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Point-of-care ultrasonography of carotid arteries in primary care: sensitivity and specificity of identification of carotid atherosclerosis and prevalence of carotid atherosclerosis in apparently healthy subjects with high and very high cardiovascular disease risk

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Abstract

Background Cardiovascular diseases (CVDs) remain a major global health concern, contributing significantly to morbidity and mortality. The use of point-of-care ultrasonography (POCUS) in primary care has grown in popularity, offering a promising approach for early atherosclerosis detection.

The objective was to investigate the sensitivity and specificity of family medicine physicians in identifying carotid atherosclerosis using POCUS and to determine the prevalence of carotid atherosclerosis in apparently healthy subjects with high or very high CVD risk.

Methods A cross-sectional study was conducted from June 2023 to January 2024 across seven family medicine practices in Slovenia. The study included 199 participants aged 40-69, with high or very high CVD risk and no prior treatment with antilipemic drugs. Two participants were excluded due to insufficient quality of ultrasonographic recordings. Participants underwent POCUS of the carotid arteries to detect atherosclerotic plaques. Sensitivity and specificity were calculated against the assessments of a certified specialist in cardiology and vascular medicine.

Results The study found a high prevalence (69.5% [62.6-75.9]) of carotid atherosclerosis among participants, with higher rates in males and older age groups. Sensitivity and specificity of POCUS for detecting carotid atherosclerosis were 96.4% [91.7-98.8] and 90.0% [79.5-96.2], respectively. Carotid atherosclerosis was more common in participants with very high CVD risk compared to those with high CVD risk.

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Conclusions Carotid atherosclerosis in apparently healthy subjects with high and very high CVD risk is much more prevalent than expected. POCUS of the carotid arteries is a highly sensitive and specific method for detecting carotid atherosclerosis in primary care. This method can significantly enhance early CVD risk assessment and intervention by family medicine practitioners.

Trial registration ISRCTN registry as ISRCTN10591599 (registration date 26.07.2024).

Keywords POCUS, Primary care, Carotid artery POCUS, CVD risk, Sensitivity and specificity, Prevalence, Family medicine

Background

Cardiovascular diseases (CVDs) in general, and atherosclerotic vascular disease (ASCVD) in particular, remain a major global health concern, representing a considerable burden on healthcare systems and contributing significantly to morbidity and mortality. Early detection of ASCVD, such as the appreciation of atherosclerotic plaques on carotid ultrasonography, has emerged as a crucial focus point in understanding the early stages of ASCVD progression and implementing preventive strategies [1]. As family medicine practitioners play an essential role in primary care and early disease detection, deeper exploration of carotid atherosclerosis within this context becomes of great significance [2, 3].

Point-of-care ultrasonography (POCUS) in primary care represents one of the fastest growing trends among family medicine doctors in Europe. POCUS currently provides a wide range of applications, including the evaluation of obstetric, abdominal, pulmonary, cardiac, vascular and musculoskeletal conditions [4]. In POCUS, unlike conventional ultrasonography, the examination is performed with the sole purpose of answering a focused clinical question with a straightforward answer. For example, when examining carotid arteries with POCUS, the question ‘Do we detect the presence of atherosclerotic plaques?’ is answered with simple responses: ‘Yes,’ or ‘No [5].

The use of non-invasive imaging, particularly B-mode ultrasonography, is a valuable tool for estimating sub-clinical atherosclerosis and assessing of cardiovascular risk [6]. While research on ASCVD initiation, progression, and response to preventive therapy has greatly benefited from ultrasonographic appreciation of carotid intima-media thickness (cIMT) as a surrogate marker for ASCVD, the presence of carotid plaques has emerged as a more specific and thus clinically relevant modifier of risk stratification [7–9]. Given the crucial role of family physicians in preventive healthcare, understanding the sensitivity and specificity of carotid ASCVD detection may represent a crucial early step in CVD risk reduction. POCUS of the carotid arteries, which has not yet been described in the literature, might present a new approach for more accurate CVD risk assessment in the primary

care setting as well as tackling low drug adherence with preventive strategies.

In this study, we aimed to investigate the sensitivity and specificity of POCUS of carotid arteries performed by family medicine physicians in identifying carotid atherosclerosis. We also aimed to determine the prevalence of carotid atherosclerosis in apparently healthy subjects at high and very high CVD risk, i.e., asymptomatic adults without established CVD who may benefit from screening for preclinical ASCVD.

Methods

Study design

A cross-sectional study was conducted.

Study duration

The study was conducted from June 2023 to January 2024.

Setting

The study was conducted in seven family medicine practices, distributed across different parts of Slovenia, one from each of the following cities/regions: Maribor, Ptuj, Kidričevo, Novo mesto, Ljubljana, Vrhnika and Žiri. All practices included a population that could be considered as a mix of urban and rural. Practices were chosen from a pool of practices with access to the required ultrasonographic device. Out of more than 70 practices that had an opportunity to participate in the study, 7 completed all the participation requirements in time, including education.

Study population

We included apparently healthy individuals aged from 40 to 69 years at high or very high CVD risk. As per the European Society of Cardiology guidelines, “apparently healthy individuals” are asymptomatic adults without established ASCVD, type 2 diabetes, or severe comorbidities, who represent candidates for conventional CVD risk factor screening and management in primary care [10].

CVD risk was determined by the family medicine doctors based on individual assessment of CVD risk using SCORE2 table and risk modifiers, however, estimated

CVD risk was not allowed to be lower than calculated CVD risk as assessed SCORE2 prediction.

Studied population was demographically diverse, reflecting the general population in Slovenia.

Inclusion and exclusion criteria

Inclusion criteria were (a) aged 40 to 69 years, (b) high or very high estimated CVD risk*, (c) no prior use of anti-lipemic drugs.

Exclusion criteria were (a) known/established CVD, (b) diabetes mellitus type 1 or type 2, (c) carotid ultrasound conducted in the past 5 years, (d) chronic kidney disease, (e) familial hypercholesterolemia, (f) active malignant disease, (g) uncontrolled psychiatric disorder, (h) language barrier (subject's knowledge of Slovene language is inadequate for appropriate communication with physician), (i) estimated life expectancy of less than 1 year.

*CVD risk was determined using two steps: (1) firstly, using SCORE2 table and/or "ESC CVD risk calculator app"; (2) additionally, using risk modifiers, which included: (a) blood triglyceride level greater or equal to 1.7mmol/l, (b) blood LDL-cholesterol level greater or equal to 5.0mmol/l, (c) blood HDL-cholesterol level lower or equal to 1.2mmol/l, (d) BMI greater or equal to 30.0 kg/m², (e) CVD event in immediate family (for men aged less than 55 years; for women aged less than 65 years), (f) non-active smokers (using "pack-years" data); (g) stress; (h) comorbidities (prediabetes, atrial fibrillation, chronic inflammation diseases (rheumatoid diseases, etc.), COPD, chronic kidney disease arterial hypertension, obesity, obstructive sleep apnoea.

Selection of subjects

Subjects were selected at random by family medicine practitioners upon identifying high and very high CVD risk during routine model practice checks.

In Slovenia, the National programme for primary CVD disease prevention was established in 2003 as a screening programme for risk factor detection and management. Family medicine practices allot dedicated time slots for apparently healthy individuals for risk factor screening, including blood pressure measurements, blood lipid analysis, etc. Every consecutive patient is included in the screening upon reaching 30 years of age.

Individuals who were invited to participate in the study were given the informed consent form to sign.

Data collection and examination of carotid arteries

General participant information was collected: gender, age, personal information, family history and other demographic data. Routine clinical examinations were performed, including fasting plasma glucose and lipid profile (i.e., total and LDL cholesterol, HDL-cholesterol and triglyceride levels). Recorded co-morbidities/

associated conditions were: prediabetes, atrial fibrillation, chronic inflammation diseases (rheumatoid diseases, etc.), COPD, chronic kidney disease arterial hypertension, obesity, obstructive sleep apnoea.

Point-of-care ultrasonography (POCUS) of carotid arteries was performed with the sole goal of identifying atherosclerosis of carotid arteries. Participating family medicine practitioners performed the examination using a linear probe on "Vscan Air" (Sonos), a portable Bluetooth ultrasonographic device. The entire left and right carotid arteries (CCA, bifurcation, ICA and ECA) were examined to the limit of visibility, using B-mode ultrasonography. On both sides of the neck, video recordings and measurements were recorded at the place of the greatest intima-media thickness. Video recordings and measurements were then uploaded in the electronic case report form (e-CRF) along with encrypted subject information and family medicine practitioner's assessment of presence of carotid atherosclerosis.

Criteria for atherosclerotic plaques were as follows: (a) any focal thickening thought to be atherosclerotic in origin and encroaching into the lumen of any segment of the carotid artery given the protrusion is *at least twice the thickness of the surroundings* or (b) in the case of diffuse vessel wall atherosclerosis, when cIMT measures ≥ 1.5 mm in any segment of the carotid artery [10].

In cases of unclear or potentially misleading video recordings and measurements performed on carotid arteries, the data was excluded from further analysis.

Education

All family medicine practitioners were educated in performing POCUS of carotid arteries prior to the study. All took part in the 5-step individual carotid artery POCUS course, which took from 2 to 6 months (depending on prior ultrasonographic experience of family medicine practitioners). Ultrasonographically less experienced practitioners attended the general POCUS course before beginning the 5-step individual carotid artery POCUS course. Individual education involved three "one-on-one" sessions, multiple follow-up image reviews and counseling via virtual meetings when needed. Every practitioner correctly performed and interpreted at least 30 carotid artery POCUS examinations before entering the study.

Validation

Every ultrasonographic recording and measurement included in the study was validated by two certified practitioners, specialists in cardiology and vascular medicine. In case of conflicting results between the two, third certified practitioner performed additional validation, resulting in deciding assessment. Final results were based solely on validators' data, as validators was considered as an "unmistakable observer".

Endpoints

The primary endpoints were to calculate the prevalence of carotid atherosclerosis in the given population and to find out the sensitivity and specificity of identification of carotid atherosclerosis by family medicine practitioners.

Sample size and power of the research

The sample size for this study was calculated using the “G*Power” sample size calculator for prevalence of carotid atherosclerosis. The parameters used were: one-tailed exact test for proportions (binomial test, one sample case), with a priori power analysis to compute sample size based on an alpha level of 0.05, a power of 0.8, and a constant proportion of 0.5 with alternative hypothesis with a constant proportion of 0.6.

Statistical analysis

Descriptive statistics were calculated. Numerical values were summarised using mean and standard deviation (SD). Categorical variables were presented by occurrence and percentages. Prevalence was reported separately for different age groups and gender as well as all together. Specific prevalence values were also calculated for “high” and “very high” CVD risk patients. The Clopper-Pearson method was used in confidence interval calculation for prevalence, sensitivity and specificity, at a 95% confidence level, using Python (version 3.10.12).

Results

Sample characteristics

The study included 199 participants, 2 of which were discarded due to unclear and potentially misleading ultrasonographic recordings. Sample characteristics are presented in Table 1 below.

Among co-morbidities, rheumatoid arthritis was most commonly reported (in 10 participants). 8 participants were reported to have been treated for hypothyroidism, 7 for anxiety and/or depression, 5 for psoriasis. COPD, sleep apnoea, atrial fibrillation, malignant disease in remission, asthma, GERD, gastritis, CIBD, schizophrenia, gout, osteoporosis and BPH were also reported as associated condition, but none in more than 4 participants.

CVD event was considered “early” in case it occurred before the age of 55 in males and before the age of 65 in females. 26,3% of all participants reported to have had “early” CVD event in the immediate family (parents/brothers/sisters/children).

In 9 subjects, fasting blood glucose levels exceeded 6.1 mmol/L, but none exceeded 6.9 mmol/L. There were 14 subjects with LDL cholesterol levels lower than 3.0 mmol/L, whereas in 37 subject’s LDL cholesterol was greater than 5.0 mmol/L, in 5 subjects even greater than 6.0 mmol/L. In 16 participants HDL cholesterol levels were higher than 2.0 mmol/L, whereas in 29 subjects HDL cholesterol levels were lower or equal to 1.0 mmol/L. Triglyceride levels were elevated above 3.0 mmol/L in 14 subjects, in 9 of those even above 4.0 mmol/L, whereas in 41 subject’s triglyceride levels were

Table 1 Characteristics of studied population

Characteristics	All	Male	Female
Sample size	197	121	76
Age (years)	57.6±6.9	56.5±6.9	59.3±6.5
40–49 (years)	31	22	9
50–59 (years)	77	52	25
60–69 (years)	89	47	42
“Very high” CVD risk	73 (37.1)	50 (41.3)	23 (30.3)
SCORE2 risk	7.1±3.2	7.2±3.2	7.0±3.1
BMI (kg/m ²)	27.9±11.2	27.7±9.8	27.9±12.6
Arterial hypertension	75 (38.1)	45 (37.2)	30 (39.5)
Active smokers	62 (31.5)	42 (34.7)	20 (26.3)
Non-active smokers	44 (22.3)	30 (24.7)	14 (18.4)
Smoke time (pack-years)	22.2±15.1	23.3±16.1	19.9±12.7
CVD event in immediate family	52 (26.4)	31 (25.6)	21 (27.6)
Co-morbidities	55 (27.9)	31 (25.6)	24 (31.6)
LDL cholesterol (mmol/L)	4.2±0.9	4.0±0.8	4.5±0.9
HDL cholesterol (mmol/L)	1.4±0.4	1.3±0.3	1.6±0.4
Triglycerides (mmol/L)	1.8±1.2	1.9±1.4	1.5±0.6
Total cholesterol (mmol/L)	6.3±1.0	6.1±0.9	6.6±1.0
Glucose (mmol/L)	5.4±0.6	5.4±0.6	5.3±0.6

Values are provided as mean ± standard deviation or number (%)

BMI Body mass index, CVD Cardio-vascular disease, LDL Low-density cholesterol, HDL High-density cholesterol, Co-morbidities include other chronic and non-chronic diseases, that may affect CVD risk

Table 2 Prevalence of carotid atherosclerosis in different age groups

Age group	Plaques identified			Plaques not identified			Prevalence		
	All	Male	Female	All	Male	Female	All	Male	Female
40 to 49	16	12	4	15	10	5	51.6% [33.1–69.8]	54.5% [32.2–75.6]	44.4% [13.7–78.8]
50 to 59	51	36	15	26	16	10	66.2% [54.6–76.6]	69.2% [54.9–81.3]	60.0% [38.7–78.9]
60 to 69	70	38	32	19	9	10	78.7% [68.7–86.7]	80.9% [66.7–90.9]	76.2% [60.5–87.5]
All	137	86	51	60	35	25	69.5% [62.6–75.9]	71.1% [62.1–79.0]	67.1% [55.4–77.5]

Table 3 Prevalence of carotid atherosclerosis “high” and “very high” CVD risk individuals

	Prevalence
High CVD risk	62.2% [52.9–70.6]
Very high CVD risk	82.9% [71.5–90.2]

lower or equal to 1.0 mmol/L. There were 32 participants who were offered lipid lowering drugs prior to study, but none of them began the treatment (has not taken even a single pill).

Prevalence of carotid atherosclerosis

Since validators were regarded as “unmistakable observers”, the true prevalence of carotid atherosclerosis was determined solely based on validator’s findings (Tables 2 and 3).

Carotid atherosclerosis was identified in 137 participants, 86 males and 51 females. Carotid plaque prevalence for the entire study population was determined at 69.5%. In male subjects the prevalence was higher than in female subjects. Prevalence of carotid atherosclerosis was also higher in elder participants and in “very high” CVD risk patients.

Sensitivity and specificity

There were 5 false negatives among carotid plaques identified by family medicine doctors, which comprised the sensitivity of the test at 96.4%.

Carotid atherosclerosis was not present in 60 participants. In 6 cases, carotid atherosclerosis was identified as false positive, comprising the specificity of the test at 90.0% (Table 4).

Validators’ evaluation

Out of 199 ultrasonographic recordings, the two validators disagreed in two cases, making it necessary to involve the third validator for evaluation in these instances.

Discussion

Findings and evaluation

Carotid artery POCUS in family medicine is an accurate method for screening asymptomatic atherosclerotic plaques, representing an accessible tool for improving ASCVD risk assessment in primary care. In our study population of apparently healthy individuals at high or very high CVD risk, seven out of ten participants had carotid atherosclerotic plaques. POCUS performed by a family medicine physician detected presence of plaques with high sensitivity and specificity— 96.3% [91.7–98.8] and 90.0% [79.5–96.2], respectively— against appreciation by a dedicated vascular specialist.

Risk assessment for ASCVD in apparently healthy individuals is a pivotal domain of family medicine. All pertinent guidelines [11–13] recommend clinical assessment (with the aid of CVD risk tables or equations based on conventional risk factors) and further imaging screening for preclinical ASCVD (with calcium score or carotid ultrasound), especially for individuals at borderline risk. While imaging with carotid ultrasonography may greatly improve risk classification, its current accessibility to family medicine precludes its more widespread application. In our study, access to a fairly inexpensive ultrasonographic device and a relatively short-term training provided family physicians with a powerful tool for improving ASCVD risk assessment in primary care— yielding high sensitivity (96.3% [91.7–98.8]) and specificity (90.0% [79.5–96.2]) for the sole goal of detecting carotid atherosclerosis. According to our study, immediate access to carotid POCUS may therefore greatly improve the access to advanced risk stratification strategies in primary care.

The prevalence of ASCVD, as determined by the prevalence of carotid plaques, was high— seven out of ten (69.5%) participants had detectable plaques on carotid POCUS. The prevalence of plaques was higher than reported in prevalence studies) [14]. The finding, however, is consistent with the inclusion of apparently healthy individuals at high or very high CVD risk,

Table 4 Sensitivity and specificity of POCUS of carotid arteries

	Carotid Plaques	Carotid Plaques not present
Test positive	132	6
Test negative	5	54
	Sensitivity = 96.3% [91.7–98.8]	Specificity = 90.0% [79.5–96.2]

wherein clinical risk assessment based on traditional risk factors is, by definition and construct, associated with presence ASCVD. Plaques were also more likely to be detected in individuals at “very high” vs. “high” CVD risk (82% vs. 62%, respectively).

Importantly, 39% of participants in our study would be reclassified from “high” to “very high” CVD risk, based on POCUS-detected carotid plaques. Presence of ASCVD confers very high cardiovascular risk and warrants more aggressive preventive interventions, such as more intensive LDL-cholesterol lowering with more stringent target levels [11]. While carotid ultrasonography at present does not represent a routine examination for CVD risk assessment, several studies have shown that ultrasonographic appreciation of carotid atherosclerosis may provide incremental information on the risk of future CVD events beyond risk tables/clinical tools [8, 9]. One likely barrier to a more widespread recommendation for carotid ultrasound is limited accessibility; providing an initial diagnostic screening tool for ASCVD directly to family physicians may improve detection of ASCVD, increase the timely uptake of preventive strategies and provide a cost-effective method for furthering the care of patients at CVD [15].

Implications for practice and research

POCUS of carotid arteries proved to be an accessible and accurate tool for detection of preclinical atherosclerosis and accurate CVD risk assessment in primary care. Conventional risk factor-derived risk estimation in asymptomatic individuals, such as the QRISK3 tool or the SCORE2/SCORE-OP equations, may lack sufficient accuracy and yield limited clinical benefit [16]. Conversely, appreciation of atherosclerotic involvement of the carotid arteries reflects systemic ASCVD and conveys very high CVD risk. In terms of systemic ASCVD, even in patients with established ASCVD, ultrasonographic detection of carotid atherosclerotic involvement (suggesting polyvascular disease) adds prognostic information on the risk of future cardiovascular events [17]. While further diagnostic testing for polyvascular disease (e.g., coronary artery calcium scoring) or repeated carotid imaging may not be necessary when plaques are small and limited [10] additional investigation may be considered with extensive atherosclerotic involvement. In terms of CVD risk management, detection of carotid plaques should trigger a more intensive preventative approach, including considering to use high-intensity lipid-lowering therapy and achieving more ambitious LDL-cholesterol targets. In this respect, importantly, POCUS of carotid arteries also has great potential for improving lipid-lowering therapy adherence in primary care, which is believed to persist at around 50% [16]. The potential of using ASCVD visualization (i.e., showing the image of carotid plaques directly

to the patient) to motivate patients for initiation and/or continuation of prescribed therapy certainly merits further research.

Strengths and limitations

The main strength of this study lies in its random, but specific and narrow study population of apparently healthy subjects.

Portable ultrasonographic devices have come a long way in aiding family medicine practitioners. Technical advancements produced small wireless ultrasonographic devices, which are very appropriate for family medicine practice settings as they are compact, space-efficient, intuitive and easy to use. The quality of picture produced by these devices allows reliable plaque detection. However, better and more expensive ultrasonographic devices would allow better image quality and could therefore be more precise in carotid atherosclerosis detection, which could present a minor limitation of this study. All family medicine practitioners used the exact same portable ultrasonographic device, which represents an important strength, however, practices were only invited to participate in the study, had they owned this exact ultrasonic device, which unveils a methodological limitation.

Included family practices may not reflect the general primary care providers, as only highly motivated physicians opted to participate in the study. Considering that these were very highly motivated doctors, who are actively engaged in their practices and are striving to be the best by constantly learning new diagnostic and treatment methods, they might not reflect an “average family medicine practitioner” in Slovenia, resulting in probable overestimation of sensitivity and specificity calculated by this study.

As validators evaluation was considered as an “unmistakable observer”, the appraisal should be regarded as detection of carotid plaque against a specialist in vascular medicine; true presence of carotid plaques could therefore be under- or over-estimated.

There were 9 participants with fasting blood glucose levels between 6.1 and 6.9. As additional tests weren't performed (OGTT, HbA1c), there is a possibility, that some of them actually had diabetes mellitus, which was not in line with our inclusion criteria (i.e., apparently healthy individuals free of CVD or diabetes).

Conclusions

POCUS of the carotid arteries is a highly sensitive and specific method for detecting carotid atherosclerosis in primary care. This method can significantly enhance early CVD risk assessment and intervention by family medicine practitioners, potentially improving outcomes for patients with high and very high CVD risk. In our study, seven in ten apparently healthy subject with high

and very high CVD risk had detectable carotid plaques, thus suggesting a very high prevalence of ASCVD in this population as well as a substantial improvement in risk classification.

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Authors' contributions

AK was the main researcher who was included in every part of the study. AK collected the data, performed data analysis, interpretation and writing. BJ contributed in the design of the study, interpretation of the data and in writing. MPŠ contributed in the design of the study and interpretation of the data. APA was consulted on study design and performed data analysis. All authors read and approved the final manuscript.

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Data availability

The original research data are securely stored on the server of the Faculty of Medicine, University of Ljubljana, Slovenia.

Declarations

Ethics approval and consent to participate

Ethics approval for the study was granted by the Slovenian Committee for Medical Ethics ("KME RS"), under reference number 0120–469/2022/3 on December 13, 2022.

This study adhered to the Declaration of Helsinki.

Every participant in the study signed a standardised written informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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