSM-IV-TR). Individuals manifest both physical and mental symptoms leading to significant distress or impairment. General anxiety disorder is a syndrome of ongoing anxiety and worry about many events or thoughts that the patient generally recognizes as excessive and inappropriate. However, the nature of “generalized worry” has been hard to describe in a categorical manner. The criteria required for making a diagnosis are evolving; these criteria clearly increase or decrease markedly the threshold for diagnosis [1]. Anxiety disorders are one of the most prevalent and highly comorbid psychiatric conditions [2]. Since the past decade, many herbal medicines have been used in people with anxiety disorders [3]. Due to the increasing popularity of herbal medications majority of the patients are consulting herbalists, naturopaths, and other healers, in addition to physicians. There is however, a limited data regarding the benefits and liability of herbal remedies. There have been few reports of serious adverse effects from these medications and by and large these medications have been considered safe and effective [4]. A persistent state of anxiety i.e lasting for at least six months, characterizes GAD. Anxiety and apprehensive expectation need to be accompanied by additional symptoms belonging to a motor tension cluster (muscle tension, restlessness and easy fatigability) or to vigilance and scanning cluster (difficulty falling or staying asleep, restless, unsatisfying sleep, difficulty concentrating and irritability). According to DSM-IV [3], the diagnosis is not made if the symptoms exclusively relate to another Axis I disorder. As sleep disturbances are part of the diagnosis requirement, a high prevalence of these symptoms is expected in General anxiety disorder. For instance, in mental health epidemiological surveys, ohayon et al [6] found that, among subjects complaining of insomnia and having a primary diagnosis of mental disorder General anxiety disorder was the most prevalent diagnosis. It has been estimated that about 60% to 70% of patients with General anxiety disorder have insomnia complaint. Whose severity parallels that of the anxiety disorder [7, 8] suggesting that insomnia could represent one of the core symptoms of General anxiety disorder. General Anxiety disorder is probably the disorder most often found with a coexisting mental order usually another anxiety disorder or a mood
disorder [9]. The ratio of women to men is about 2:1. The cause of General anxiety disorder is not known. The primary symptoms of General anxiety disorder are anxiety, motor tension, autonomic hyperactivity and cognitive vigilance [9]. DSM IV [10] employs the following criteria for General anxiety disorder; excessive anxiety and worry, occurring more days than not for at least 6 months, about a number of events or activities that are difficult to control. Autonomic symptoms are no longer required for diagnosis. The principal neurotransmitter systems thought to modify anxiety are the gamma aminobutyric acid (GABA) system and the noradrenergic, serotonergic, dopaminergic and histaminergic system [11, 12]. GABA is an important and abundant inhibitory transmitter in the mammalian nervous system. Three types of GABA receptor may be distinguished on the basis of their pharmacological properties and physiological consequences of their activation; GABA$_A$, GABA$_B$, and GABA$_C$. GABA$_A$ receptors can be allosterically regulated by a diverse range of both naturally occurring and synthetic compounds [13-18]. These substances include the barbiturates and benzodiazepines, which have important sedative, anxiolytic and anticonvulsant uses [19-24]. The most effective treatment of patients with General anxiety disorder is probably one that combines psychotherapeutic, pharmacotherapeutic and supportive approaches. Because of the long term nature of the disorder, a treatment plan must be carefully thought out. The primary mechanism action passiflora involves modulation of neuronal communication, via specific plant metabolites binding to neurotransmitter/neuromodulator receptors [25] and via alteration of neurotransmitter synthesis and general function [26]. Other mechanism involve stimulating or sedating CNS activity and regulating or supporting the healthy function of endocrine system. [25-27] This plant is a benzodiazepine receptor partial agonist and causes GABA system mediated anxiolysis.

2. Material Methods

This study was conducted as on the cases available from December 2016 to December 2017. The present study was carried out in Department of Pharmacy at Bhartish Homeopathic Medical College, Hospital and Research Center, Belgaum, Karnataka. Out of thirty patients, 30 to 60 years age group selected for this Pilot study. They are taken regular Out Patient Department after eligibility criteria, inclusion and exclusion criteria history and interview were taken as per the standard Proforma, reference to a different Psychiatric, Homoeopathic Materia Medica [28]. Repertory and therapeutic book was done. Follow up: Each Patient was reviewed every 15 days for 6 month and after six month up to one year (or) as per requirement of the case.

Symptomatic Assessment: This study was conducted over one year duration. Taken consultant signature from patients, Psychiatrist and Counselor opinion. Clinical reexamination was performed at end of three months, six months and one year. The test applied for analysis of date was T Test. Outpatient in group one received fixed daily doses of passiflora Homeopathic Mother Tincture 20 drops/day. Thirty out patients (15 women and 15 men), diagnosis of General anxiety disorder (duration of illness 6 months) and had a score of 14 or more on the Hamilton anxiety rating scale (HAM-A) were recruited. Patients were excluded if screening showed a history of a serious ideation an unexpected recent panic attack or full DSM IV panic disorder within the previous 6 months, a life time diagnosis of DSM IV mania, psychosis, obsessive compulsive disorder (OCD), hypomania or major depression. Pregnant and lactating women were also excluded. Prior to the study the patients were free from all psychotropic medication for a minimum of one week. Study was carried out after the approval and following the guidelines of the institutional Ethical Committee.

3. Result

Among thirty General anxiety disorder patients with mean ± SD, maximum cases were observed in age group of 20 to 30 years in 7 (23.33%) cases, 30-40 years in 15 (50%), 40-50 years in 5 (16.66%), 50 – 60 years in 3 (10%). Out of thirty General Anxiety Disorder patients distributed according to sex are males 15(50%) and females 15(50%).

Table 1: Distribution of General anxiety disorder according to Sex

<table>
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<tr>
<th>Sex</th>
<th>No of Cases</th>
<th>Percentage (%)</th>
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<tr>
<td>Male</td>
<td>15</td>
<td>50.00</td>
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<tr>
<td>Female</td>
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<td>50.00</td>
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<tr>
<td>Total</td>
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Table 1: Distribution of General anxiety disorder according to Age group

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<tr>
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</tr>
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<td>20-30</td>
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<tr>
<td>50-60</td>
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<td>10.00</td>
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<tr>
<td>Total</td>
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<td>100</td>
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</tbody>
</table>

Fig 1: Distribution of Treatment out come in General anxiety disorder

Associated symptoms were the symptoms that had no direct relation with the disease but were present in the patients of General anxiety disorder. It was observed that 7% not improved, 37% improved and 56% patients are recovered during Pilot Study.

4. Discussion

General anxiety disorder is a syndrome of ongoing anxiety and worry about many events or thoughts that the patient generally recognizes as excessive and inappropriate. However, the nature of generalized worry has been hard to describe in a categorical manner. The criteria required for making a diagnosis are evolving: these criteria clearly increase or decrease markedly the threshold for diagnosis. This pilot study was conducted on the patients who attended the out patients department at Bhartish Homeopathic Medical college, Hospital and Research Center, Belgaum, Karnataka. Among thirty General anxiety disorder patients
with mean ± SD, maximum cases were observed in age group of 20 to 30 years in 7 (23.33%) cases, 30-40 years in 15 (50%), 40-50 years in 5 (16.66%), 50-60 years in 3 (10%). Out of thirty General Anxiety Disorder patients distributed according to sex are males 15(50%) and females 15(50%). The pilot study was observed that 7% not improved, 37% improved and 56% are recovered during Pilot Study.

5. Conclusion
General anxiety disorder (GAD) is common in the community. Individuals manifest both physical and psychological symptoms leading to significant distress or impairment. Most homoeopathy medications may serve as alternatives to traditional anxiolytics in patients who do not tolerate them as they have a favorable safety profile and are free from major side effects. To the best of our knowledge the present pilot study is controlled trial of Passiflora in the treatment of GAD (General anxiety disorder). Our main overall finding was that passiflora extract Homoeopathic tincture are effective in the treatment of GAD (General anxiety disorder). Significant effects were observed by first month, three months and six months. The study depicts that 56% of patients got relief from the Passiflora Homoeopathic Mother Tincture and this is not a small Scale. There were no side effect during the treatment and it can be concluded that Passiflora Homoeopathic Mother Tincture can be helpful to the patient to take a new lease on life. With the help of use of Homoeopathic Mother Tincture even other system drugs side effect was avoided. A large scale trial is justified.

6. References