



## Clinical identification of older adults with hypovitaminosis D: Feasibility, acceptability and accuracy of the ‘Vitamin D Status Diagnosticator’ in primary care

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### ABSTRACT

The 16-item Vitamin D Status Diagnosticator (VSDS) tool was built to diagnose, without resorting to a blood test, hypovitaminosis D among healthy seniors living at home. The objective of this study was to determine the feasibility of the VSDS by general practitioners (GPs), the acceptability to outpatients, and the diagnostic accuracy of the VSDS in primary care. Ten French GPs were asked from March to May 2015 to perform the VSDS in 30 consecutive outpatients aged  $\geq 70$  years, living at home, presenting with a history of recurrent falls and/or osteomalacia, and taking no vitamin D supplements. Feasibility was defined as a proportion  $> 70\%$  of VSDS forms fully completed. Completing time, acceptance rate and, when applicable, the reasons for non-completing were assessed, together with the metrological properties of the VSDS to identify hypovitaminosis D  $\leq 75$  nmol/L, or  $\leq 50$  nmol/L or  $\leq 25$  nmol/L. Of the 242 enrolled patients, 218 (mean,  $79 \pm 6$  years; 46.3% women) received a VSDS, i.e. completing rate of 90.1%, with an average completing time of 1 min and 48s. The acceptance rate by the patients was 98.8%, and all GPs were satisfied with the tool. The VSDS identified hypovitaminosis D  $\leq 75$  nmol/L with an accuracy of 84.7%, hypovitaminosis D  $\leq 50$  nmol/L with accuracy 75.4%, and hypovitaminosis D  $\leq 25$  nmol/L with accuracy 71.0% ( $n = 183$  assays). The 16-item VSDS can be considered as feasible, acceptable and accurate for diagnosing hypovitaminosis D among older outpatients in primary care without resorting to an expensive blood test.

### 1. Introduction

Hypovitaminosis D is common among seniors and accompanied by various skeletal and nonskeletal adverse health events [1,2]. Although effective for correcting hypovitaminosis D, universal supplementation remains, however, not recommended due to potential risk of intoxication [3,4] and lack of evidence for cost-effectiveness [5]. While few side effects on phosphocalcic metabolism are reported with vitamin D supplements up to 4000 IU/day [6], other risks such as accidental falls may appear with moderate-to-high doses in individuals who already exhibit

desirable vitamin D status [7]. For this reason, determining vitamin D status before initiating supplementation is useful [8], and the use of blood tests increases dramatically, especially in primary care [9]. For instance, 8,061,115 assays of 25-hydroxyvitamin D (25OHD) were performed in France in 2012, of which the vast majority ( $n = 6,183,825$ ; 77%) were prescribed in primary care [9]. Given the relatively high cost of these blood tests, and to prevent insurmountable health costs in the future, new strategies should be urgently developed to detect older community-dwellers with hypovitaminosis D without resorting to a blood test. In this perspective, we recently built the

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Vitamin D Status Diagnosticator (VSD), a 16-item questionnaire with algorithm able to accurately identify, among older community-dwellers, those with vitamin D insufficiency (i.e., serum 25OHD concentration  $\leq 75\text{nmol/L}$ ) [1,2] and deficiency (i.e., serum 25OHD concentration  $\leq 25\text{nmol/L}$ ) who may be administered vitamin D supplements without blood test [10]. However, although the VSD tool was designed for everyday practice, its feasibility in primary care has not been examined yet. Also, the tool was developed in healthy seniors living at home, but its diagnostic accuracy in outpatients (i.e., in a context of healthcare) remains unknown. We hypothesized that the VSD tool is both feasible and accurate in primary care to identify older adults with hypovitaminosis D. Our main objective was to determine the feasibility of the VSD by general practitioners (GPs) and the acceptability to patients in primary care. Our secondary objective was to determine the diagnostic accuracy of the VSD tool for the identification of older patients with hypovitaminosis D in primary care.

## 2. Materials and methods

### 2.1. Participants

We studied outpatients recruited in the VSD-PC (Vitamin D Status Diagnosticator for Primary Care) study. The VSD-PC study is an observational study designed to apply the VSD among outpatients seen in consultation by ten GPs in the great western France from 20 March 2015 to 22 May 2015. Each participating GP was asked to enrol the first 30 outpatients aged 70 and over, living at home, and presenting with a history of recurrent falls and / or suspicion of osteomalacia. Of note, history of falls and osteomalacia are the two main indications for 25OHD assay adopted by the National Authority for Health in France (HAS) [9]. Exclusion criterion was current vitamin D supplementation. After giving their informed consent for research, included participants received a full medical examination consisting of a blood test, structured questionnaires and a standardized clinical examination. The study was conducted in accordance with the ethical standards set forth in the Helsinki Declaration (1983). The entire study protocol was approved by the local Ethical Committee (No 2015-02).

### 2.2. Vitamin D status diagnosticator

Included participants underwent a full clinical examination by a physician. The following 16 items from the original VSD were collected in a standardized manner [10]: gender, age (in years), number of therapeutic classes used per day, body mass index (BMI, in  $\text{kg/m}^2$ ), use walking aids, use psychoactive drugs (i.e., benzodiazepines, anti-depressants or neuroleptics), wearing glasses, sad mood, fear of falling, history of falls in the preceding year, cognitive disorders, undernutrition, polymorbidity, history of vertebral fractures, living alone, use anti-osteoporotic substances (e.g. bisphosphonates, strontium or calcium supplements). The BMI was calculated based on anthropometric measurements. Undernutrition was defined as BMI below  $21\text{kg/m}^2$  and / or serum albumin concentration below  $35\text{g/L}$  [11]. Polymorbidity was defined as having more than three chronic diseases (i.e., diseases of indefinite duration or running a course with minimal change). A fall was defined as an event resulting in a person coming to rest unintentionally on the ground or at other lower level, not as the result of a major intrinsic event or an overwhelming hazard, according to the French society of geriatrics and gerontology (SFGG) and the French HAS [12]. The history of vertebral fractures was sought for patients' and relatives' interview and from the medical records. The fear of falling was sought using the following standardized question "Are you afraid of falling?", as previously published [13]. The presence of cognitive disorders was identified using the Mini-Mental State Examination [14] and/or the history of dementia with or without delirium from medical records. Finally, sad mood was sought using the following question from the 4-item Geriatric Depression Scale: "Do you feel

discouraged and sad?" [15].

### 2.3. Feasibility

The primary endpoint was the completing rate of the VSD administered by GPs. The completing rate was calculated as the percentage of VSD forms fully completed on the number of patients recruited. Feasibility was defined as completing rate  $> 70\%$ . We also assessed the completing time of the VSD (in minutes). Finally, at the end of the study, a standardized questionnaire was administered by one author (JLM) to each participating GP during a face-to-face interview. The questions focused on their overall feeling about the VSD tool including questions on their feelings about the simplicity and completing time, questions about the potential use of the VSD on a routine basis, and the possible impact on the search for hypovitaminosis D in outpatients.

### 2.4. Acceptability

The endpoints were i) the acceptance rate in patients, and ii) when applicable, the reasons for not completing the VSD including the omission and the lack of time.

### 2.5. Diagnostic accuracy

Venous blood was collected for the measurement of serum 25OHD concentration by radioimmunoassay in various laboratories during the week following the VSD assessment. Interlaboratory measurement variability improved in recent years thanks to the DEQAS program (International vitamin D quality assessment scheme), even if inter-technical variability persists. This inter-technical variability justifies following the changes of 25OHD concentrations using the same technique, but not necessarily within the same laboratory [16]. The intra- and interassay precisions of radioimmunoassay were 5.2% and 11.3%, respectively (range 30–125 nmol/L in normal adults aged 20–60 years). Based on previous literature, three different threshold values were used consecutively to define hypovitaminosis D: 25, 50, and 75 nmol/L (to convert to ng/mL, divide by 2.496). Finally, we applied the algorithm previously published [10] to the 16 items of the VSD in order to identify among participants those with hypovitaminosis D (i.e., with serum 25OHD  $\leq 25$ , or  $\leq 50$ , or  $\leq 75\text{nmol/L}$ ), without knowledge of the blood test result [1].

### 2.6. Statistical analysis

The GPs' and participants' characteristics were summarized using frequencies and percentages or means  $\pm$  standard deviations, as appropriate. The feasibility and acceptability of the VSD were described among the whole sample of participants. Finally, the metrological properties of the VSD tool were evaluated for the identification of hypovitaminosis D in all outpatients with a blood test. P-values  $< 0.05$  were considered significant. All statistics were performed using SPSS (v19.0, IBM Corporation, Chicago, IL), R 3.1.0 (GNU project), NetBeans IDE 8.0, and Dag-stat [17].

## 3. Results

Of ten GPs solicited (four women and six men;  $13.2 \pm 12.4$  years of practice on average), all participated in the VSD-PC study and enrolled at least one patient. Nine GPs were incumbents, and one was a substitute physician. Seven physicians were practicing in semi-rural areas, two in rural areas, and one in an urban area. The mean number of patients included by every physician was  $24.2 \pm 8.2$ . The mean interval between the first and the last inclusion was  $53.6 \pm 12.7$  days (range, 25–63 days).

Among the 242 outpatients who met the inclusion criteria, the

**Table 1**  
Participants data (n = 218).

Characteristics	Cohort	
	Summary value	(95% CI)
Item 1- Female gender	101 (46.3)	(39.7 ; 59.9)
Item 2- Age, years	78.8 ± 5.6 [70 – 101]	(78.0 ; 79.5)
Item 3- Number of drugs daily taken	4.5 ± 3.0 [0 – 16]	(4.1 ; 4.9)
Item 4- Body mass index, kg/m <sup>2</sup>	26.9 ± 4.3 [16.4 – 42.0]	(26.3 ; 27.4)
Item 5- Use walking aids	34 (15.6)	(10.8 ; 20.4)
Item 6- Use psychoactive drugs	64 (29.4)	(23.4 ; 35.5)
Item 7- Wearing glasses	170 (78.0)	(72.5 ; 83.5)
Item 8- Sad mood	49 (22.5)	(20.0 ; 28.0)
Item 9- Fear of falling	71 (32.6)	(26.4 ; 38.8)
Item 10- History of falls	62 (28.4)	(22.4 ; 34.4)
Item 11- Cognitive disorders	19 (8.7)	(5.0 ; 12.4)
Item 12- Undernutrition	15 (6.9)	(3.5 ; 10.3)
Item 13- Polymorbidity	111 (50.9)	(44.3 ; 57.5)
Item 14- History of vertebral fractures	14 (6.4)	(3.2 ; 9.7)
Item 15- Living alone	58 (26.6)	(20.7 ; 32.5)
Item 16- Use anti-osteoporotic substances	2 (0.9)	(0.0 ; 2.2)
25-hydroxyvitamin D, nmol/L*	45.1 ± 23.9 [3.6 – 158.3]	(41.6 ; 48.6)
Hypovitaminosis D ≤ 75 nmol/L*	162 (74.3)	(68.0 ; 80.6)
Hypovitaminosis D ≤ 50 nmol/L*	119 (54.6)	(47.4 ; 61.8)
Hypovitaminosis D ≤ 25 nmol/L*	40 (18.3)	(12.7 ; 23.9)

Data presented as mean ± standard deviation [range] or n (%) where applicable. CI: confidence interval; \*: data available for 183 participants.

VSDS was completed in 218 individuals (mean ± standard deviation, 79 ± 6years; 46.3% female). Among them, 183 patients (mean, 79 ± 6years; 45.9% female) had a blood test for the measure of the serum 25OHD concentration (mean, 45.1 ± 23.9 nmol/L). Among these 183 participants, 162 (74.3%) had serum 25OHD ≤ 75 nmol/L, 119 (54.6%) had 25OHD ≤ 50 nmol/L, and 40 (18.3%) had 25OHD ≤ 25 nmol/L (Table 1).

Table 2 shows that the completing rate was 90.1% (i.e. greater than the 70% expected) meaning that the VSDS tool could be considered as feasible. The mean completing time was 1 min and 48 s (range 1–5 minutes). Interestingly, the completing time was inversely correlated to the number of years of practice ( $r = -0.18$ ,  $P = 0.006$ ). Regarding the reasons for not completing the VSDS, only three patients refused the VSDS (1.2%); one patient because s/he was tired, the other one because s/he did not feel concerned, and the last one without giving any explanation. In parallel, two questionnaires (0.8%) were not completed because the physicians considered it was not feasible in the

**Table 2**  
Feasibility and acceptability of the VSDS tool.

	Summary value
<b>Feasibility</b>	
Completing rate*, %	218 (90.1)
Completing time†, min	1.8 ± 0.7
<b>Acceptability*</b>	
Patients acceptance rate	239 (98.8)
Reasons for non-completing the VSDS (n = 24)	
Patient refusal	3 (1.2)
Infeasible in the clinical context	2 (0.8)
Physician lack of time	11 (4.5)
Physician omission	8 (3.3)
<b>Physicians satisfaction‡</b>	19 (8.7)
Physicians globally satisfied with the VSDS	10 (100)
Physicians satisfied with the completing time	10 (100)
Physicians finding the VSDS easy to use	10 (100)
Physicians considering the VSDS usable on a routine basis	9 (90)
Physicians likely to use the VSDS on a routine basis	8 (80)
Physicians likely to seek more frequently hypovitaminosis D in their patients if they had the tool	7 (70)

Data presented as mean ± standard deviation or n (%) where applicable. \*: data available for 242 participants; †: data available for 218 participants; ‡: data available for 10 participants.

clinical context, eight (3.3%) due to omission, and eleven (4.5%) due to lack of time. The latter eleven instances involved seven physicians out of the ten who took part in the study.

Regarding their feeling towards the VSDS, all physicians were satisfied with the tool, with the completing time, and found it easy to use. Nine out of ten would consider using it in everyday practice, and eight would be particularly prone to use it. Finally, although only three GPs reported to seek hypovitaminosis D ordinarily before the study, four additional GPs (total, seven GPs) thought they would be more likely to seek hypovitaminosis D in their patients with the VSDS tool (Table 2).

Finally, Table 3 reports the metrological properties of the VSDS for the identification of hypovitaminosis D in this sample. The best (i.e., highest) performance was found for the diagnosis of hypovitaminosis D ≤ 75 nmol/L (diagnostic accuracy 84.7%, with positive likelihood ratio 2.1 and negative likelihood ratio 4.9). The VSDS was also effective in diagnosing hypovitaminosis D ≤ 50 nmol/L and hypovitaminosis D ≤ 25 nmol/L, although with lower accuracy (respectively, 75.4% and 71.0%) (Fig. 1). The OR for hypovitaminosis D ≤ 75 nmol/L was 10.0 [95% confidence interval (CI): 3.7–27.0] while using ‘not combining items’ as a reference, OR = 7.7 [95CI: 3.9–15.5] for hypovitaminosis D ≤ 50 nmol/L, and OR = 6.3 [95CI: 2.9–13.9] for hypovitaminosis D ≤ 25 nmol/L (Fig. 1).

#### 4. Discussion

Our results showed that the 16-item VSDS was feasible, acceptable and accurate to identify hypovitaminosis D among older outpatients in primary care.

Although numerous studies have examined the variables influencing the serum 25OHD concentration, only few were designed to identify hypovitaminosis D among older adults, and mainly in academic or hospital contexts [18–21], but not in primary care. Moreover the feasibility and acceptability of such procedures have not yet been examined. Thus the present study complements previous literature by providing the first evidence that our VSDS tool is feasible and acceptable to patients, and was accurate during primary care consultation.

The short and noninvasive VSDS questionnaire was very well accepted to patients. The acceptance rate, which amounted to 98.8%, showed that the majority of non-completed VSDS questionnaires were related to physicians due to a lack time (45.8%) or omission (33.3%).

**Table 3**

Metrological properties of the VSD tool for the diagnosis of hypovitaminosis D according to the different threshold values (n = 218).

Hypovitaminosis D	True positive	False positive	True negative	False negative	Sensitivity, %	Specificity, %	Positive predictive value	Negative predictive value	Positive likelihood ratio	Negative likelihood ratio	Accuracy, %
≤ 75 nmol/L	143	9	12	19	88.3	57.1	94.1	38.7	2.1	4.9	84.7
≤ 50 nmol/L	99	25	39	20	83.2	60.9	79.8	66.1	2.1	3.6	75.4
≤ 25 nmol/L	29	42	101	11	72.5	70.6	40.9	90.2	2.5	2.6	71.0

Stressing the physicians' lack of time may appear contradictory with the relatively short completing time of less than 2 min, but GPs indicated that their impression of lack of time was mainly due to delays in the consultations that could be considerable. They added that the VSD tool appeared particularly suited for consultations aimed at renewing the patients' treatments, which are usually more amenable to the patient global assessment.

GPs were globally satisfied with the VSD tool. The strengths they identified were the following: i) the VSD is a relatively standard questionnaire, thus easy to integrate into everyday practice; ii) the completing time was short since most items were already known by GPs; and iii) the VSD gave the opportunity to less experienced physicians to address the issues of falls, autonomy and mood. Instead, the limitations they identified were as follows: i) there is a need to incorporate the VSD into a software for the calculation of the risk of hypovitaminosis D; ii) using the VSD was difficult during the consultations for acute organic decompensations; and iii) the VSD would be an additional unlisted act in primary care. Overall, the majority of GPs would be willing to use the VSD in routine consultations, and even 70% felt that they would seek more frequently hypovitaminosis D in their patients with this tool because they would get the result immediately without the delay of the blood test and because its diagnostic accuracy was high.

The VSD was able to identify hypovitaminosis D among older outpatients in primary care (Table 3 and Fig. 1). Age-related hypovitaminosis D is all the more prejudicial in this population as it is highly frequent and it results in various adverse health events including osteomalacia, propensity to fall, diabetes mellitus, cognitive disorders, cancers, sarcopenia and viral infections, among others [1,2]. Importantly, hypovitaminosis D and related adverse events may be corrected by oral supplementation [22,23], of which the dose and schedule depend on the identification of hypovitaminosis D [8]. However, currently, the only way to detect hypovitaminosis D relies on blood tests, which are expensive and whose results are available only after a waiting period. That is why, to rationalize the use of serum 25OHD

assays and to save health costs, clinical diagnostic tools like the VSD are needed to identify individuals at high risk of hypovitaminosis D; the blood tests being then restricted to people whose vitamin D status remains indeterminate. Moreover, since 75 nmol/L is the broadest definition of hypovitaminosis D [1], it is likely that our VSD tool, which is particularly accurate for the identification of hypovitaminosis D ≤ 75 nmol/L (Fig. 1), will be valuable and helpful for the clinicians in decisions to supplement their patients. This is the most important difference with other tools built for the same purpose [20,21], which are especially effective for identifying hypovitaminosis D ≤ 25 nmol/L, and therefore miss people with serum 25OHD concentration between 25 and 75 nmol/L for whom starting vitamin D supplementation would, however, be appropriate. Here, our VSD tool was able to diagnose vitamin D status ≤ 75 nmol/L, which corresponds to all concentrations ranging between 0 and 75 nmol/L, and exposes individuals to all skeletal and nonskeletal events accompanying low levels of vitamin D [1,2].

Some limitations should be acknowledged. First, the study cohort was restricted to outpatients with a history of falls or osteomalacia who were probably frailer and with lower 25OHD concentrations than the population of all older outpatients. It is also possible that they have been more accepting of the VSD as they had a history of falls or osteomalacia and thus possibly a better understanding of the importance of vitamin D compared to a wider sample of patients. Second, it is possible that participating GPs may not be representative of the entire profession, although several generations were selected with a variety of years of experience, and both rural and urban practices were represented. Third, our sample size was relatively small and could not be calculated *a priori*. Fourth, the inclusion period from March to May may have influenced the proportion of hypovitaminosis D here. However, it is noticeable that, unlike the present study, the VSD tool was initially built (and its metrological qualities examined) from blood tests carried out throughout the year [10], including at the end of summer / beginning of autumn during which the 25OHD concentrations are the highest in France.

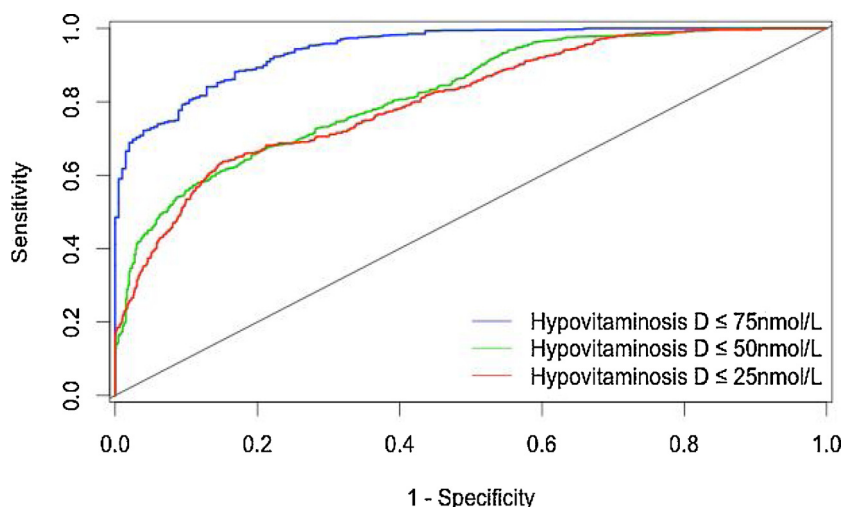


Fig. 1. ROC curves for the diagnosis of hypovitaminosis D with the VSD tool, according to the different definitions of hypovitaminosis D.

## 5. Conclusions

In conclusion, the 16-item VDSD was feasible, acceptable and accurate for identifying hypovitaminosis D among older outpatients in primary care. Such an inexpensive and noninvasive tool may undoubtedly help GPs in decisions to supplement their geriatric patients without routinely resorting to an expensive blood test. Additional studies are needed to determine the cost-effectiveness of the tool, and its efficiency for replacing monitoring blood tests after the initiation of vitamin D supplements. Future steps are to provide the tool on a larger scale for consultations using dedicated computerized support.

### Authors contribution

- CA has full access to the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analyses.
- Study concept and design: CA.
- Acquisition of data: JLM and GA.
- Analysis and interpretation of data: GA, CA, JLM, DJL and JR.
- Drafting of the manuscript: CA, JLM and GA.
- Critical revision of the manuscript for important intellectual content: SNK, DJL and JR.
- Obtained funding: Not applicable.
- Statistical expertise: CA and JR.
- Administrative, technical, or material support: CA.
- Study supervision: CA.

### Sponsor's role

None.

### Declaration of Competing Interest

The authors report no conflict of interest with this manuscript. They have no relevant financial interest in this manuscript.

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