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ORIGINAL RESEARCH

THE INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH IN SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE.

ZASTOSOWANIE MIĘDZYNARODOWEJ KLASYFIKACJI FUNKCJONOWANIA, NIEPEŁNOSPRAWNOŚCI I ZDROWIA (ICF) W PROFILAKTYCE WTÓRNEJ CHORÓB UKŁADU KRĄŻENIA.

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ABSTRACT

Introduction

Patients with established cardiovascular disease (CVD) have a high risk of subsequent CVD events. Monitoring of the risk factors is crucial in order to prevent recurrent CVD events.

Aim

The aim of this study was to develop a protocol of the risk factors of recurrent CVD based on the ICF (The International Classification of Functioning, Disability, and Health) framework.

Material and Methods

An original ICF assessment sheet which contains risk factors of recurrent CVD was developed based on up-to-date data from the literature. The evaluation criteria for each category were determined based on recommendations defined in the ESC (European Society of Cardiolo-gy),AHA(American Heart Association) EFSD(European Foundation for the Study of Diabetes) and KDIGO(Clinical Practice Guideline for Glomerulonephritis) guidelines.

Results

The ICF assessment sheet contains CVD risk factor categories such as comorbidities, measures of liver and renal impairment, disorders of carbohydrate and lipid metabolism, pharmacological treatment and lifestyle-related factors.

Conclusions

The ICF assessment sheet, which contains multiple risk factors for CVD in one place can make monitoring this pa-rameters to be easier in doctor's office.

Keywords: ICF; secondary prevention; risk factors; cardiovascular disease;

STRESZCZENIE

Wstęp

Pacjenci z rozpoznaną chorobą sercowo-naczyniową (CVD) mają wysokie ryzyko kolejnych incydentów CVD. Monitorowanie czynników ryzyka ma kluczowe znaczenie dla zapobiegania nawrotom CVD.

Cel
Celem tego badania było opracowanie protokołu czynników ryzyka nawrotu CVD w oparciu o ramy ICF (Międzynarodowej Klasyfikacji Funkcjonowania, Niepełnosprawności i Zdrowia).
Materiał i metody
Na podstawie aktualnych danych literaturowych opracowano oryginalny arkusz oceny ICF, który zawiera czynniki ryzyka nawrotu CVD. Kryteria oceny dla każdej kategorii zostały ustalone na podstawie zaleceń określonych w wytycznych ESC (European Society of Cardiology), AHA (American Heart Association), EFSD (European Foundation for the Study of Diabetes) oraz KDIGO (Clinical Practice Guideline for Glomerulonephritis) .
Wyniki
Oryginalny arkusz oceny ICF zawiera kategorie czynników ryzyka CVD, takie jak choroby współistniejące, parametry niewydolności wątroby i nerek, zaburzenia metabolizmu węglowodanów i lipidów, leczenie farmakologiczne i czynniki związane ze stylem życia**.**
Wnioski
Arkusz oceny ICF, który zawiera wiele czynników ryzyka CVD w jednym miejscu, ma na celu wskazanie, które czynniki ryzyka wymagają szczególnego monitorowania, co może ułatwić podejmowanie decyzji klinicznych.

Słowa kluczowe: ICF; profilaktyka wtórna; czynniki ryzyka; choroba sercowo-naczyniowa;

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Introduction

Patients with a history of prior myocardial infarction (MI) or stroke have a high risk for subsequent cardiovascular events (Roth et al., 2015). The mortality rate for patients with a history of MI is 5% per year, which is six times higher than that of age-matched individuals who did not have prior MI (Global Burden of Disease Study.Collaborators, 2013). Likewise, in patients with a history of prior stroke the risk for recurrent stroke is increased by 10%–12% the first year and by 5%–8% each subsequent year (O'Donnel et al., 2010).

According to World Health Organization (WHO) experts, about 80% of recurrent cardiovascular events could be prevented if major risk factors are eliminated (Menids et al., 2005) From the point of view of the primary healthcare provider, close monitoring of modifiable risk factors for CVD is crucial in the prevention of recurrent CVD events (Sung et al., 2019; Lee et al., 2019, Lucki et al.,2021).There is a need for a simple health tool that would be easy to implement.The International Classification of Functioning, Disability, and Health (ICF) is an excellent instrument that transforms information into simplified, categorized charts (Meng et al., 2018; Geyh et al.., 2004, Lucki et al., 2021).

Aim

The aim of the study was to develop an original protocol based on the ICF framework which contains modifiable CVD risk factors for use in secondary prevention.

Material and methods

An original ICF assessment sheet which contains risk factors of recurrent CVD was developed based on up-to-date data from the literature. This trial was registered in the Clinical Trial Registry under the number NCT04590287.

2.1. Risk Factors in Secondary Prevention

First, we performed a review of the literature, searching the Web of Science and PubMed databases for articles on the risk factors of recurrent ischemic heart disease events and stroke. The search included the following keywords: [secondary prevention] and [risk factors] and [cardiovascular disease], and [secondary prevention] and [risk factors] and [stroke]. The following criteria in articles of studies (Meng et al., 2018; Geyh et al., 2004; Liu et al., 2009; Lip et al.,2017; Orrapin et al., 2017; Yuan et al., 2012; Brown et al., 2019; We et al., 2013; Amarenco et al., 2006; Weiner et al., 2004; Narum et al., 2013;Breen et al., 2003; Ois et al., 2008) were included: (1) related to secondary prevention, (2) written in English, (3) included patients with a history of previous cardiovascular events, (4) study groups were above 300 patients, (5) the results were statistically significant. We excluded articles that were: (1) related to the primary prevention of CVD, (2) not written in English, (3) publicated in non-peer-reviewed journals.

2.2. ICF Categorical Profile

Based on data from the literature, an original ICF assessment sheet was developed. It contains modifiable risk factors in the secondary prevention of both ischemic heart disease and stroke. The qualifiers were then assigned to each ICF category using a five-point scale, from 0 to 4, measuring the level of disability or deficiency. The qualifiers were further specified by adding criteria defined in the guidelines published by professional organizations and associations, such as the European Society of Cardiology (ESC), the American Stroke Association (ASA), the European Association for the Study of Diabetes (EFSD) and Clinical Practice Guideline for Glomerulonephritis (KDIGO) (Oreapin et al., 2017; Brown et al., 2019; Narum et al.2013; Breen et al., 2003; Sattelmair et al., 2011; Ceccerini et al., 2014, Cappuccio et al., 2011; Hart 2003; Cuspidi et al., 2018; Inker et al., 2014; Pisters et al.,2010; Björck et al., 2016; Wormeser et al., 2011; Inzucchi et al., 2015; Schwart et al., 2018; Wood et al., 2018; Maeda et al., 2003).

Results

Risk Factors in the Secondary Prevention of CVD

Our review of the literature confirmed that widely recognized modifiable risk factors in the secondary prevention of CVD include comorbid conditions (arterial hypertension, atrial fibrillation (AF), carotid artery disease, depression, insomnia, diabetes mellitus, or dyslipidemia), renal and liver impairment, medication use, and lifestyle factors (smoking, alcohol abuse, or limited physical activity). A detailed literature review is provided in Table 1.

Table 1. Secondary Prevention of CVD.

Study design [year of publication]	Objective	Study group characteristics and research tools	Size				Median age (years)		
			CG		EG		CG	EG	
			M	F	M	F			
Randomized, double-blind study (Liu et al., 2009)	Effect of lowering blood pressure on the risk of recurrent stroke and other cardiovascular events	Patients with a history of stroke or TIA CG TIA without treatment EG treated with indapamide	2,040	785	2,037	803	60.4	60.1	Significant reduction events
Retrospective cohort study (Lip et al., 2017)	Effect of AF diagnosis and diagnosis timing on the incidence of recurrent stroke	Patients with a history of stroke or TIA	179,160 (53.7% female patients)				67		Stroke patients diagno of onset (late AF) ar
Meta-analysis of ndomized, controlled trials (Orrapin et al.,2017)	Benefit–risk assessment of carotid endarterectomy and selection of the best medical treatment	Patients with symptomatic carotid artery stenosis CG – no intervention EG – CEA surgery The study assessed 5-year risk for stroke (including ipsilateral stroke) and the risk for death during surgery.	2,166	842	2,338	909	90% of participants <75 years of age		En - increased 5-year risk patients with - decreased risk in pat
Multicenter prospective cohort study (Yuan et al., 2012)	Effect of post-stroke depression on the risk for recurrent stroke during one-year follow-up	CG – patients with a history of stroke without depression EG – patients with a history of stroke with post-stroke depression assessed according to the DSM-IV classification	843	389	281	200	61.2	62.1	After one-year follo stroke was 1.55 times depression than
Prospective cohort study Brown et al., 2019)	Association between SDB and recurrent ischemic stroke and mortality rates	Patients with a history of ischemic stroke CG –REI <10 EG – REI >10	128	188	129	397	65	65	SDB is associated wit of recur
Multicenter prospective cohort study (Wu et al., 2013)	Association between HbA1c and the risk of recurrence after acute ischemic stroke	Patients with a history of stroke CG without recurrent stroke EG with recurrent stroke	810	490	130	110	61	64	HbA1c level ≥6.1% i risk of rec
Randomized, double-blind study (Amarenco et al., 2006)	Effect of lowering LDL-C on the risk of recurrent stroke	Patients with a history of stroke or TIA with blood LDL-C level between 100 and 190 mg/dL CG without treatment EG treated with Atorvastatin	1,395	970	142	939	62.5	63	The incidence of str rates, as well as the ris was significant
Literature review (Weiner et al., 2004)	Effect of CKD on the risk of subsequent cardiovascular events	Patients with CVD CG without CKD EG with CKD	3,519		759		-	-	The presence of CKD is associated with i
Adverse Event Register (Narum et al., 2013)	Analysis of bleeding-related adverse events associated with warfarin therapy	Patients receiving warfarin	713				71% of participants >70 years of age		Treatment with warfa including intracereb with
Adverse Event Register (Breen., 2003)	Analysis of bleeding-related adverse events associated with drug therapy, including NSAIDs	Patients receiving drug therapy including NSAIDs	213				-	-	Treatment with NSA events, inclu
Prospective cohort study (Ois et al., 2008)	Effect of heavy alcohol consumption on the risk of recurrent stroke in patients with a history of stroke or TIA	Patients with a history of stroke or TIA CG – not heavy alcohol drinkers EG – heavy alcohol drinkers	643		46		71.73		Consuming 60 g of a increased risk o
Prospective cohort study (Ebstein et al., 2017)	Effect of smoking cessation on the risk of recurrent cardiovascular events in patients with a history of ischemic stroke or TIA	CG – patients currently smoking EG – patients who quit smoking	410	212	295	155	58	58	Smoking cessation associated with de myocardi
Retrospective cohort study (Sattelmair et al., 2019)	Effect of physical activity on mortality rates in patients with a history of CVD	CG – patients with no history of CVD EG – patients with a history of CVD	170,487	139,753	66,030	65,528	57.8	63.8	Regular physical activ risk of recurrent C secon

ACU- Acute coronary syndrome; AF- Atrial fibrillation; HbA1c - Glycated hemoglobin 1c; CEA- Carotid endarterectomy; CG - Control group; CKD - Chronic kidney disease; CVD - Cardiovascular disease; DSM IV - Diagnostic and Statistical Manual of Mental Disorders IV; EG – Experimental group; INR - International normalized ratio; MACE- Major adverse cardiovascular events; LDL- C *Low-density* lipoprotein; NSAIDs - Nonsteroidal anti-inflammatory drugs; REI - Respiratory event index; RHR- Resting heart rate; SDB - Sleep-disordered breathing; TIA -Transient ischemic attack.

Discussion

ICF Profile

The original ICF assessment sheet in Table 2 consists of the risk factor categories associated with both an increased risk of CVD in stroke patients and ischemic heart disease in secondary prevention.
ICF categories constitute commonly indicated increased risk factors in secondary prevention presented in Table 1. The category criteria were adopted according to the following guidelines

The effect of depressive disorders on the risk of a recurrent CVD event was assessed using ICF category **b152: emotional functions**. The following Beck Depression Inventory (BDI) scores were used to measure the severity of depression [22]: qualifier 0: BDI total score 0 to 11 – no depression; qualifier 2: BDI total score 12 to 19 – mild depression; qualifier 3: BDI total score 20 to 25 – moderate depression; qualifier 4: BDI total score 26 to 63 – severe depression.

The effect of sleep disturbance on the risk of a recurrent CVD event was assessed using ICF category **b134: sleep functions.** The following criteria were used to measure the severity of insomnia [23]: qualifier 0 – no sleep disturbance (sleep time 6–9 h); qualifier 4 – sleep disturbance (sleep time <6 or >9 h), and sleep disordered breathing (SDB) [13]: qualifier 0: <10 respiratory events during sleep; qualifier 4: >10 respiratory events during sleep.

The increased risk of CVD related to heart rhythm disorders were encoded as ICF category **b4101: heart rhythm**. The following criteria were used [24]: qualifier 0 – normal sinus rhythm; qualifier 4 – atrial fibrillation.

The effect of carotid artery stenosis on the risk of a recurrent CVD event was assessed using ICF category **b4150: functions of arteries.** The following criteria were used [19]: qualifier 0 – <50% carotid stenosis; qualifier 3 – 50% to 69% carotid stenosis; qualifier 4 – >70% carotid stenosis.

The effect of increased blood pressure on the risk of a recurrent CVD event was assessed using ICF category **b4200: increased blood pressure.** The following BP values were used [25]: qualifier 0 – BP <130/80 mm/Hg; qualifier 1 – BP >130/80 mm/Hg; qualifier 2 – BP >140/90 mm/Hg; qualifier 3 – BP >160/90 mm/Hg; qualifier 4 – BP >180/110mm/Hg.

The effect of liver and renal impairment on the risk of a recurrent CVD event was assessed using ICF category **b4301: metabolite-carrying functions of the blood.** The following criteria were used to classify renal impairment [27] : qualifier 0 – eGFR >90 ml/min/1.73 m²; qualifier 1 – eGFR 60–89 ml/min/1.73 m²; qualifier 2 – eGFR 30–59 ml/min/1.73 m²; qualifier 3 – eGFR 15–29 ml/min/1.73 m²; qualifier 4 – eGFR <15 ml/min/1.73 m², and liver impairment [26] : qualifier 0 – bilirubin level <2x the upper limit of normal (ULN) and ALT/AST/Alkaline phosphatase <3x ULN; qualifier 4 – bilirubin level >2x ULN and ALT/AST/Alkaline phosphatase >3x ULN.

Patients receiving anticoagulants due to increased risk of bleeding require INR monitoring [28]. This parameter was encoded as ICF category **b4302: functions related to the coagulation of blood.** If taking VKA following values were used : qualifier 0 – INR 2.0–3.0; qualifier 4 – INR <2.0 or >3.0. If taking NOAC following values were used : qualifier 0 – NO; qualifier 4 – YES. The effect of physical activity on the risk of a recurrent CVD event was assessed using ICF category **b455: exercise tolerance functions.** The

following qualifiers were defined [21]: 0 – at least 150 minutes of physical activity per week; 4 –less than 150 minutes of physical activity per week.

The effect of BMI on the risk of a recurrent CVD event was assessed using ICF category **b530: weight maintenance functions.** The following BMI values were used [29]: qualifier 0 – normal body weight; qualifier 1 – overweight; qualifier 2 – class 1 obesity; qualifier 3 – class 2 obesity; qualifier 4 – class 3 obesity.

The effect of impaired glycemic control on the risk of recurrent CVD event was assessed using ICF category **b5401, carbohydrate metabolism.** The following HbA1c values were used [30]: qualifier 0 – HbA1c <7%; qualifier 4 – HbA1c >7%.

The effect of LDL-C levels on the risk of a recurrent CVD event was assessed using ICF category **b7302, lipid metabolism.** The following LDL-C values were used [31]: qualifier 0 – LDL-C <55 mg/dL; qualifier 2 – LDL-C 55 mg/dL-70 mg/dL, qualifier 3 – LDL-C 71 mg/dL-115mg/dL, qualifier 4 – LDL-C >116 mg/dL.

Alcohol consumption is an additional risk factor associated with increased risk of a recurrent CVD event. This risk factor was assessed using ICF category **e1100, food: alcohol consumption.** The following criteria were used [32]: qualifier 0 – alcohol intake per day <10 g; qualifier 4 – alcohol intake per day >10 g. The increased risk of CVD related to NSAID [17] or anticoagulant use [18] and to smoking [33] was estimated using ICF categories **e1101, drugs** and **e1109, products or substances for personal consumption,** respectively. The following criteria were used: qualifier 0 – NO; qualifier 4 – YES.

Table 2. ICF Assessment Sheet with Risk Factors in Secondary Prevention of CVD.

ICF Category			EXAM #1 DATE ….. Impairment/Disability			
			4	3	2	1	0
			Complete	Severe	Moderate	Mild	No
			96%–100%	50%–95%	25%–49%	5%–24%	0%–4%
Body Functions		**Scoring**					
b152	Emotional functions (Ceccarini et al.., 2014)	BDI	26–63	20–25		12–10	0–11
b 134	Sleep functions (Cappuccio et al..,2011)	Sleep time [h]	<6 and >9				6 to 9
		REI	>10				<10
b410 1	Heart rhythm (Hart, 2003)	Heart Rhythm	Atrial Fibrillation				Normal sinus rhythm
b415 0	Functions of arteries (Orrapin et al.., 2017)	Stenosis [%]	>70	50–69			<50
b 4200	Increased blood pressure (Cuspidi et al.., 2018)	BP [mmHg]	>180/110	>160/90	>140/90	>130/80	<130/80
b430 2	Metabolite-carrying functions of the blood (Inker et al., 2014; Pisters et al.., 2010)	eGFR (ml/min/1.73 m²)	<15	15–29	30–59	60–89	>90
		Bilirubin [ULN]	>2x				<2x
		ALT/AST/Alkaline phosphatase [ULN]	>3x				<3x
b430 3	Clotting functions, Functions related to the coagulation of blood (Björck et al.,2016)	INR*	<2.0 or >3.0				2.0–3.0
		NOAC	YES				NO

b455	Exercise tolerance functions (Sattelmair et al.., 2011)	Physical activity	< 150/min/week				>150 min/week
b530	Weight maintenance functions (Wormser et al.., 2011)	BMI	>40	35–40	30–35	25–30	20–25
b5401	Carbohydrate metabolism (Inzucchi et al.., 2015)	HbA1 [%]	>7				<7
b7302	Lipid metabolism (Schwartz et al.., 2018)	LDL-C [mg/dL]	>116	115-71		70-55	<55
Environmental factors							
e1100	Food (Wood et al.., 2018)	Alcohol consumption [g]	>10				<10
e1101	Drugs (Narum et al., 2013; Breen et al.., 2003)	NSAIDs	YES				NO
		Anticoagulants	YES				NO
e1109	Products or substances for personal consumption, other specified (Maeda et al.., 2003)	Smoking	YES				NO

*If taking VKA **ALT - *Alanine* transaminase; AST – Aspartate transaminase; BMI – Body mass index; BDI - Beck *depression* inventory; BP – Blood pressure; CVD- Cardiovascular disease; eGFR – Estimated *glomerular filtration rate;* ICF - International Classification of Functioning, Disability and Health; INR - International normalized ratio; HbA1c - Glycated hemoglobin 1c; HR- Heart rate; LDL-C - *Low-density* lipoprotein ; NSAIDs - Nonsteroidal anti-inflammatory drugs; REI - Respiratory event index; ULN – Upper limited of normal;**

A large number of ICF categories and subcategories defined in the WHO's ICF Core Sets makes their use challenging in everyday clinical practice (Men et al., 2018; Geyh et al., 2004). This article describes a proposed brief ICF assessment sheet (see Table 1) designed to assess only those categories that are relevant to the treatment and prevention of recurrent CVD events.

A coincidence of these risk factors is associated with increased rates of recurrent cardiovascular events (Ge et al., 2019). Multimorbidity has been demonstrated to increase the risk of recurrent CVD. Yuan et al. 2012 showed that the odds of recurrent stroke were 1.55 times greater in patients diagnosed with poststroke depression (PSD) than in those without PSD, according to the criteria set by the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV). Currently, due to the limited data available from studies using DSM-IV diagnostic criteria for depression, the Beck Depression Inventory (BDI) was employed in the proposed ICF assessment sheet (Ceccarini et al., 2014).

Ge et al. (2019) demonstrated that insomnia, manifested as difficulty falling asleep and non-restorative sleep, was associated with an increased risk of recurrent CVD and cardiovascular disease mortality. A study by Cappuccio et al. (2011) yielded similar results. Therefore, we used insomnia (sleep time <6 and >9 h) as a criterion in our ICF assessment sheet. Moreover, Brown et al. (2019) reported in their study that SDB was associated with recurrent ischemic stroke. Therefore, we also used their criteria to characterize sleep functions (see Table 1).

Hypertension is a well-documented risk factor for CVD. Lewington et al. (2002) demonstrated that an increase in usual blood pressure [BP], measured either in the doctor's office or at home, is associated with adverse events such as ischemic and hemorrhagic stroke, myocardial infarction, or sudden cardiac death in all age groups. Liu et al. (2009) found that lowering BP significantly reduced the incidence of cardiovascular events in patients with cerebrovascular disease (stroke or TIA). Ettehad et al. (2016) recommended that the first objective should be to lower BP to less than 140/90 mmHg in patients with CVD events, and target BP values during treatment should be 130/80 mmHg or lower, provided that the treatment is well-tolerated.

In their study, Lip et al. (2017) found that having AF first diagnosed more than seven days post-stroke (late AF) was highly associated with recurrent stroke/TIA. It is worth noting that among patients with at least 1 year of follow-up, only 2.6% and 9.7% had ambulatory ECG monitoring in the 7 days and 12 months post-stroke, respectively.

The reports in the literature suggest that there is less benefit from revascularization with carotid endarterectomy [CEA] in patients with moderate stenosis of 50%–69%. CEA may be considered for patients with 50%–69% symptomatic stenosis, but the clinician should consider additional adverse risk factors such as contralateral occlusion, uncontrolled diabetes mellitus, labile hypertension, or left-sided carotid disease (Orrapin et al., 2017).

Chronic kidney disease (CKD) is another risk factor for cardiovascular disease. A study by Wang et al. (2012) demonstrated that lower eGFR levels were strongly associated with a higher prevalence of CVD. Weiner et al. (2004) also demonstrated that CKD was associated with an increased risk of recurrent CVD events.

Liver impairment—manifested as abnormal liver function test results (Pistes et al., 2010) —and the use of medications, in particular anticoagulants and NSAIDs, (Narum et al., 2013; Breen et al., 2003) are both associated with a higher risk of intracerebral hemorrhage. Unstable INR values that exceed the therapeutic range (Björck et al., 2016) also increase the risk of bleeding and thromboembolism.

Regular physical activity has been shown to decrease the risk of recurrent cardiovascular events due to its favorable effect on weight loss, glucose tolerance, and lowering BP (Ois et al., 2008).

Patients with diabetes mellitus are at a higher risk of atherosclerosis and often have other independent risk factors, such as hypertension or dyslipidemia (Wu et al., 2013). Amarenco et al. (2006) demonstrated that in patients with recent stroke, lipid-lowering therapy reduced the overall incidence of serious cardiovascular events. Moreover, Wormser et al. (2011) showed that a high Body Mass Index (BMI) is associated with an increased risk of CVD or type 2 diabetes mellitus.

Ois et al. (2008) found an independent association between excessive alcohol intake (>60 g/d) and a significant increase in the risk of recurrent ischemic stroke in patients with history of stroke or transient ischemic attack.

Cessation of cigarette smoking significantly reduces the overall risk of CVD (Maeda et al., 2003). Epstein et al. (2017) demonstrated that smoking cessation after ischemic stroke or TIA was associated with a lower 5-year risk of stroke, myocardial infarction, or death.

Conclusion

The use of a single tool, such as the ICF assessment sheet, which contains multiple risk factors for CVD may increase the effectiveness of preventative measures, and thus decrease the recurrence rate of cardiovascular events.

Created profile collects commonly recognized CVD risk factors in one sheet, is to indicate which risk factors require special monitoring in clinical practice, which will simplify making clinical decisions.

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