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Association between Knowledge and Vitamin D Serum Level among Vitamin D Consumers in Tehran, Iran

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ABSTRACT

Background: Results of studies in Iran indicated a high prevalence of vitamin D deficiency, making its rational use to be critical. So assessing people's knowledge about the rational use of vitamin D and its safety is worthwhile to pursue. This study aimed to evaluate the level of consumers' knowledge about vitamin D and its relationship with vitamin D serum levels in Tehran, Iran.

Methods: A cross-sectional survey was designed to assess consumers' knowledge and its association with demographic characteristics, lifestyle, habits and the serum 25-hydroxy vitamin D3 (25(OH)D) level in 10 community pharmacies in Tehran, Iran.

Results: Totally, 384 individuals participated in this study, among whom 345 (89.8%) requested large doses of vitamin D. The average knowledge score was 23.67±7.76 out of 50. The average serum level of vitamin D was 49.01±32.01 ng/mL, showing that 117 (30.5%) subjects were in "insufficient", 224 (58.1%) were in "sufficient", and 44 (11.4%) were in "hypervitaminosis" levels. There was a significant inverse association between knowledge and age, weight, body mass index (BMI), educational level, vitamin D serum level, and monthly dose. Also, a significant inverse relationship was detected between knowledge in terms of toxicity and vitamin D level. Further, participants' knowledge of "hypervitaminosis" was lower than those with "sufficient" level.

Conclusion: More than 50% of consumers had a sufficient knowledge on vitamin D level, however the lack of knowledge about vitamin D was evident that could lead to misuse and hypervitaminosis, which were noticed in 11.4% of participants.

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Introduction

As a prohormone, vitamin D plays a crucial role in regulating main body functions such as calcium metabolism, nervous system activity, and the immune system (1-4). The deficiency of and the need for vitamin D have been the subject of much scientific debate, leading to publishing much research. Studies conducted on various diseases such as multiple sclerosis, diabetes, asthma, hypertension, and Alzheimer's show that people with vitamin D deficiency are more vulnerable to these diseases. This stream of research has

led to the increasing demand for vitamin D (5-7). Therefore, one primary concern of public health is the irrational consumption of vitamin D (8, 9) which is detectable in blood serum. Global statistics showed a huge market for vitamin D consumption (10). Some vitamin D supplements are good enough and potent to supply the daily requirement. There is no risk of hypervitaminosis, if taken wisely; however, some forms of vitamin D that contain much more than the daily requirement may cause the risk of hypervitaminosis D; if taken in excessive doses. Unreasonable consumption of high amounts of vitamin D products can cause hypervitaminosis, and acute or chronic toxicity. Symptoms of acute toxicity include hypercalcemia, binge drinking, hyperuricemia, confusion, anorexia, and nausea; symptoms of chronic toxicity include kidney stones and bone demineralization (11, 12).

With the emergence of social media and its over-growing influence in recent years, it has become the most available means for information seeking within communities. In most, the information provided is not accurate and evidence-based and overshadows people's behavior in taking remedies or supplements by applying promotional messages (13-16). Field evidence suggests that the increasing promotion of vitamin D supplement access to products containing large doses of vitamin D together with the lack of public awareness of the possibility of performing tests to determine vitamin D levels can lead to increased irrational consumption of vitamin D and increased risk of hypervitaminosis D (17).

Considering that food sources of vitamin D are limited and this vitamin is mostly produced through exposure to natural sun exposure to the skin, elderly people, pregnant women and people who wear hijab are more prone to its deficiency (18, 19). The intake of vitamin D supplements in Iran has been reported significant (20). According to the official records of the Food and Drug Organization (FDA) of Iran, the sale of pharmaceutical forms of vitamin D from March 2017 to March 2018 was about 246,000,000 pearls (50,000 IU) and 19,000,000 (300,000 IU). It should be considered that the population of Iran was about 80,000,000 people (16). This high level of consumption has occurred based on information in the media about the prevalence and precautions of vitamin D deficiency in Iran (21). Much encouragement to prevent vitamin D deficiency has changed people's attitudes to widespread use of vitamin D (22). The availability of various forms of vitamin D products that contain high doses and the significant investment of supplement manufacturing companies in promoting their market and only stating the positive properties of vitamin D and not mentioning the facts about the complications of hypervitaminosis and its toxicity have raised concerns about the occurrence of vitamin D increased toxicity (23). Recently, we have emphasized the concern of irrational and unsupervised consumption of vitamin D as a double-edged sword, which increases the risk of toxicity (24).

Given the above facts and arguments, it is evident that the consumption pattern of vitamin D is mainly subject to the extent to which people know about the symptoms of deficiency, the beneficial effects of vitamin D, the amount ingested, nutritional sources, and exposure to sunlight. Therefore, surveying consumers' knowledge about vitamin D supplements in community pharmacies has recently gained much attention. In line with this trend, the present study aimed to evaluate consumers' knowledge about vitamin D and its association with its serum level.

Materials and Methods

A cross-sectional study was designed to assess the general knowledge of applicants who requested vitamin D supplement from 10 community pharmacies in Tehran, Iran. In addition, serum level of vitamin D was assessed by quantitative analyses. So a panel of experts consisted of 11 specialists in clinical pharmacy, pharmacy practice, family medicine, pharmacology and toxicology that was familiar with nutrition science was enrolled. The expert panel defined six different domains to determine the knowledge of people about vitamin D. Also, a questioner was designed based on the defined domains including dietary sources, necessity of use, sunlight exposure, vitamin D daily requirement, deficiency, and toxicity. Primary version of final questionnaire was sent to 10 other experts, consisted of pharmacists, family medicine specialists and nutritionists. Then, the content validity index (CVI) and content validity ratio (CVR) were calculated, CVI of greater than 0.8 was considered as acceptable threshold. Internal consistency of questionnaire was also assessed in a pilot pre-study on 50 samples. Questions in the final version were weighted by the expert panel, then in Excel sheet with the ability to accurately calculate the results and finally, the obtained data from the options of each question was entered into a sheet and automatically the score was determined.

This study was conducted from April to November 2021 in 10 community pharmacies in different districts of Tehran, while Tehran was divided into 5 regions of north, south, east, west and the center. Two pharmacies were selected in each region based on a previous report with thea risk of vitamin D toxicity (24). The insurance organizations

were asked about the pharmacies with more vitamin D prescription to be invited for an online meeting. The research plan was explained to them, and finally 10 pharmacies that volunteered to cooperate and had space for questions and answers were included. To adhere to the standard report, the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement was followed (25). The study protocol was approved by the ethics committee of Shahid Beheshti University of Medical Sciences (SBMU) with the registered code of IR.SBMU.PHARMACY.REC.1397.257 and IR.SBMU.PHARMACY.REC.1397.256. Participation in the study was voluntarily and subject to written informed consent. The data sets used and analyzed during the current study are available on: https://reshare.ukdataservice.ac.uk/cgi/users/home?screen=EPrint::Summary&eprintid=855731.

Individuals older than 18 years old that had requested vitamin D and had regularly taken vitamin D in the past two months were invited to participate in this study. The logic behind this lag time was that some scholars believed it to take about 6-12 weeks for this vitamin to reach a steady state in the body (8, 26). The available pharmaceutical dosage forms included soft gels containing 50,000 international units (IU), tablets, soft gels containing 1000 and 2000 IU, and ampoules containing 300,000 IU. If the participants met eligibility criteria, a questionnaire was filled out by phone call. The patient was invited to determine the vitamin D level in the specified laboratories. All laboratories measured vitamin D level with high-performance liquid chromatography (HPLC) method.

The exclusion criteria were refusal to sign the questionnaire, history of autoimmune and gastrointestinal diseases affecting vitamin D absorption, chronic kidney disease, William's syndrome, sarcoidosis, hypo/hyperparathyroidism, and history of cancers. Any recent history of using medications and conditions that interrupted vitamin D absorption and metabolism, such as orlistat, phenytoin, and carbamazepine, pregnant women, and nursing mothers were also excluded. All participants were classified by sex, age, race, educational level, alcohol consumption, marital status, and occupation. Considering any form of vitamin D consumed by the patient, the average doses of vitamin D per month were calculated. All participants were referred to a medical diagnostic laboratory to determine their serum vitamin D level. The results of the laboratory tests were provided for the participants. Individuals with serum 25(OH)D levels below 29 ng/mL were classified as "insufficient", between 30 and 99 as "sufficient", and above 100 as "hypervitaminosis" (8). A knowledge score ≤12.5 was considered a person with poor knowledge, between 12.5 and 25 as moderate, between 25 and 37.5 as good, and ≥37.5 as excellent.

The designed questionnaire consisted of two parts. The first part collected participants' demographic information, and the second part included 15 multiple-choice questions. The questionnaire was designed to assess participants' knowledge of six domains of vitamin D including dietary sources (one question, 4 scores), sunlight exposure (two questions, 6 scores), the necessity to use (two questions, 9 scores), the daily requirement (two questions, 8 scores), its deficiency (five questions, 12 scores), and its toxicity (three questions, 11 scores). The total score ranged from zero to a maximum of 50.

The first bias has to do with the selection bias. To address this bias, individuals who fully met the eligibility criteria were only invited. As the knowledge has been evaluated using scientific questions, no social desirability bias could happen. As for recall bias, given the nature of research, there was no possibility for this. Using the Cochran formula and the confidence level as 95%, a sample size of 385 was calculated (27). IBM SPSS software (Version 26.0, Chicago, IL, USA) was used to analyze the data. The Kolmogorov-Smirnov test was first used to test the normality of data. The t-test and Kruskal-Wallis test were also performed to compare the groups. The Pearson correlation test was utilized to determine the relationships between the groups. Post-hoc analysis (Tukey's HSD) was employed to examine the differences between the groups. According to what was offered by Waltz and Baussel, CVI and CVR of simplicity, clarity, and relativeness were calculated (28). The internal consistency of the final instrument was evaluated using Cronbach's alpha. A p value less than 0.05 was considered statistically significant.

Results

CVI of the questionnaire for simplicity, clarity, and relevance was 0.85, 0.83, and 0.87, respectively, and the internal consistency ratio of the questionnaire was about 0.69. Table 1 shows the findings in details. Between April 2020 and November 2021, 469 individuals were interviewed at the pharmacies, where they requested vitamin D products. Nineteen of them were excluded because of not meeting the eligibility criteria, and 48 refused to participate in the study. The remaining 402 participants completed the questionnaire and were presented to the laboratories of this study to perform the test to determine the 25(OH) vitamin D level. Seventeen of the subjects did not go to the laboratory within the

Table 1: Validity and internal consistency of the developed knowledge questionnaire.

Variable	Question number	CVI			CVR	Cronbach's Alpha if Item Deleted
		Clarity	Simplicity	Relevance		
Dietary sources	Q1	0.82	0.86	0.89	0.69	0.71
Necessity of use	Q2	0.78	0.83	0.91	0.73	0.73
	Q3	0.87	0.85	0.88	0.63	
Sunlight exposure	Q4	0.91	0.85	0.86	0.68	0.65
	Q5	0.85	0.87	0.87	0.69	
Daily requirement	Q6	0.79	0.8	0.91	0.62	0.58
	Q7	0.83	0.86	0.85	0.66	
Deficiency	Q8	0.8	0.82	0.88	0.68	0.67
	Q9	0.87	0.84	0.85	0.8	
	Q10	0.9	0.79	0.89	0.62	
	Q11	0.9	0.83	0.82	0.61	
	Q12	0.85	0.79	0.88	0.78	
Toxicity	Q13	0.82	0.8	0.88	0.66	0.72
	Q14	0.89	0.84	0.85	0.7	
	Q15	0.88	0.84	0.83	0.83	
Total		0.85	0.83	0.87	0.69	0.73

Q: Question, CVI: Content validity index, CVR: Content validity ratio.

period set by the researchers. Therefore, the total number of subjects who completed the questionnaire and checked for the vitamin D level was 385. While entering the data according to case report forms (CRF), one participant who mistakenly took calcitriol instead of vitamin D within the last two months was removed from the study. Participants were 100 males (26.0%) and 284 females (74.0%), with an average age of 42.07±11.88 years. Table 2 shows the characteristics of participants in details.

Analyzing the results of the pattern of consumption showed 345 (89.8%) participants requested products containing high doses of vitamin D (≥50.000 IU). The average monthly dose of vitamin D was 6300±3974 IU. Analysis of the findings regarding the type of requests showed that 110 (28.6%) of the participants had a doctor's prescription and 274 (71.4%) were those without any prescription. A total of 271 (70.6%) subjects had no previous monitoring history of vitamin D level, 96 (25%) had previous tests in the area of 30-100 ng/mL, and 16 people in the area of <30 ng/mL. The mean total knowledge of the participants was 23.67±7.76 out of 50. Table 3 demonstrates the level of knowledge of participants in defined domains.

Laboratory results of 25(OH) vitamin D level illustrated a mean of 49.01±32.01. The frequency of participants based on vitamin D level exhibited 117 (30.5%) subjects to be in the "insufficient", 223 (58.1%) in the "sufficient", and 44 (11.5%) were in the "hypervitaminosis" level. The knowledge score of 42 (10.9%) participants was poor, 267 (69.5%) showed a moderate level, 63 (16.4%) had a good level of knowledge, and only 12 (3.2%) reported an excellent level of knowledge about vitamin D in all domains. The mean knowledge of single participants was significantly better than the married and divorced ones (p=0.02). In addition, as for the occupational variable, teachers showed the highest score, and housewives had the lowest score (p<0.0001). Also, the knowledge of participants with "hypervitaminosis" was significantly lower than those with "sufficient" level (18.61±5.35 vs. 24.31±7.79, p<0.0001), and also their monthly intake was significantly higher (407,723±215,482, vs. 824,26±132,438 p<0.0001). There was not any significant difference between race, educational level, alcohol consumption, marital status, and occupation with knowledge on vitamin D. The association between demographic variables, vitamin D level and participants' knowledge was presented in Table 4. Using the logistic regression model to investigate any relationship model between variables showed that vitamin D knowledge could be estimated as; 29.99 - (0.054 * Age) – (0.229 * BMI) – (0.034 * Vitamin D Level).

Discussion

Iranian people are strongly encouraged to take vitamin D supplements (18, 19, 29, 30). Vitamin D is provided free of charge at schools and in health centers. But the irrational administration and use of vitamin D, for example, taking mega doses of vitamin D in short intervals, has turned it into a double-edged sword. Based on numerous reports of inappropriate consumption of vitamin D, we issued the first alarm for health professionals and policymakers in Iran (24). Vitamin D toxicity may persist for a long time because vitamin D is a fat-soluble vitamin with a high rate of accumulation in adipose tissue.

Table 2: Characteristics of the participants (N=384).

Variable		**Mean±SD** **Median (IQR)**
Age (Year)		42.07±11.88
Weight (Kg)		72.17±11.84
Height (cm)		166.26±9.18
BMI (Kg/m^2)		26.13±3.89
Gender	Female	284 (74%)
	Male	100 (26%)
Race	Fars	233 (60.7%)
	Turkmen	12 (3.1%)
	Turkish	69 (18.0%)
	Lorish	36 (9.4%)
	Armenian	3 (0.8%)
	Kurdish	20 (5.2%)
	Afghan	2 (0.5%)
	Baluchi	2 (0.5%)
	Lakish	7 (1.8%)
Education level	Illiterate	4 (1%)
	Elementary	14 (3.6%)
	Secondary	39 (10.2%)
	High school	16 (4.2%)
	Diploma	95 (24.7%)
	License	120 (31.3%)
	Master	41 (10.7%)
	Postgraduate	55 (14.3%)
Alcohol consumption	Non-alcoholic	338 (88%)
	Alcoholic	46 (12%)
Marital status	Married	293 (76.3%)
	Single	72 (18.8%)
	Widow	19 (4.9%)
Occupation	Home keeper	128 (33.33%)
	Freelance	108 (28.13%)
	Clerk	41 (10.68%)
	Student	27 (7.03%)
	Retired	22 (5.73%)
	Health care	20 (5.21%)
	Teachers/Trainers	20 (5.21%)
	Engineer	10 (2.60%)
	Jobless	8 (2.08%)
25(OH)D serum levels(ng/mL)		49.32±32.01
Monthly dose of 25(OH)D received by the participants (IU)		50,000 (100,000)

N: Number; SD: Standard deviation; IQR: Interquartile range, BMI: Body mass index; IU: International Unit.

Table 3: Knowledge of the participants in different fields.

Knowledge Field	**Score (mean±SD)**
Diet containing vitamin D	2.40±1.00 (out of 5)
Relationship between sunlight and vitamin D	0.75±0.54 (out of 5)
Necessity of vitamin D consumption	4.40±1.74 (out of 10)
Vitamin D toxicity	4.33±3.07 (out of 11)
Daily requirement of vitamin D	3.24±2.22 (out of 8)
Vitamin D deficiency	8.53±3.01 (out of 11)
Total knowledge	23.67±7.76 (out of 50)

Table 4: The association between different demographic variables with vitamin D level and participants' knowledge.

Knowledge level	Pearson correlation	*P* value
Age	-0.206	<0.0001
Weight	-0.116	0.023
BMI	-0.201	<0.0001
Vitamin D level	-0.221	<0.0001
Monthly dose of Vitamin D	-0.138	0.009
Education levels	0.346	<0.0001

Notably, 25(OH)D level as high as 500 ng/mL have been presented in some reports, indicating an irrational use of vitamin D that can lead to severe toxicity (29, 30). Vitamin D toxicity is associated with several serious problems. Therefore, it is necessary to use effective strategies to correct this irrational pattern of vitamin D consumption. An appropriate vitamin D regimen should be prescribed based on age, associated risk factors, and 25(OH)D level. Necessary training should also be provided for health care providers and the general public. Also, there should be a structure in place so that pharmacists do not provide mega-dose vitamin D products in pharmacies without obtaining a proper medical/nutritional history. Apart from the medical staff and pharmacies, the general public's knowledge about this vitamin is very important.

Considering the media advertising on informing vitamin D deficiency and its benefits in recent years, there is a common belief that vitamin D deficiency is prevalent in all individuals. To investigate any association between knowledge about vitamin D and its serum level, this study was designed, however beside this, the possibility of hypervitaminosis among Iranian people, the pattern of use, and the serum levels were determined. In this study, a valid questionnaire was designed to assess the applicants' knowledge-seeking vitamin D supplements from pharmacies. To the best of our knowledge, this is the first population-based study that reported the association of knowledge about vitamin D in different domains and social as well as demographic characteristics and vitamin D levels. Also, it is the first study that reports the frequency of vitamin D hypervitaminosis in Iran. The results of this study showed that the knowledge of those who went to the pharmacy to get vitamin D products is weak regarding this vitamin, and this weakness intensifies irrational consumption.

From the data obtained, the overall knowledge of the study population was less than 50% of the total score. Among the subgroups, the lowest score was for knowledge of vitamin D production and sunlight exposure. The highest score was for knowledge of the complications of vitamin D deficiency. In a 2015 study by Boland *et al.*, out of 1,088 students in Canada, 29% of the participants answered the vitamin D knowledge questionnaire correctly (31). In a 2020 study by Tariq *et al.* in Pakistan, only 9% of the 900 study participants knew about the sources of vitamin D in the diet. Also, their knowledge about the production of vitamin D in the skin and its beneficial effects on bone was 36% and 33%, respectively (32). However, in the present study, the mean knowledge level of the applicants who asked for vitamin D in pharmacies was 47%. The post-doc analysis to examine the one-to-one differences between the groups showed that differences in educational level resulted in significant variations in customers' knowledge of vitamin D.

The results showed that the knowledge level of the participants had nothing to do with their gender. Still, there was a significant association between overall knowledge, literacy level, and occupational position. The post-hoc analysis showed that housewives had the lowest knowledge among the different occupational groups. However, their serum levels of vitamin D were higher than those of other occupational groups, except for retired participants; we suggest that social media influenced housewives' health behavior more. Evaluation of serum vitamin D levels compared with overall knowledge also showed that participants with less knowledge were more likely to take inappropriate exogenous vitamin D and more likely to have hypervitaminosis complications.

Epidemiological studies showed that vitamin D deficiency was common in Iranian society (18, 19, 29, 33). To correct it, various advertising contents were implemented to encourage people to use vitamin D products by the health system. For instance, the pearl of 50,000 IU of vitamin D was freely distributed in health centers and at schools (33). However, the results of this study showed that vitamin D applicants had a sufficient average level of vitamin D and, in some cases, even they were exposed to hypervitaminosis. Comparing the results with the results of previous studies (18, 19, 24, 29, 30), the target population can be divided into two spectrums; the spectrum that consumes vitamin D products, which are mainly at the desired level and in some cases are exposed to hypervitaminosis and the other spectrum who do not receive vitamin D

adequately. The limitation of this study was that some aspects of lifestyle were not considered, such as the amount of sun exposure, sunscreen usage, and women's clothing.

Conclusion

The results of this study confirmed our previous hypothesis regarding the increased possibility of vitamin D hypervitaminosis following widespread advertising and access to products containing mega-doses of vitamin D. The lack of knowledge about vitamin D was evident in various domains, including sources, deficiency, daily requirements, and toxicity. The lack of knowledge about daily requirements and toxicity has led people being exposed to hypervitaminosis. It is suggested for healthcare policymakers that by promoting educational programs and providing knowledge about vitamin D deficiency, the importance of measuring the level of vitamin D, hypervitaminosis, its risks, and the reasonable amount of vitamin D consumption, the healthcare system should prevent the hypervitaminosis risks.

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Conflict of Interest

None declared.

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