

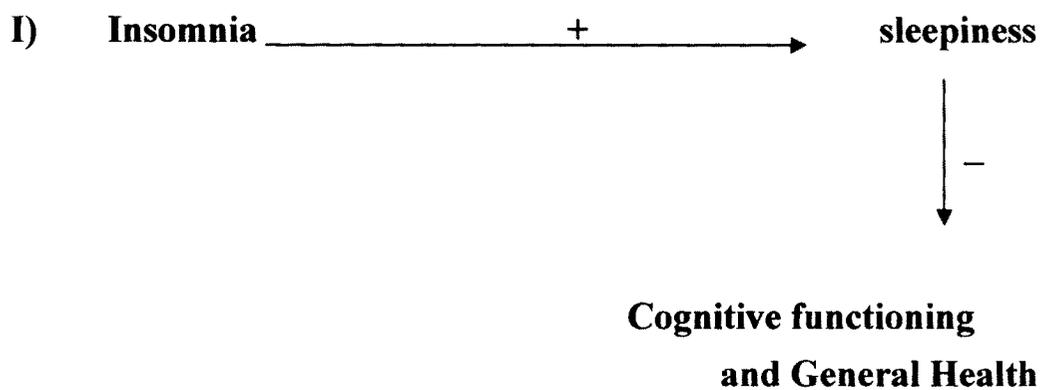
CHAPTER-V

DISCUSSION

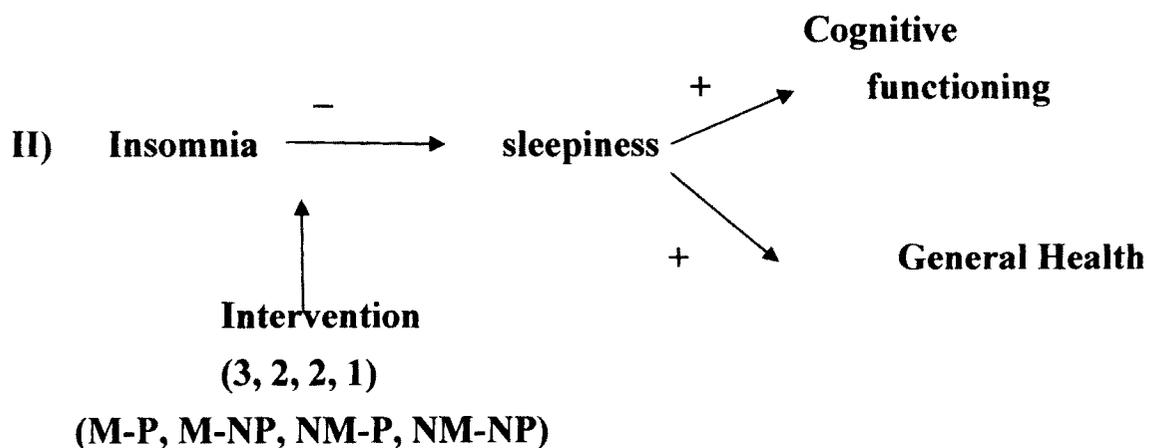
DISCUSSION

The present study was carried out to determine the alterations in cognitive and psychological aspects of life, some selected variables being sleepiness, reaction time, learning, memory and health and its assessment and finally suggest some suitable measures of management in insomniacs to overcome the related problems. Data were collected on adult population. The sample was taken from the clinics. Data obtained were analyzed and the results obtained have thus been presented in detail in previous chapter. The discussion thus follows with respect to the obtained result and proposed hypotheses.

Model



In above model it is shown that insomnia or disturbed sleep would lead to increased daytime sleepiness and in turn sleepiness would result into poor and slow cognitive functioning and reduced general health.



In this model, it is evident that insomnia leads to increased daytime sleepiness but when intervened accordingly it can result in improvements in both cognitive functioning and general health. There is predictive intervention impact on sleepiness as well as simple reaction time, learning, memory and general health.

The overall impression from the data in our study is that three months later, few patients still had insomnia, although there was a general improvement in cognitive functioning and health. The number of nights per week of disturbed sleep decreased, subjective total sleep time increased, daytime sleepiness declined, there was an increase in feeling refresh in the morning and there was a trend toward decreased global complaints of poor sleep.

At a three month follow up, insomniacs tended to do better regardless of treatment modality of the four conditions given (both Management and Prescription, only Management, only Prescription, neither Management nor Prescription but placebo), management was found to show statistically significant improvement at follow up. CBT holds promise as a potential treatment alternative for chronic insomnia. Interestingly, Hauri (1993) found that even a single session could improve insomnia for many of his patients.

Insomniacs had both psychological and cognitive alterations as compared to control group

The results of the present study demonstrate that chronic insomnia in adults is associated with impairment in cognitive performance and psychological variables. Overall, the results demonstrate that for almost all aspects of cognitive and psychological performance, tested via the validated tests, insomnia exhibit altered cognitive and psychological functions than normal controls. More specifically, the results reveal significant differences between insomniac participants and normal participants in sleepiness, reaction time, learning, memory and health. These results are exciting in light of the growing interest and emphasis on understanding and finding solutions for cognitive and psychological impairment among insomniacs.

- **Daytime Sleepiness among insomniacs was more prominent.**

Physicians often ignore sleep disorders such as insomnia in clinical practice, in part because of increasing time constraints and because of poor preparation to deal with sleep disorders (Zorick, Roth and Hartse, 1981). Nowell, Mazumdar et al in 1997 reviewed 10,000 medical records from 9 family practice clinics, finding only 123 records that contained a note about the patient's sleep; not a single record suggested an effective response to the patient's sleep complaint. Ignoring insomnia can have major implications for public health, however. Insomnia increases the risk of occupational injury and traffic accidents; a recent study concluded that driving while sleepy was at least as dangerous as the risk of driving under the influence of alcohol (Ferrans and powers, 1992). Similarly, a 1991 national survey showed that respondents with chronic insomnia are more likely to feel sleepy when driving, to have impaired concentration, and to have problems in accomplishing daily tasks (Cameron, Whiteside et al, 2000).

Numerous studies in the general population have demonstrated that poor or reduced amounts of sleep and in turn excessive daytime sleepiness adversely affect a variety of quality of life and functional health status indicators (Dinges, Pack et al, 1997; Gottlieb, Redline et al, 2006; Hoddes, Zarconce et al, 1973; Lichstein, Wilson et al, 1994; Briones, Adam et al, 1996). Both problems have also recently been associated with cardiovascular disease (Janson-Frojmark and Linton, 2008; LeBlanc, Merette et al, 2009). Thus, we examined how sleepiness is related to both subjective and objective measures of sleep in a sample of insomnia patients. Sleep complaints that characterize insomnia (Benca, Ancoli-Israel and Moldosfky, 2004) including difficulty initiating sleep, early morning awakenings, and feeling unrefreshed in the morning, are particularly important. A study by Weiss, Kasinoff and Bailey (1962) also noted that complaints of insomnia were associated with pain, depression, increased sleepiness and decreased physical functioning.

These findings suggest that the assessment and treatment of insomnia-related complaints should be included in any overall plan of care designed to optimize sleepiness as well as other important clinical outcomes.

Numerous pharmacological and/or cognitive behavioral techniques are efficacious for treatment of insomnia but controlled clinical trials designed to evaluate their effectiveness in insomnia patients

remain to be conducted (Buysse, 1997; Fetveit, Arne et al, 2003; Kales and Kales, 1974; Fry, 1963). Excessive daytime sleepiness and decreased functional status are prevalent in health community samples that are sleep restricted to this extent (Dinges, Pack et al, 1997; Roehrs and Roth, 2003; Spielman, Saskin and Thorpy, 1987). Because sleep requirements vary, overall perceived sleep quality, including subjective responses to sleep and the ability to function optimally during the day, may be more important than absolute amount of sleep obtained.

It is interesting to note that Sadeh et al demonstrated an increased risk of mortality associated with chronic nocturnal sleep periods less than or equal to six hours (Sadeh, Hauri and Kripke, 1995). In a 10-year follow-up from NHANES I, Quan et al. also found an increase in stroke in persons who reported greater than eight hours or less than six hours per night (Quan, Howard et al, 1997). Increased napping has also been associated with increased mortality in the elderly (Reynold, Frank et al, 1997; Bursztyn, Ginsberg and Stessman, 2000; Benca, Ancoli-Israel and Moldosfky (2004). Because of the high prevalence of both sleep abnormalities and divorce in the HD population, investigations of the effects of sleep problems on marital relationships represents an important area for future research.

- **Cognitive performances i.e., Simple Reaction Time, Learning and Memory were affected by insomnia**

There is a major link between sleep deprivation and performances on reaction time. Many people don't get just how badly their reaction time can suffer if they are sleep deprived. Lives have been, and continue to be, forfeited because of this wide misconception. The latest studies show that any person missing out on sleep operates at nearly the same proficiency level (really low) like a person who is legally intoxicated.

When suffering from a lack of sleep, our brain basically goes into "low power" mode. In this "status", one may be able to function and perform typical daily tasks, unfortunately though, one will not be able to do too much more than that because, aside from reaction time being worse than usual, our hand-to-eye coordination and concentration will be seriously affected too. Consequently, any and all problems, emergencies, and/or "advanced" responsibilities are going

to be completely out of our hands and performances would be affected.

Sadly, many of us don't understand nor care about the relationship between sleep deprivation and reaction time. We think that sleep deprivation is normal and everyone will be missing out on sleep sooner or later. Although this is true, it's not an excuse to ignore chronic insomnia signs. By overlooking our sleep deprivation or insomnia problems, you're not just endangering our own life (by means of accidents and potential illnesses), but are also endangering the lives of others as well.

If believed one may possibly be suffering from serious insomnia problems -- which 30%-50% of the general population is -- then one ought to immediately search for sleep deprivation treatment. Depending on the intensity of ones insomnia sleep problems, one will be able to either treat it by using natural cures for insomnia or may consult a specialist in your area.

These preliminary data also support our initial hypothesis that **memory traces may be impaired in patients with chronic insomnia**. Evidence for this is that the percentage of improvement in draw time from before to after sleep in Wechsler Memory Scale-III was significantly lower in patients with insomnia, compared with matched healthy controls.

Point to be noted here is that patients with insomnia made significantly fewer errors during Wechsler memory scale implementum (with each session).

It would be informative to further assess whether patients with insomnia differ from good sleepers in terms of recall or recognition which might represent a predisposition for the development of insomnia, a consequence of poor sleep, or both. However, the larger improvement among controls in the main outcome parameter of the questionnaire indicates that memory consolidation during sleep may be impaired in patients with primary insomnia. The present findings are preliminary in nature. Their replication and validation would indicate that patients with insomnia may experience difficulties in activities that require procedural learning, such as physical or skilled fine motor activities. The lack of severe deficits indicates that memory consolidation is—assuming that the sleep-memory hypothesis is valid—only to a limited part dependent on sleep.

Interestingly, sleep-related improvement in Wechsler memory scale clearly differed between patients with insomnia and healthy controls, but sleep parameters did not.

In conclusion, the present data suggest that sleep-related consolidation of memory may be impaired in patients with chronic insomnia.

Alternatively, and not excluding the previous hypothesis, there may be interrelationships between age-related changes in sleep and memory through mechanisms of memory consolidation during sleep (i.e., chronic insomnia in the older adults may be a risk factor for cognitive decline). Changes in sleep characteristics in late-life insomnia may lead to impaired memory consolidation during sleep, thereby leading to impaired daytime cognitive performance in these patients (Ancoli-Israel, Kripke et al, 1991; Foley, Monjan et al, 1995; Walsh and James, 2004).

Another potential mechanism for the decline in cognition with insomnia is that disturbed sleep may result in fatigue and decreased alertness during the day (Carskadon and Dement, 1977), which in turn may lead to disturbed waking cognition. This decreased alertness may reduce performance in attention-demanding processes. An additional consequence of the decreased alertness during the day is that it can lead to reduced exposure to cognitively challenging situations that help maintain cognitive abilities. For instance, fatigue can result in decreased interest in reading, hobbies, social involvement, physical activity, and other engagement with one's environment.

The fact that in the present study risk factors contributing to cognitive decline (i.e., education, age, etc.) were controlled supports the conclusion that sleep may be one of the factors contributing to the decline of cognitive functioning in the adults. Our findings suggest that poor quality sleep contributes to cognitive decline in adults and, as a result, renders the insomniac population more susceptible to cognitive deficiencies. Thus, it is particularly important for health care practitioners to screen for, evaluate, and treat insomnia symptoms in patients, particularly those with known cognitive impairments. The findings of this study offer hope that treatment of insomnia in adults can have beneficial effects in improving cognitive functioning in these patients. Thus, attention to and effective treatment of chronic insomnia in these persons may not only improve the quality of their nighttime sleep, but conceivably may also maintain cognitive function, thus improving their overall quality of life.

- **Insomnia had a significant effect on General Health**

Health and insomnia are often linked. Lack of sleep often ends up making people feel exhausted and fatigued and, as a result of chronic exhaustion or fatigue, people start slipping into unhealthy patterns of living. Therefore, both general health and insomnia seem to work together and take a huge physical and psychological toll on people going through these conditions. Initially, a person might experience lack of energy and tiredness, and these will affect the person's thought processes and mood. All of these ultimately result in poor overall health. Thus, general health and insomnia are closely tied. Insomnia or lack of sleep, or sleep deprivation as it is referred to, can create a lot of turmoil for people affected by this condition. This is mainly because they tend to worry and obsess about sleep all the time. Every night, they lay awake in this tension of whether they will be able to fall asleep or not. Slowly, they will lose interest in their personal and professional life, imagine that they are suffering from serious problems, and start becoming depressed. In such cases, it becomes very important to treat the problem of insomnia first and then tackle the issue of health issues. If people suffering from insomnia are able to start sleeping well at night, all their fears will begin to disappear, they will feel revitalized and re-energized every morning, and slowly all the other symptoms of poor general health will soon also fade away.

Our results extend the results of previous investigations by demonstrating that insomnia is independently associated with a significant decrease in overall general health for patients with chronic illness. We found that such decrements worsened with increased levels of sleep disturbance and that these decreased values persisted even after accounting for psychological and cognitive alterations. These findings are similar to the results of a recent population-based investigation, in which insomnia was associated with global decreases in GHQ, even after excluding subjects who met *DSM-IV* criteria for depression or anxiety (Walsh and Engelhardt, 1999). Another possible explanation for the negative association between insomnia and good health is that patients with insomnia report functional impairment in a systematic fashion. This phenomenon has been described as "negative thinking bias, (Ferrans and Powers, 1985) and it is possible that insomnia also leads to biased reporting. While it is difficult to rule this out, analyses of the health care behavior of patients with insomnia provides indirect evidence of the functional impairment of these patients, as measured by their increased use of medical and

mental health services (Evans, Radder and Mannien, 1990; Evans, 1991; Briones, Adams et al, 1996).

There was a strong association between insomnia and mental and physical health that persisted after controlling for known predictors of health. **Compared with 'good sleepers', 'poor sleepers' had lower health in all domains.** The association between insomnia and health may be explained by a direct influence of insomnia on health (or vice versa), an association of both constructs with one or more confounding variables. We hypothesize that health impact directly on sleep and vice versa. These findings are consistent with previous studies (Breslau, Roth and Rosenthal, 1996). In the present study, insomnia remained a significant predictor of mental and physical health. In the present study, insomnia and health were measured using validated questionnaires. The GHQ-12 has been rigorously evaluated as a tool for the measurement of general health.

Time (duration of treatment) plays an important role in improving psychological and cognitive functions.

Chronic insomnia should not be confused with chronic treatment of insomnia. All US Food and Drug Administration (FDA) - approved and later-stage investigational insomnia treatment medications have been evaluated with subjects meeting the criteria for chronic insomnia. Typically these studies required the insomnia to have persisted for atleast 3 months. Potential subjects with significant medical or psychiatric disorders generally are excluded; therefore, the insomnia study subjects are considered to have chronic insomnia. Generally, the efficacy studies of chronic insomnia, however, have been for relatively short term treatment duration – 2 to 5 weeks in most cases. Only over the past few years has long-term treatment efficacy been evaluated in chronic insomnia subjects. Double-blind, placebo-controlled clinical trials of nightly medication use have been reported for 6 months of use. Longer open-label studies without placebo controls do not directly assess efficacy, but are valuable to monitor safety and tolerability.

Management was found to be effective in the treatment of insomnia and its related consequences.

We would like to suggest first that chronic insomnia in the adults represents a treatable syndrome using non-medicated sleep therapy: cognitive behavioral interventions, secondly, that cognitive dysregulation is associated with insomnia and normalizes when sleep improves. It remains to be shown whether the performance of insomniacs on the simple tasks represent a specific characteristic, or whether sleep deprivation in healthy subjects would result in the same effects. As the therapy consisted of a multi-component intervention, it is indicated it has been most effective in alleviating the sleep disorder. This study expressly chose to standardize the sleep therapy rather than tailor the therapy to the individual patient. We admit that this approach precludes any speculation as to which element of the therapy was most effective. Each of the elements has, nevertheless, separately been shown in previous work to be effective against insomnia.

The aim of this study was not to investigate the contribution of separate elements of the sleep therapy; rather, we aimed at measuring the effects of improved sleep on cognition. As sleep disorders are a frequent correlate of neurological and psychiatric diseases, it is relevant to consider their possible contribution to cognitive dysfunction normally seen as part of these disorders. An implication of the current findings would be that if the sleep disorder is treated adequately, cognitive functioning might improve, which would benefit further cognitive or behavioral interventions aimed at the primary diagnosis (Kales and Kales, 1974). Sleep therapy could in that sense be regarded as a means to optimize the mental status of the patient, allowing full benefit from subsequent interventions.

In stylus maze learning, following sleep-dependent performance gains, the capacity for additional rehearsal-based learning appeared to temporarily stall, with continued retesting (rehearsal) across day 20 yielding no further improvements in motor-skill speed. It would therefore appear that the large increase in performance produced by a night of sleep comes at the expense of potential improvement with rehearsal the next time. But, as discussed below, this diminished learning potential does not represent the end of all further improvement. A previous

report has demonstrated that performance on this task continues to improve with repeat testing across many weeks (termed the slow component of learning).

The profile of performance fits with the hypothesis of a decrease performance on tasks (reaction time and learning) in the insomnia patients (Williamson, Edward and Haines, 1966).

Upon the therapy in our group of patients, performance and the slow responses on the complex task significantly returned to normal, i.e. performance after sleep therapy was comparable to that of healthy well sleeping age-matched controls. This would indicate that the **cognitive sequel of insomnia, are responsive to treatment.**

The results from this study indicate that cognitive-behavior therapy is an effective method for the management of sleep disturbances in a heterogeneous group of insomnia sufferers seeking treatment at a sleep clinic. Improvement rates ranging on the main target symptoms of sleep onset latency, wake after sleep onset, and early morning awakening are comparable to those previously reported with insomnia patients solicited for participation in research studies (Lacks and Morin, 1992; Lichstein, Durrence et al, 2003; Morin, Kowatch and Wade, 1989). These findings are also consistent with estimates that cognitive-behavior therapy is effective for improving sleep patterns in about 70 to 80% of patients with chronic insomnia (Hauri, 1993; Morin, Culbert, and Schwartz, 1994), and that one third of patients become good sleepers by the end of treatment (Lacks and Powlishta, 1989). The magnitude of improvement was very similar across measures of sleep induction (sleep latency) and sleep maintenance (wake after sleep onset, early morning awakening) with the absolute values of all three variables falling below or returning near the 30-min cut-off criteria typically used to define insomnia.

About one half of all patients suffering from insomnia achieved an improvement rate and many reached a dual criterion of clinical improvement; i.e., they achieved a huge reduction of their target symptoms, while the absolute value of that symptom also fell below 30 min.

The modest gain obtained on total sleep time was not unexpected, because baseline sleep duration in insomniacs does not differ greatly from that in good sleepers. More often, it is sleep efficiency that is diminished, in that patients with insomnia need to spend more time in bed than people without insomnia to achieve the same sleep duration. For this reason, sleep efficiency represents a better index of improvement than sleep duration alone in that it reflects more

adequately on one's abilities to initiate and sustain sleep relative to total amount of time spent in bed. Sleep efficiency data indicate that many patients moved from a dysfunctional to a normative range from baseline to post-treatment. The clinical significance of the present findings is most noteworthy when outcome is evaluated in terms of changes in use of sleep medication. For instance, the number of patients in the total sample who were habitual users of sleep aids, mostly benzodiazepine-hypnotics, decreased a lot by the end of treatment. These results are particularly meaningful given that discontinuation of benzodiazepines, or of any sleep aid, is a rather difficult task (Espie, Lindsay and Brook, 1988; Kirmil-Gray, Eagiaston et al., 1985; Lichstein and Johnson, 1993; Morawetz, 1989). Although psychological interventions are more acceptable than pharmacotherapy (Morin, Gaulier, Barry, and Kowatch, 1992), many insomnia patients have developed drug dependency by the time they seek more specialized treatment. This could explain why only a few patients complaining of insomnia ever seek treatment (Mellinger, Batler and Uhelenhuth, 1985), perhaps fearing that the only intervention available is pharmacologic in nature.

The degree of change in sleep patterns was quite similar across diagnostic subgroups.

It is unclear whether long-term outcome is related more to absolute change scores or to end-point functioning. Longitudinal studies should examine the relationship between these indices of improvements and future sleep patterns, treatment-seeking behaviors, and medication use. The lack of differential treatment response across insomnia subtypes may also suggest a common thread or some overlap among these diagnostic subgroups (Reynolds, Kupfer et al, 1991). Although various factors may initially precipitate insomnia, behavioral and cognitive factors are almost always involved in perpetuating sleep disturbances over time (Morin, 1993; Spielman, Saskin and Thorpy, 1987). The present data suggest then that, regardless of the origin of insomnia, cognitive-behavior therapy is useful in alleviating sleep disturbances, particularly when they have become chronic.

Previous outcome studies have typically excluded patients whose insomnia was associated with medical or psychiatric disorders, or those who were unable to discontinue medication prior to entering a research trial. Although these requirements have yielded more homogeneous samples, composed mostly of young and healthy psychophysiological insomniacs, it has also limited the generalizability of the findings. Because insomnia is so frequently associated with co-morbid psychological and medical disorders, these are the type of patients most likely to seek clinical '

treatment. The clinical relevancy of future controlled trials would be enhanced by including those individuals who are at greatest risk for sleep disturbances and those most in need of nonpharmacological interventions.

The review provides evidence that relaxation therapy and cognitive/behavioral therapy are effective treatments in subsets of the chronic insomnia population.

The benzodiazepines, non-benzodiazepines and antidepressants had a significantly greater risk of harm than placebo, while melatonin did not.

The efficacy of relaxation therapy was greater with short-term treatment compared to long-term treatment. There were no salient differences in the design, population, intervention or method of measurement of sleep outcomes between short- and long-term studies that could explain the differences in effect of relaxation therapy with length of treatment. The possibility exists that the subgroup for long-term treatment did not have sufficient power to detect a statistically significant difference between relaxation therapy and placebo. There were too few long-term studies of cognitive/behavioral therapy to arrive at a conclusion regarding the difference in efficacy of this intervention with short- and long-term treatment. There was no evidence to suggest that treatment efficacy is affected by age or gender distribution of the population. It is noteworthy that many of the sub-group analyses were conducted with very few studies in sub-groupings, and some analyses could not be performed at all due to lack of data. Thus, the results of these analyses should be interpreted with caution. It is important that future research examine the role of factors such as psychiatric illness, length of treatment, age and gender in treatment efficacy in chronic insomnia.

We made an *a priori* decision to combine summary estimates of outcomes even if they were measured by different methods i.e. (ESS and sleep diary). We assumed that any differences between methods would be cancelled out when absolute differences in the effect of treatment and placebo were obtained. This assumption is correct as long as the differences in measurement between methods were not correlated with the value of the measurement, which is a reasonable assumption in our view. There was no evidence of an effect of barbiturates, hormone therapy,

alcohol and low energy emission therapy on sleep onset latency of chronic insomniacs. The lack of evidence may reflect the low number of studies and/or participants encompassed by these categories. It would be worthwhile to explore these interventions in future research on chronic insomnia.

Non prescription or placebo was found effective in treating insomnia and its related cognitive and psychological alterations

For decades, the gold standard of medical research has been the double-blind, placebo-controlled clinical trial. However, in our study we used single-blind, placebo-controlled research. One group of patients is given physicians prescription, and another group a *dummy pill* that has no active ingredients. The patients were not aware of this and doctors knew who is getting which.

Placebo trials are used to tell researchers whether a tested drug has any healing effect beyond that which occurs a certain percentage of time when people take an inert pill. A patient's belief in a pill – a *supposed* medicine, but chemically innocuous – is thought to activate their body's healing powers.

It is a fact that studies that have utilized placebos have produced some rather remarkable. and at the same time unexplainable, results. Rather than looking at it as a nuisance, we should be looking at the placebo as a key to ascertain a remarkable phenomenon that seems to be a part of the human psyche. Similar results were obtained in our study. Placebo proved to be a useful and imperative in the treatment of insomnia and the cognitive functioning and general health of the patients.

The effectiveness of a placebo in any given circumstance also varies greatly. In nine double-blind studies comparing placebos to aspirin, placebos proved to be 54 percent as effective as the actual analgesic. From this, one might expect that placebos would be even less effective when compared to a much stronger painkiller such as morphine, but this is not the case. In six double-blind studies placebos were found to be 56 percent as effective as morphine in relieving pain.

In the book, *The Psychobiology of Mind-Body Healing*, written by Ernest Lawrence Rossi, we find the following mention about the 55-60% placebo connection, “In other words, the effectiveness of placebo compared to standard doses of different analgesic drugs under double-blind circumstances seems to be relatively constant...it is worth noting that this 56% effectiveness ration is not limited to placebo versus analgesic drugs. It is also found in double-blind studies of non-pharmacological insomnia treatment techniques (58% from 14 studies) and psychotropic drugs for the treatment of depression such as tricyclics (59% from 93 studies reviewed by Morin & Espie, 2003) and lithium (62%). Thus, it appears that placebo is about 55-60% as effective as active medications irrespective of the potency of these active medications.”

Use of placebos is not immoral or unethical. In reality, it seems that the medical profession’s lack of understanding and utilization of the mechanism of the placebo in the healing process is tragic, shortsighted and cowardly. Cowardly in the aspect that it has been far easier for doctors to simply say that the placebo response is worthless, and nothing more than someone’s wishful thinking or trickery of the mind. The bottom line is the response; for whatever reason, placebos seem to work... patients get better.

Despite the fact sleeping pills are the most frequently prescribed treatment for insomnia, and newer generation medications are being introduced, they are not recommended for long-term treatment of insomnia. This is due to numerous and well-documented side effects, such as dependency. Prior studies also indicate that insomnia patients prefer non-drug approaches. These results of this study suggest that CBT should now be considered the first line treatment for insomnia and placebo can be considered next. Medication or prescription should be avoided to an extent as they did not prove much beneficial.

Conclusions

Even after accounting for the presence of chronic medical co-morbidities, depression, and anxiety, insomnia is associated with significantly worsened health, particularly in the domains of mental health, vitality, and general health perceptions. By identifying and treating chronic insomnia, including any predisposing conditions that may perpetuate insomnia, clinicians can

significantly improve the quality of life of patients with chronic illness. Chronic insomnia is a major public health problem affecting millions of individuals, along with their families and communities. Little is known about the mechanisms, causes, clinical course, co-morbidities, and consequences of chronic insomnia. Evidence supports the efficacy of cognitive-behavioral therapy and benzodiazepine receptor agonists in the treatment of this disorder. Very little evidence supports the efficacy of other treatments, despite their widespread use. Moreover, even for those treatments that have been systematically evaluated, the panel is concerned about the mismatch between the potential lifelong nature of this illness and the longest clinical trials, which have lasted 1 year or less. A substantial public and private research effort is warranted, including the development of research tools and the conduct of longitudinal studies and randomized clinical trials. Finally, there is a major need for educational programs directed at physicians, health care providers, and the public.

Insomnia is a considerable worldwide health issue because of its influence on concomitant pathologies, increased burden on healthcare resources, and associated number of lost workdays. In spite of its prevalence and significant negative impact on the health, insomnia receives inadequate attention from health authorities and physicians. This is reflected at the diagnostic level, as insomnia is not always promptly recognized, mainly because more than one-half of patients with insomnia do not refer symptoms to their general physician. In a study carried out by the WHO, < 50% of insomnia patients were identified by their primary-care physician and other reports have confirmed that insomnia goes unidentified in about two-thirds of sufferers (Shochat, Umphress and Israel 1999). In 1995, a representative German study reported that only 17% of individuals with insomnia for < 2 years and 49% of those with insomnia lasting > 2 years presented to their primary-care physician for insomnia (Tsoi and Kua, 1984; Bixler, Kales et al, 1979). A study in 1997 involving a cohort of 10 000 subjects representative of the general population in Italy confirmed a tendency not to communicate symptoms of insomnia to general physicians, even when experienced at high frequency (Bellantuono, Fiore et al, 1987). This is attributed to the fact that insomnia is considered to be a personal problem; indeed, when symptoms were referred, this was often during consultation for other medical problems (Bellantuono, Fiore et al, 1987; Carskadon and Dement, 1977). Thus, it would seem that the general physician has a key role in modifying the current management of insomnia. Such a

hypothesis was confirmed by the Morfeo studies in Italy and, in fact, the greater involvement of general physicians in the clinical management of sleep disturbances led to an increase in the proportion of patients undergoing pharmacological treatment from 16% to 44% in only 2 years in that country (Brunton, Lazo and Parker, 2006; Simon and Vonkorf, 1997). Thus, general physicians should be viewed as the primary physicians for treatment of insomnia and, moreover, as having the professional knowledge necessary for its management. Consensus protocols or guidelines are essential for the correct management of any pathology. While several valid guidelines for insomnia management have been proposed, they have not been notably implemented, possibly because they have been targeted to specialists rather than towards general physicians in routine practice. While the general physician cannot inquire about every aspect of patient's health because of practical time limitations, in the case of pathologies potentially involving insomnia, the general physician should specifically inquire about sleep habits and disturbances. Insomnia can be accompanied by a variety of pathologies including psychiatric disturbances and different medical conditions, as well as cardiovascular and neurological pathologies. Moreover, insomnia has an important influence on the prognosis of concomitant pathologies. Therefore, correct diagnosis and management of insomnia leads to a greater probability of successful cure of other conditions. In order to address lack of general physician-focused guidelines for insomnia, the Italian consensus study described here was initiated. This is the first time that general physicians have been directly involved in producing guidelines of this type, reflecting the importance of their role in the appropriate and timely diagnosis and treatment of insomnia. The consensus study group was carefully selected and contained adequate representation from both sleep specialists and general physicians. Formalized procedures, based on structured methodology, were used to obtain consensus. The consensus identified several key statements that are central to the management of insomnia in a routine clinic setting. Importantly, insomnia was considered as an authentic pathology, and, as such, one that should be treated. It should be diagnosed in those patients who report appropriate symptoms, and the causes should be carefully examined. In the presence of concomitant pathologies, considerable care should be given to treatment of insomnia as it can influence prognosis. Moreover, insomnia should be promptly managed and carefully followed up. Correct treatment should consider both the causes of the condition and the characteristics of available drugs. For hypnotic therapy, preference

should be given to drugs with a short half-life in order to limit the appearance of residual effects on the morning after use.

Tablets are favored over liquid preparations as they are less likely to lead to patient-adjusted dosages and dependence. Finally, non-BZD hypnotics are preferred to classic BZDs as they are more selective and reduce the risk of undesirable effects. BZD drugs should be utilized only in selected cases. The results of the present consensus study confirm that general physicians play a key role in the management of insomnia. The guideline statements identified by general physicians and specialists in sleep disturbances can provide more applicable and useful criteria for effective insomnia management in the routine general practice setting. Furthermore, the participation of general physicians in the development of the consensus should be a key factor in enabling the guidelines to be implemented in clinical practice. To help people sleep well, it is important to exercise well, eat a balanced diet, meditate, listen to soft music, read at night, drink some hot relaxing herbal tea, and sleep on a mattress that is comfortable and cozy. There are also several simple but very important remedies that will help people sleep well at night, and some of them include aromatherapy, oil massages, acupuncture, etc, which are extremely effective in helping people go into a deep slumber. Dealing with depression and insomnia using drug medications for sleep should be a last resort, because sleep medications can prove to be extremely harmful to the human body. Further, creating a dependency on these pills or tablets will only create more problems. Natural forms of inducing sleep are always the best options people should exercise, mainly because these are long lasting and do not have any side effects. The ultimate goal is to sleep well and naturally, therefore massages, aromatherapy, herbal remedies, etc, work best and should be given priority in treating insomnia. Once insomnia is treated and cured, all related problems will disappear, affected persons will start feeling better, and sleepiness, cognitive deficits and health symptoms and insomnia problem will be slowly eradicated.

In conclusion, chronic insomnia is a condition that affects many people but can be managed successfully with the proper procedures.

- There is evidence that the prevalence of chronic insomnia in outpatient and clinical populations is larger than in the general population.

- There is evidence that chronic insomnia is associated with older age, female gender, present or past psychiatric illness and psychological problems, medical conditions and poor general health, increased healthcare utilization, lower quality of life and social relationships, socioeconomic status (marital separation, unemployment, poorer working conditions and lower social status), and decrements in memory, mood and cognitive function.
- Additional studies are needed to determine the incidence and natural history of chronic insomnia in adults and to explore the relationship between chronic insomnia and race/ethnicity, shift-work, absenteeism and work performance, accidents, falls in the elderly, and the direct and indirect costs of the disorder. It is necessary that longitudinal studies be undertaken to explore the risk factors and consequences of chronic insomnia.
- There is evidence that benzodiazepines and non-benzodiazepines are effective in the management of chronic insomnia. There is some evidence that antidepressants are effective in the management of chronic insomnia: more research is required in this area. There is evidence that prolonged use of benzodiazepines, non-benzodiazepines and antidepressants pose a risk of harm.
- There is evidence that relaxation therapy and cognitive/behavioral therapy are effective in the management of chronic insomnia in subsets of the chronic insomnia population. Additional large-scale, randomized trials are needed in order to determine its efficacy across subsets of the chronic insomnia population.
- There is insufficient evidence to conclude if there are differences between the short-term and long-term efficacy and safety of the various categories of interventions in the management of chronic insomnia; additional long-term studies are needed.
- There is insufficient evidence regarding the efficacy and safety of combined treatments of pharmacological and psychological interventions, and sequential treatments, in the management of chronic insomnia; additional studies are needed in these area.

Limitations

Every study has its own limitations due to constraints of time and resources available to a researcher. The present study was carried out to understand the cognitive and psychological alterations due to insomnia and possible assessment and management techniques among adults. To determine this, a sample of 200 adults was taken out of which 100 were control group and 100 were insomniacs from Delhi/NCR region. The sample could have been larger but to analyze these relationships to a deeper extent, it was assumed that the study carried out on larger sample was considered sufficient to generalize the results of the study as applicable for the whole population of insomniacs in the country. This study could have been further strengthened by adopting larger samples of population, addition of more survey techniques (such as observations, interviews, etc of the representative sample) as well as qualitative techniques, e.g. narratives on typical cases, participative action research strategies.

The limitations of our study deserve comment. First, the study included a select group of physicians and their patients who agreed to participate in a comprehensive study of medical care. Noteworthy, however, is that the prevalence of mild or severe insomnia in the sample was comparable with that reported in a recent study of managed-care enrollees. Second, this analysis is based on cross-sectional data. We cannot rule out the possibility that decreased health leads to insomnia (i.e., reverse causality). The causal relation of insomnia to diminished health is supported by longitudinal data suggesting that insomnia is an important precursor of sleepiness, simple reaction time, learning, memory and health. Indeed, prior work has shown that worsening of chronic conditions tends to be associated with worsening of insomnia during follow-up, and vice versa. While health and insomnia overlap considerably, pharmacologic and behavioral approaches, including light therapy and exercise, have potential to significantly lessen the burden of chronic insomnia and its effect on health. In addition, clinicians should identify (and treat, if possible) predisposing conditions associated with insomnia.

The main limitation of this study is the absence of polysomnographic data without which it is not possible to ascertain the exact causes of insomnia and sleep disturbance. Because of the cross-sectional design it is not possible to establish cause and effect in the associations examined. It is not possible to accurately measure all variables that may impact on quality of

sleep and the selected variables in the study, and the sample size of the study would limit the examination of numerous independent predictors of health.

Another limitation is the number of and reasons for dropouts in our study. Sixteen patients who were assessed for insomnia and enrolled in the study did not return for treatment or appointments. These patients may have had strong expectations for medications, perceived a lack of treatment credibility, or they may have improved to the point that they did not believe their sleep warranted further care.

Further studies would benefit from attempts to contact dropouts and assess reasons for discontinuance. Lastly, a sampling bias may exist because our sample only included individuals referred by physicians. Providers may have referred only those individuals who they thought would benefit from behavioral interventions, thereby excluding other potential participants and loading the sample with patients more likely to have a positive response.

Because psychopathology reflecting unresolved emotional conflicts typically underlines chronic insomnia, psychotherapy has an important role in treatment. A psychiatric referral should be made when specialized psychotherapeutic techniques are required. However, the general physician should be familiar with basic psychotherapeutic principles useful in treatment insomnia and incorporate them into an overall treatment strategy for approaching the insomniac patient in a supportive, holistic manner.

In treating transient insomnia, the physician should aim at strengthening the patient's ego defenses and adaptive mechanisms, utilizing techniques of brief supportive psychotherapy is more difficult to because of the patient's frequent denial of emotional conflict and the presence of secondary gain.

Review of numerous controlled studies indicates that psychotherapy is beneficial for alleviating many psychiatric conditions. Studies also show that behavioral therapies generally result in symptomatic improvement but are less effective in improving global measures of adjustment. Supportive, psychodynamic, interpersonal, and behavioral therapies often are used in combination, depending upon the patient's clinic features, underlying personality organization, and the multiaxial diagnoses, as well as the expertise of the physician. In this chapter we

discussed the psychotherapy of the disorders that are most commonly associated with chronic insomnia. These disorders include: sleepiness, cognitive dysfunctions and poor health.

The general therapeutic goals include: initial and gradual withdrawal of excessive or inappropriate medication; symptom relief by appropriate pharmacologic means if necessary; education regarding basic sleep hygiene; establishment of improved coping mechanisms for handling stress; development of insight regarding personal vulnerability; improvement in the quality of interpersonal relationship; and restructuring the patient's life style so that it does not revolve around the symptom of insomnia.

The most common therapeutic issues are: denial of any problem areas other than insomnia; strong resistance to exploration of problem areas; need for control, as expressed by manipulation of medications and lack of compliance with general measures; reluctance to become an active participant in the therapeutic alliance, with excessive dependence upon the physician; and withholding of direct expression of negative feelings.

Behavior therapy techniques are often useful in the adjunctive treatment of chronic difficulty in falling asleep and aimed directly at the elimination of the symptom itself. The usefulness of behavior therapy is based upon the observation that insomniacs have high levels of presleep muscle tension and automatic arousal, they habitually associate the bedroom with sleep-incompatible behaviors, and they do not attribute to themselves the ability to sleep. They also hold many misconceptions and negative thoughts about sleep.

Behavior therapy techniques that are most applicable to treating insomnia are: relaxation procedures, stimulus control methods, attribution techniques, and cognitive restructuring. Relaxation and behavior therapy techniques achieve the most favorable results when they are a part of a comprehensive treatment plan and the primary complaint is difficulty falling asleep. Improvement is generally limited to the patient's sleep difficulty and does not extend to other psychological and adjustment problems.