Biobehavioral Processes in Tako-Tsubo Cardiomyopathy: a controlled study concerning physiological and psychological responses to stress

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2. STUDY OBJECTIVESSpecific Aim 1. To determine whether Tako-Tsubo cardiomyopathy is associated with hyper reactivity of the neurohormonal and cardiovascular systems. Hypothesis 1: Patients with a clinical history of Tako-Tsubo cardiomyopathy have...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON39364

Source
ToetsingOnline

Brief title
Biobehavioral Processes in Tako-Tsubo Cardiomyopathy

Condition

- Heart failures

Synonym
broken heart syndrome, Left ventricular apical ballooning syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: catecholamines, psychosocial factors, stress, Tako Tsubo Cardiomyopathy

Outcome measures

Primary outcome

- cardiac contractility

- catecholamines

- cortisol levels

- heart rate variability

- blood pressure

Secondary outcome

- psychological measures such as depression, anxiety and personality.

- Ambulatory physical activity levels

Study description

Background summary

1. BACKGROUND
Significance
Tako-Tsubo cardiomyopathy (TTC) is characterized by major cardiac left ventricular dysfunction with typical apical ballooning of the left ventrical and symptoms and signs mimicking acute coronary syndromes. The most common presentation includes chest pain and/or dyspnea with ST-segment elevation or T-wave inversion with a mild increase in troponin I. The typical precipitants of Tako-Tsubo syndrome involve mental and emotional arousal or distress. About 75% of the patients with TTC report a preceding event incorporating physical and/or emotional distress. TTC is also known as *appical ballooning syndrome* (ABS), *broken heart syndrome* (BHS), *stress cardiomyopathy*, *ampulla cardiomyopathy*, *neurogenic stunning* and *transient left ventricular apical ballooning*. The clinical course of patients who survive till hospital admission is good, but little is known about the psychophysiological

characteristics of patients with Tako-Tsubo cardiomyopathy. Catecholamines may be an important link between emotional stress and cardiac injury.
This study examines whether neurohormonal (catecholamines, ACTH and cortisol) and hemodynamic (heart rate, blood pressure and cardiac contractility) responses to a standardized mental challenge task are exaggerated in individuals with a history of Tako-Tsubo cardiomyopathy as compared to healthy controls and patient controls with stable heart failure, matched for time since diagnosis, sex and age. Data obtained during the challenge study will be cross-tabulated with 24-hour ambulatory ECG monitoring and psychological questionnaires assessing behavioral traits. This study will establish biobehavioral characteristics that identify patients with Tako-Tsubo cardiomyopathy and determine pathophysiological characteristics of this disorder.

Epidemiology and treatment of Tako-Tsubo cardiomyopathy
The prevalence of Tako-Tsubo cardiomyopathy ranges from 0,7 % to 4.87% in patients admitted with symptoms and signs of acute coronary syndrome. Tako-Tsubo is more common in women (90.7%) than men, and most women with TTC are postmenopausal. The age of clinical presentation is often after 55 years. A relatively large number of TTC patients has age-related comorbidities, including cancer (23,6%.
The diagnosis of Tako-Tsubo syndrome is based on 1) akinesia or dyskinesia of the apical and/or midventricular segments of the left ventricle with regional wall motion abnormalities that extend beyond the distribution of a single epicardial vessel; 2) Signs and symptoms suggesting acute coronary syndrome (i.e., new-onset ECG abnormalities such as ST-segment elevation and/or T-wave inversion, modest elevation in cardiac troponin levels, and/or typical angina complaints); and 3) absence of obstructive coronary artery disease, pheochromocytoma or myocarditis that could account for the condition. Typical in TTC are an intense emotional trigger and marked increases in circulating catecholamines, but those are not necessary conditions for TTC. Differential diagnoses of TTC from other cardiac conditions with heart failure can be complicated.

The catecholamine levels during admission are 2 to 3 times higher among patients with TTC than among a control group of patients with Killip class III myocardial infarction, and 7 to 34 times published normal values, suggesting exaggerated sympathetic stimulation as a causal factor in TTC.

The optimal treatment of Tako-Tsubo has not been established. Hemodynamic stabilizing and standard therapy invariably leads to spontaneous recovery. Because the presentation of TTC mimics that of myocardial ischemia, initial management should be directed toward the treatment of this acute coronary syndrome combined with ECG monitoring, echocardiography and administration of aspirin, heparin and β-blockers as needed.

1.1. The role of psychosocial factors in Tako-Tsubo cardiomyopathy

Psychological triggers, such as intense mental challenges and emotional arousal are typical precipitants of Tako-Tsubo cardiomyopathy. Typical triggers include news of an unexpected death, experiencing fear, having a fierce argument and situations such as a surprise party can function as a trigger of TTC. A recent study by Martin et al. suggests that patients with Tako-Tsubo cardiomyopathy might be characteristically hyper-reactive to mental and emotional challenges in terms of neurohormonal and hemodynamic responses as well as increased reactive hyperemia compared to patients with a history of myocardial infarction or healthy controls. Little is known about background cardiovascular measures (e.g., history of coronary artery disease, hypertension, cardiac arrhythmias) and psychological factors such as depression, hypochondria and personality types (such as hostility and Type D personality) as risk factors for TTC. The general aim of this project is therefore to examine the neurohormonal and hemodynamic characteristics of patients with a history of Tako-Tsubo cardiomyopathy at rest and in response to a low-grade standardized mental challenge task (simple mental arithmetic, a speech task about the stressful event that preceded the episode of TTC, followed by a low-intensity physical stress task) and to cross-tabulate these measures with 24-hour ambulatory ECG monitoring and psychological questionnaires. Two comparison groups will be used: healthy age- and sex-matched controls and patient controls with stable class I-II heart failure.

Study objective

2. STUDY OBJECTIVES

Specific Aim 1. To determine whether Tako-Tsubo cardiomyopathy is associated with hyper reactivity of the neurohormonal and cardiovascular systems.
Hypothesis 1: Patients with a clinical history of Tako-Tsubo cardiomyopathy have elevated neurohormonal (norepinephrine, epinephrine, cortisol and ACTH) and hemodynamic (systolic and diastolic blood pressures, heart rate and cardiac contractility) responses to mental challenge tasks compared to healthy controls or patients with stable heart failure. No differences will be found between these groups in response to physical challenge.

Specific Aim 2. To determine whether psychological traits associated with increased levels of distress are more common in Tako-Tsubo cardiomyopathy than matched controls.
Hypothesis 2:
Patients with Tako-Tsubo cardiomyopathy experience more psychological distress (perceived stress scores, depressive symptoms and anxiety) and psychological vulnerability factors for distress (hostility, Type D personality, and somatization) in comparison to healthy controls or patients with stable heart failure. It is further hypothesized that patients with higher levels of psychological distress have elevated neurohormonal and cardiovascular reactivity during the laboratory/clinic evaluation (Aim 1).

Specific Aim 3: To establish whether increased reactivity observed during laboratory testing in the clinic generalizes to daily life situations as documented using 24-hour ECG and mood state monitoring. This would support the ecological validity of the laboratory/clinic-based studies.

Hypothesis 3: Patients with Tako-Tsubo cardiomyopathy have elevated heart rate and reduced heart rate variability combined with elevated levels of distress during daily life activities compared to healthy controls and patients with heart failure. It is further hypothesized that challenged induced cardiovascular responsiveness (Aim 1) are associated with 24-hour ambulatory measures.

Study design

This study has a cross-sectional observational design using three groups.

Study burden and risks

Other than the stand risk for collecting blood samples, there are no risks associated with study participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Hisotry of Tako Tsubo Cardiomyopathy
Two control groups matched for age, sex, martital status and education.
Control group I: diagnosis of congestive heart failure
Control group II: healthy participants

Exclusion criteria

Exclusion criteria
1. Patient is over 85 years old
2. history of liver or kidney disease
3. current active treatment for cancer or other life-threatening condition
4. currently on hormone replacement therapy
5. severe cognitive impairment interfering with completion of tasks or questionnaires

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-03-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35988.008.11