Section: Orthopaedics

Case Series

A 4 WEEK PROSPECTIVE STUDY ASSESSING THE QUALITY OF SLEEP AND PAIN IN PATIENTS WITH CHRONIC LOW BACK ACHE USING LEMBOREXANT : CASE SERIES FROM HILLY REGION OF INDIA

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Abstract

Background: Sleep disruptions are common in individuals with chronic pain, and many of them also take sleep aids in addition to analgesics. Few studies have examined the effectiveness of sleep medicine therapies for alleviating sleep disruptions and reducing pain in people with chronic pain, despite the fact that there have been sporadic reports of negative pain-sleep interactions. We looked back at the effectiveness of lemborexant, an orexin receptor antagonist, in treating chronic pain in patients' sleep disruptions and assessing pain intensity.

INTRODUCTION

Chronic low back pain (CLBP) is frequently linked to negative emotions, functional disability, and a bad quality of life. Poor sleep quality is also recommended by many individuals with chronic pain issues.[1] For instance, Tang and colleagues.[2] discovered that patients with chronic pain had a 53 percent prevalence of clinical sleeplessness, which is 18 times greater than the rate in the healthy control group. An increasing body of research indicates that the neurobiology of chronic pain shares mechanisms with sleep disorders, which could account for the well-established reciprocal association between chronic pain and sleep issues in patients with fibromyalgia, osteoarthritis, and chronic low back pain (CLBP), among other conditions.[3] Research from both longitudinal and experimental studies has confirmed that in healthy individuals, sleep disturbances lead to decreased endogenous pain inhibition and generalized hyperalgesia.[4] A vicious cycle that can be made worse by painkillers negatively impacting sleep might occur when pain gets worse and interferes with sleep.[5]

Through the stimulation of wake drive and arousal, the orexin/hypocretin system contributes significantly to the regulation of the sleep/wake cycle. Targeting the orexin system, DORAs are believed to reduce wakefulness and promote sleep by inhibiting orexin-mediated wake drive. Additionally, compared to benzodiazepine receptor agonists, DORAs might have a better safety profile.[6] One of the novel DORA drug is Lemborexant which acts as a competitive antagonist at both type 1 and type 2 orexin receptor.[7] This study aims to analyse the quality of sleep using the tool Pittsberg Sleep Quality Index (PSQI) at the start and during a 4 week follow up in patients having chronic low back pain for approximately 4-5 years after administering them with Lemborexant 5mg orally for 4 weeks.

Selection Criteria

Inclusion Criteria

1. Age between 35 – 60 yrs
2. Low back ache less than 6yrs

Exclusion Criteria

1. Any neurological deficit
2. Any traumatic brain organicity
3. Pregnancy
4. Substance abuse

Case series 1:

A 49-year-old male patient with history of diabetes for past 3years came to Orthopedics OPD with chief complaint of chronic back pain since 1 year. He was investigated for blood parameters. His Hb was 13.8g/dl, ESR 18mm/hr, serum calcium was 9.1mg/dl, vitamin D was 25ng/l, serum vitamin B12 was 180pg/ml. His BMD value was -2.3.

He was also adviced for regular physiotherapy excersies. After 1 week of follow up his back pain further aggravated and was also associated with decreased sleep. He had difficulty in initiating sleep.

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He would go to bed at 10pm and sleep would be initiated around 1-2pm and also he would wake late in the morning. This further hampered his daily routine life and work. He was admitted and psychiatry consultation was sought for. He was given analgesics along with tab clonazepam 0.25mg and after 2 days it was hiked to 0.5mg. Still there was impairment in his sleep pattern. Clonazepam was stooped and Lumborexant (Dayvigo) 5mg oral tablet was started at night. There was no other psychiatry illness such as depression or psychosis. At day 0 his PSQI was evaluated and the score was 18/21 and he was classified as "poor sleeper" and the level of pain using NPS score was 8 (severe). After 4 weeks follow up with continuation of Lumborexant 5mg his PSQI was again assessed. His PSQI score came to be 10/21 and NPS score was 5 (moderate).

Case series 2:

A 54-year-old female with single kidney and past history of hysterectomy 10years back came to Orthopedics Opd with chief complaint of chronic back pain for past 8months, deceased sleep and generalised weakness and lethargy. Her blood investigations were done. Hb was 9.8g/dl, ESR 20 mm/hr, serum calcium was 8.1mg/dl, vitamin D was 31ng/l, serum vitamin B12 was 280pg/ml. Her BMD value was -1.3. and MRI LS Spine was done which was suggestive of Spondylo degenerative changes. Patient had reported that she used to take over the counter tablets such as Alprazolam 0.25mg as and when she required for a good sleep. She also reported that at times she had to consume 2-3 tabs per night for a proper sleep. Patient was adm. Psychiatry consultation was sought for insomnia and counselling sessions had been also initiated in view of any deep rooted stress. At day 0 her PSQI was evaluated and the score was 17/21and NPS score was 10 (most severe). She was started with Lumborexant 5mg by psychiatrist 1 tablet at night. She was discharged with the continuation of 5mg Dayvigo (Lumborexant). After 4 weeks of follow up her PSQI was again assessed and the score was 8/21and NPS score was 5 (moderate).

Case Series 3:

A 54-year-old female presented with back pain for 2 years with past history of hysterectomy 4 years back. Her back pain had persistently increased for past 3months which was also associated with decrease sleep, low mood, irritability, generalized fatiguabilty. She is also known case of Hypothyroidism and is Tab Eltroxin 50mcg /day. On investigation Hb was 9.8g/dl, ESR 20 mm/hr, serum calcium was 8.1mg/dl, vitamin D was 31ng/l, serum vitamin B12 was 280pg/ml. Her BMD value was -1.3. She was treated on drugs like muscle relaxants, NSAIDs and multivitamin supplements. After 1 week of follow up she reported improvement in her back pain but her sleep pattern was deteriorating. Psychiatry consultation was sought for and was diagnosed of short term insomnia not otherwise specified. She was started on Dayvigo (Lumborexant) 5mg orally at night. Her PSQI at day 0 was 18/21 and was classified as poor sleeper and NPS score was 9 (severe). After 4 weeks of follow up she reported of marked improvement in her sleep pattern. Her PSQI score was 8/21 and NPS score was 5 (moderate). This also improved her mood fluctuations

Table 1: Assessment of quality of sleep using pittsberg sleep quality index (PSQI) at day 0 and week 4 case 1.

Components of PSQI	PSQI at day 0	PSQI at week 4
Subjective sleep quality	3	2
Sleep latency	3	2
Sleep duration	2	2
Habitual sleep efficiency	2	1
Sleep disturbances	3	1
Use of sleep medications	2	0
Daytime dysfunction	3	2

Table 2: Assessment of quality of sleep using pittsberg sleep quality index (PSQI) at day 0 and week 4 case 2.

Components of PSQI	PSQI at day 0	PSQI at week 4
Subjective sleep quality	3	2
Sleep latency	3	2
Sleep duration	3	2
Habitual sleep efficiency	3	1
Sleep disturbances	2	1
Use of sleep medications	2	0
Daytime dysfunction	1	0

Table 3: Assessment of quality of sleep using pittsberg sleep quality index (PSQI) at day 0 and week 4 Case 3.

Components of PSQI	PSQI at day 0	PSQI at week 4
Subjective sleep quality	3	1
Sleep latency	2	1
Sleep duration	3	2
Habitual sleep efficiency	3	1
Sleep disturbances	3	1
Use of sleep medications	1	0
Daytime dysfunction	3	2

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DISCUSSION

In this study, patients suffering from chronic low backache were also experiencing insomnia which had further deteriorated the low backache. Subjects receiving lemborexant in this trial reported better sleep on both objective and subjective assessments. Lemborexant was generally well tolerated. In comparison to the placebo group, rates of somnolence in the lemborexant groups shown evidence of a dosage response. Over time, lemborexant was not linked to clinically significant residual morning sleepiness. Subjects did not observe any appreciable increases in residual morning tiredness within 15 minutes, an hour, or two hours. There was also improvement in the NPS score from maximum severe intense pain at starting of the study shifted to moderate pain after 4 weeks of administering Lemborexant.

The primary limitation of this study was the 4-week treatment duration, which precluded the evaluation of long-term efficacy or the development of drug tolerance. Extended use of commonly prescribed medications for insomnia has been linked to safety concerns, including rebound insomnia and addiction.

CONCLUSION

According to the study's findings, lemborexant might be safe and useful in treating insomnia and can also help in decreasing the pain in patients suffering from chronic backache in actual clinical settings.

Conflict of Interest: None declared

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