

Knowledge, Attitude and perceived safety of community Pharmacists about the effectiveness of Melatonin supplements

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Abstract: *Introduction: Melatonin is a naturally occurring hormone found In the brain that is also utilized as dietary supplement and medication. Melatonin is a hormone secreted by the pineal gland that has a role in sleep-wake cycles. It is commonly used as a supplement to treat interrupted sleep patterns, such as those caused by jet lag or shift work, and is usually taken orally. Melatonin is classified as dietary supplement by the United States Food and Drug Administration (FDA) and so has not been licensed for any medical applications. It received medical approval in the European Union in 2007. Objectives: This study aim to explore knowledge, Attitude and perceived safety about the effectiveness of Melatonin supplements. Method: This study is a cross-sectional study, conducted from August- December 2024 in community pharmacist setting. This study was done in Baghdad, Alkarkh and Alrusafa. A sample of 77 pharmacists were chosen. Results: A total of 77 community pharmacists were recruited in this study. The most age participated in this study was (20-29) by about (37.5%) and no participants were reported above the age of 50. Self-medicating patients represent the most common purchasing of melatonin supplements (46.8%). Awareness rate about melatonin supplement pharmacokinetics and pharmacodynamics among community pharmacists were (66.2%) and (70.1%) respectively. community pharmacists reported relatively high rates of awareness of melatonin supplement pharmacokinetics and pharmacodynamics. Conclusion: Melatonin has several benefits in regulating sleep and circadian rhythms. However, its current misuse, in high doses, and without medical advice, has led to numerous negative effects, especially on children.*

Keywords: Melatonin, community Pharmacists, Knowledge, Attitude.

1. Introduction:

Melatonin (MEL) N-acetyl-5-methoxytryptamine is a hormone produced by the pineal gland [1]. MEL is secreted into the general circulation and cerebrospinal fluid, and hence circulates throughout the body and brain [2]. Its production is regulated by a clock in the hypothalamic suprachiasmatic nuclei (SCN). This clock regulates the circadian cycle of MEL secretion. In the brain, extra pineal MEL functions similarly to neurotrophic factors (NTFs) [3, 4].

Melatonin secreted in a diurnal rhythm, peaking at night and lasting approximately 8 hours. During the day, melatonin levels drop by tenfold and last for around 16 hours [5]. Because melatonin receptors are exposed to melatonin on a regular basis for extended periods of time, desensitization is regarded to be an important factor in melatonin's functional effects in the body. Prolonged melatonin administration causes desensitization of both endogenous and recombinant MT1Rs [6]. Furthermore, prolonged exposure of recombinant MT2Rs to melatonin causes desensitization [7].

The use of melatonin among adults in the United States increased dramatically. Not only that, but doses greater than 5 mg have witnessed an upsurge in recent years among children while it is used less in children than in adults [8], it is still considered high, particularly in the United States, and its aims are to aid sleep.

Despite its popularity and widespread use [9], there is a lot of research that shows that corporations lack credibility between the melatonin dose printed on the label and the actual dose, and that the actual melatonin content ranges from 83% less to 478% higher than indicated on the label.

This study aims to explore knowledge, Attitude and perceived safety about the effectiveness of Melatonin supplements.

2. Materials and Methods

2.1. Study Design

A cross-sectional observational study was conducted among licensed pharmacists in private sector in Baghdad to assess their knowledge, experience and attitudes toward melatonin supplement use for sleep disorders. This study was conducted over 4 months from September 2024 to December 2024 in Baghdad/ Iraq.

2.2 Materials

1. Questionnaire: the questionnaire was developed to collect data and it had six parts. Part one included demographic characteristics of participating pharmacists like (Age of the pharmacist, pharmacist qualifications, years of experience). Part two reported dispensing and prescription of melatonin supplement while part three reported pattern of melatonin indications. Part four take in consideration the dispensing patterns and the most common forms of melatonin that are reported by community pharmacists. Part five was about the knowledge and experience of community pharmacists about pharmacokinetics and pharmacodynamics of melatonin. Part six was about the community pharmacists' attitude towards safety and effectiveness of melatonin. Questionnaire were developed in reference to other relevant literature search [10,11].

2. Participants: 100 community pharmacists were participated in this study.

3. Setting: community pharmacists working in community pharmacies.

2.3 Method

2.3.1 Sampling

2.3.2 Data collection

The questionnaire was administered as online survey platforms to participants throughout Facebook pharmacists groups and what's up or telegram groups.

Data analysis

The results were coded and entered in Excel and revised. Descriptive statistics (frequencies and percentages) were used to summarize with all parts of the questionnaire.

2.3.3 Ethical considerations

Informed consent was obtained from participating pharmacists.

3. Result:

Demographic characteristics of the participating community pharmacists were showed in table (1)

Table 1: Demographic data of the pharmacists

Demographic characteristics	Frequency (%)	
Age	20-29.	37.5%
	30-39	32.1%
	40-49	30.4%
	>50	0%
Gender	Male	35.1%
	Female	64.9%
Pharmacist qualifications	Pharm Basic (Bachelor of science)	63.6%
	Pharm D	
	Master degree	7.8%
	PhD	7.8%
Years of experience	1-5 years	83.1%
	6-10 years	10.4%
	11-20 years	2.6%
	>20 years	3.9%

The majority of community pharmacists participated in this study reported dispensing and or prescribing melatonin in the pharmacies where they worked (81.8%). Most of the reported indications for melatonin dispensing were insomnia (59.7%).

Table 2: Reported melatonin supplement prescription patterns

Items	Frequency (%)	
Reported dispensing and or prescribing melatonin by the participant	Yes	81.8%
	No	18.2%
Reported pattern of melatonin indications	Insomnia	42.6%
	Jet lag	7.4%
	Better sleep quality	36.1%
	Jet lag and insomnia	13.9%

As shown in Table 3, self-medicating patients represented the most common purchasing of melatonin supplement (46.8%), while the lowest percentage was for prescription by physicians (22.1%). The most common dosage form of melatonin that was prescribed and dispensed is gummies (74%) followed by tablets (39%). Furthermore, the most common dose of melatonin that is dispensed is 3 mg (46.3%) and 5 mg (37.6%).

Table 3: Patterns of dispensing and the most common forms of melatonin by pharmacists.

Items	Frequency (%)	
Purchasing of Melatonin supplements most commonly due to the following	Prescription by physicians	22%
	Recommendations of pharmacists	31.2%
	Self-medicating patients	46.8%
The Most commonly dosage forms of melatonin supplements that are prescribed or dispensed	Tablets	14.2%
	Capsules	28.3%
	Gummies	53.8%
	Sublingual	3.7%
The most common dose of melatonin supplements that are dispensed	1 mg	19.1%
	3-5mg	72.7%
	6 mg	3.5%
	>6 mg	4.7%

Table 4 shows a fair level of knowledge for the pharmacists that were participated in this study. From these pharmacists (66.2%) were aware of drug–drug interactions and pharmacokinetic interactions of melatonin supplements, while (70.1%) of them were aware of the adverse reactions and pharmacodynamics of melatonin supplements. The majority of pharmacists (75.3%) were not reported any adverse drug reactions with the use of melatonin in the last three months. The most reported adverse drug reactions were noted among pediatrics (54.5%) followed by females (32.3%).

Table 4: Experience and knowledge of community pharmacists about pharmacokinetics and pharmacodynamics properties of melatonin supplements.

Question	Responses	Frequency (%)
Are you aware of drug–drug interactions and pharmacokinetic interactions of melatonin	Yes	66.2%
	No	33.8%

supplements?		
Are you aware of the Adverse drug reactions and pharmacodynamics of melatonin supplements?	Yes No	70.1% 29.9%
In the last three months. Are you noticed any adverse drug reactions present with the use of melatonin Supplements?	Yes No	24.7% 75.3%
In what groups of patients do you observe the ADR occurring?	Males Females Toddlers Pediatrics	17.7% 27.3% 7% 48%

Table 5 shows a Likert scale pattern to determine the attitudes of community pharmacists towards effectiveness and safety for the use of melatonin supplement in sleep disorders. Most pharmacists were strongly agreed or agreed to take the past medical history of the patients before dispensing melatonin (64.45%). Also, the majority of pharmacists were either strongly agreed or agreed that melatonin is effective in sleeping disorders in adults (74.95%) and pediatrics (73.26%). Likely (72.6%) were strongly agreed or agreed that melatonin is safe in general. On the other hand (68%) of the community pharmacists said that there is misuse in melatonin supplements (42.8% strongly agreed, (25.2%) agreed).

Table 5: Attitudes of Community pharmacists toward effectiveness and safety for the use of melatonin supplement in sleep disorders

Items	Strongly agree	Agree	Neutral	disagree	Strongly disagree
It is important to me, before prescribing or dispensing melatonin, to take past medical history of the patient	48.1%	16.4%	10.8%	14.3%	10.4%
Melatonin is effective in sleep disorders in adults	54.5%	20.4%	18.1%	7%	0%
Melatonin is effective in sleep disorders in pediatrics	50.6%	22.7%	17%	6.8%	2.9%
In general Melatonin is safe	48.2%	24.6%	12.2%	5.9%	9.1%
There is misuse in Melatonin supplements.	42.8%	25.2%	13.5%	13.3%	5.2%

4. Discussion

This study revealed a relationship between pharmacists' age and their understanding of the mechanism of action of melatonin supplements. Younger pharmacists (aged 24–29) constituted the majority of participants, likely due to their greater presence in community pharmacies, which undoubtedly influenced the levels of knowledge demonstrated in this study. This finding was confirmed by the results of a study by (Faris et al. (2016))[12], which showed that pharmacists' knowledge and understanding of the uses of dietary supplements varied by age. However, these results were inconsistent with another study in Saudi Arabia by (Almutairi et al)[13], which found no relationship between pharmacists' age and knowledge level. This may be due to changes in age group classification or differences in professional training programs, which vary by region and the age of attending pharmacists.

Regarding academic qualifications, this study confirmed that a bachelor's degree is the most common qualification among community pharmacists, proportionate to their age. As in previous research, this influences the dispensing of nutritional supplements, including melatonin. Numerous studies, including (Faris et al. (2016))[12], have confirmed that pharmacists with higher academic qualifications and training are more familiar with the dispensing mechanisms of nutritional supplements, their interactions, and potential side effects.

Additionally, the study confirmed a higher rate of melatonin use to treat insomnia (42%) and improve sleep quality (36%), compared to a higher rate among patients taking it over-the-counter compared to those using it with a prescription, according to a study (Adeyinka et al. (2019)[14]. This study confirms that there are differences in the basis for prescribing and dispensing medications. The recent increase in melatonin dispensing rates coincides with a study (Wakefield et al. (2020)[15], which confirms that modern sleep disturbances are linked to melatonin overuse.

With regard knowledge Community pharmacists' of the pharmacokinetics and pharmacodynamics of melatonin supplements was relatively good, but a high dispensing rate was observed, with 81% of surveyed community pharmacists reporting frequent dispensing of melatonin supplements.

This highlights the challenges of educating pharmacists about supplement use. Despite the widespread availability of melatonin, only 24% of pharmacists in this study reported experiencing side effects, with children being the most affected group (48%). Combined with the results, we find a significant inverse relationship between pharmacists' knowledge of the pharmacokinetics and pharmacodynamics of melatonin and dispensing rates, suggesting that increased awareness may contribute to more prudent dispensing practices.

Furthermore, the study showed that pharmacists were highly likely to review medical history before dispensing melatonin supplements. This is consistent with other studies demonstrating the importance of assessing contraindications before prescribing or recommending melatonin(Wakefield et al., 2020)[15] . However, a significant percentage expressed concerns about melatonin supplement misuse, which is linked to the increasing incidence of patients self-medicating and misusing sleep aids, including melatonin(Almutairi et al)[13].

Overall, the relationship between patients and pharmacists is very close, so pharmacists play a pivotal role in educating patients about the risks of misuse or irregular use of dietary supplements, including melatonin. Educating patients about proper use and the importance of adhering to medical guidelines can help prevent long-term side effects of these supplements. Pharmacists also collaborate with healthcare professionals to identify, address, and reduce misuse. Furthermore, further research is needed to explore potential interventions aimed at enhancing pharmacist education and regulatory guidelines regarding melatonin use.

5. Conclusion:

Melatonin is frequently prescribed and distributed to individuals as a self-administered dietary supplement without a prescription. Melatonin undoubtedly helps to improve sleep quality. However, its present usage, at large doses and without medical supervision, has resulted in several severe consequences, particularly in Pediatric. Melatonin use in children is frequently reported by healthcare providers and community pharmacists. The greater danger caused by these supplements stems from some producers' greed and a lack of credibility over the actual melatonin dosages in their formulations. Community pharmacists should be aware of the risks associated with over-the-counter melatonin supplements, such as misdiagnosis, misuse, and overdose. There is also an obvious need for uniform recommendations and patient education, with a special focus on melatonin's chronobiological mechanics, its risks and benefits, and evidence-based approaches to formula manipulation.

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