TREATMENT SATISFACTION QUESTIONNAIRE FOR MEDICATION (TSQM - VERSION 1.4): CEILING AND FLOOR EFFECTS, RELIABILITY AND CONSTRUCT VALIDITY

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Background and Significance

- Worldwide, ***Hypertension*** affects 1.13 billion people and is one of the most important prevention concerns of the World Health Organization.
  - Brazil:
    - > 17 million people have hypertension and cardiovascular disease
    - Prevalence in the general population around 32,5%
- Asymptomatic disease
- Non-treated significantly increases the risks of heart failure, myocardial infarction and stroke

Background and Significance

- ***Patient satisfaction*** has an impact on health-related decisions, particularly in chronic diseases where patients must commit to a long-term therapy regiment, such as those with hypertension.

  Predict:

  - Continuity of care
  - Correct use of medication
  - Adherence to the therapeutic regimen

Background and Significance

TSQM (version 1.4) was created by Atkinson *and colleagues in* 2004 to measure patient satisfaction with medication

- It is a generic measure of patient satisfaction with medication
- Valid and reliable tool in various languages
- It is the only available questionnaire to measure patient satisfaction with medication in Brazil
  - Translation and Cultural adaptation into Brazilian Portuguese were performed by the Center for Outcomes Research and Education – CORE

Aim

Evaluate the acceptability, ceiling and floor effects, reliability and construct validity of the Brazilian version of the Treatment Satisfaction Questionnaire for Medication (TSQM - version 1.4) in patients with hypertension

Methods

Design: Cross-sectional descriptive exploratory study

Sample: 300 patients with hypertension in an outpatient setting in the southeast region of São Paulo state in Brazil

Ethical aspects: Study approved by the local Research Ethics Board No. 182.435. All enrolled patients signed the consent form.

Methods

Psychometric properties:

- ***Acceptability:*** % of answered items
- **Ceiling and Floor effect:** participants with 15% highest & lowest possible scores of the scale: 20% were considered as substantial
- ***Reliability:*** Cronbach's alpha
- ***Construct validity:*** *known group analysis*
  - Medication adherence
  - Different stages of hypertension
  - Diagnoses of Left Ventricular Hypertrophy
  - Occurrence of side effects

Questionnaire:

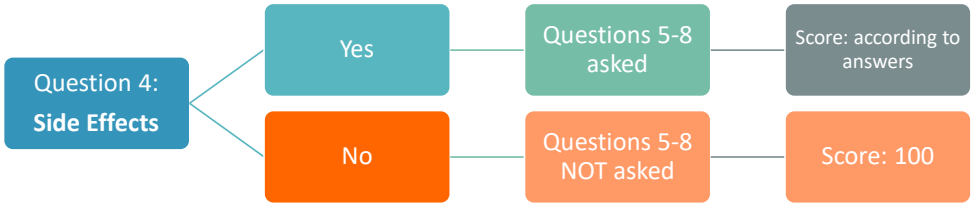
Brazilian version: *TSQM* (*version 1.4*)

Created by Atkinson and colleagues in 2004 to measure patient satisfaction with medication, during the previous two or three weeks, or since the last time the patient took the medication.

Responses: Likert-type scale of five or seven points

Questionnaire:

Brazilian version: *TSQM* (*version 1.4*)



Medication adherence Questionnaires

Proportion of medication adherence: It was used for the purpose of identifying and quantifying the medications and the way they were used by participants.

How to measure adherence? Patient-report of missed doses, frequency and description of the use compared to the prescription

When: past 24-hours, week and month

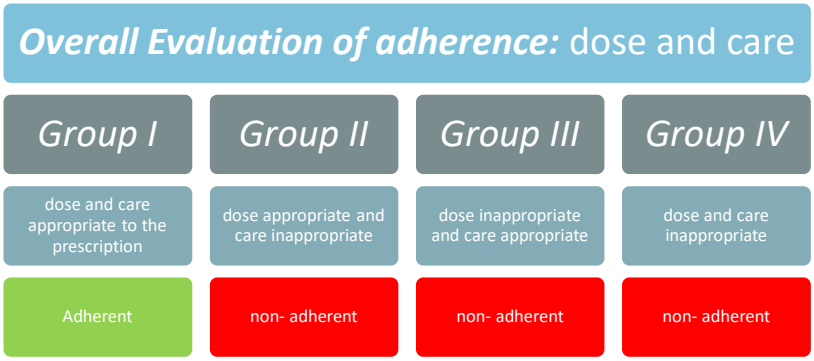
$$\text{Percent of adherence} = \left[\frac{(\text{prescribed doses} - \text{missed doses})}{\text{prescribed doses}} \times 100\right]$$

Adherent: $\geq$ 80%

More than one medication: average

Medication adherence Questionnaires

Overall Evaluation of adherence: the medication dosing and care were evaluated by name, number and frequency of medication taken and their association with the time markers, such as fasting, breakfast, lunch and dinner



Blood Pressure & LVH Measurement and Classification

Device: OMRON® brand HEM 742-INT digital device

Measurement: According to the Brazilian & American Heart Association guidelines

Classification:

Group 1	• **Good:** SBP <120 mmHg and DBP <80 mmHg • **Normal:** SBP <130 and/or DBP <85 mmHg • **Borderline:** SBP between 130 and 139 mmHg and/or DBP between 85 and 89 mmHg
Group 2	• **Stage 1:** SBP between 140 and 159 mmHg and/or DBP between 90 and 99 mmHg
Group 3	• **Stage 2:** SBP between 160 and 179 mmHg and/or DBP between 100 and 109 mmHg • **Stage 3:** SBP ≥180 mmHg and/or DBP ≥110 mmHg

Left Ventricular Hypertrophy: Echocardiogram

Sample Characteristics

Sociodemographic Variables	n (%)	Mean (SD)	Min-Max
Gender: Female	160 (53.7)		
Education (years)		7 (3)	4-18
Age (years)		56 (10)	23-87
Ethnicity: Caucasian	217 (72.3)		
Professional Status: unemployed or retired	114 (38.0)		
Income (in monthly wages)			
Individual	--	1.7 (2.0)	0-16.2
Household	--	2.7 (2.4)	0-20.6
Time since hypertension Diagnosis (years)		13 (11)	0.08-50
Echocardiogram (n=145)			
Ejection Fraction (%)		66.3 (11.3)	33-135
Diastolic Dysfunction	51 (17.0)		
Left Ventricular Hypertrophy (LVH)	132 (44.0)		
Systolic Blood Pressure		139.0 (23.7)	83-236
Diastolic Blood Pressure		80.28 (13.2)	44-124
Hypertension stages			
Good/Normal/Borderline	164 (54.7)		

Medications

Class	Ex	n (%)
Beta-blocker	Carvedilol Atenolol Propranolol	59.7%
Diuretics	Hydrochlorothiazide Furosemide Chlorthalidone Amiloride Hydrochloride	58.7%
Angiotensin-Converting Enzyme	Captopril Enalapril Benazepril	50.3%
Angiotensin Receptor Blockers	Valsartan Losartan	33.3%
Calcium Channel Blockers	Minoxidil Amlodipine Diltiazem Nifedipine	30%
Antiadrenergics	Methyldopa	7%
Vasodilators	Hydralazine	5.3%

TSQM	Mean (SD*)	Median	Range	
Effectiveness	70.4 (18.0)	66.7	11.1-100	
Side Effects	93.6 (18.7)	100	12.5-100	267 (89)
Convenience	69.7 (17.1)	66.7	5.6-100	
Global Satisfaction	73.6 (17.3)	71.4	14.3-100	87 (29)

Reliability: Floor effect (version 1.4)

	Brazilian version of the TSQM							
	Effectiveness	t (p-value)	Side effects	t (p-value)	Convenience	t (p-value)	Global Satisfaction	t (p-value)
	Mean (SD)		Mean (SD)		Mean (SD)		Mean (SD)	
Proportion of adherence								
Adherent (n=248)	70.9 (17.4)	-1.3 (0.19)	95.2 (15.6)	**-3.45 (0.001)**	70.4 (17.1)	-1.5 (0.13)	74.8 (16.4)	**-2.7 (0.007)**
Non-adherent(n=50)	67.3 (20.3)		85.4 (28.6)		66.3 (16.5)		67.6 (20.6)	
Overall Evaluation								
Adherent (n=148)	73.5 (17.8)	**-3.01 (0.002)**	95.6 (14.7)	-1.9 (0.06)	72.9 (16.3)	**-3.2 (0.001)**	77.0 (14.6)	**-3.4 (0.001)**
Non-adherent (n=150)	67.2 (17.6)		91.5 (21.8)		66.5 (17.1)		70.2 (19.1)	

T-test

Known Group Validity: *Adherence*

Hypertension stage	Brazilian version of the TSQM							
	Effectiveness	F (p-value)	Side effects	F (p-value)	Convenience	F (p-value)	Global Satisfaction	F (p-value)
	Mean (SD)		Mean (SD)		Mean (SD)		Mean (SD)	
Good/Normal/Borderline SBP<139; DBP<89 mmHg (n=161)	73.3 (17.0)	**6.41 (0.002)**	93.0 (19.6)	0.85 (0.43)	70.6 (17.6)	0.85 (0.43)	75.2 (18.0)	2.01 (0.13)
Stage 1 SBP 140-159 and/or DBP 90-99mmHg (n=69)	69.0 (17.0)		95.9 (13.7)		67.4 (16.8)		72.4 (15.7)	
Stages 2 and 3 SBP>160 and/or DBP>100 mmHg (n=64)	64.1 (19.7)		91.9 (21.4)		70.0 (16.3)		70.3 (17.0)	

one-way ANOVA

Known Group Validity: *Hypertension*

Left Ventricle Hypertrophy	Brazilian version of the TSQM							
	Effectiveness	t (p-value)	Side effects	t (p-value)	Convenience	t (p-value)	Global Satisfaction	t (p-value)
	Mean (SD)		Mean (SD)		Mean (SD)		Mean (SD)	
Yes (n=131)	70.8 (18.0)	**1.92 (0.05)**	93.7 (17.9)	-(0.23) 0.84	69.9 (18.3)	0.33 (0.56)	74.4 (16.79)	-0.12 (0.90)
No (n=15)	81.0 (11.5)		94.8 (18.0)		73.1 (17.4)		75.0 (11.99)	

T-test

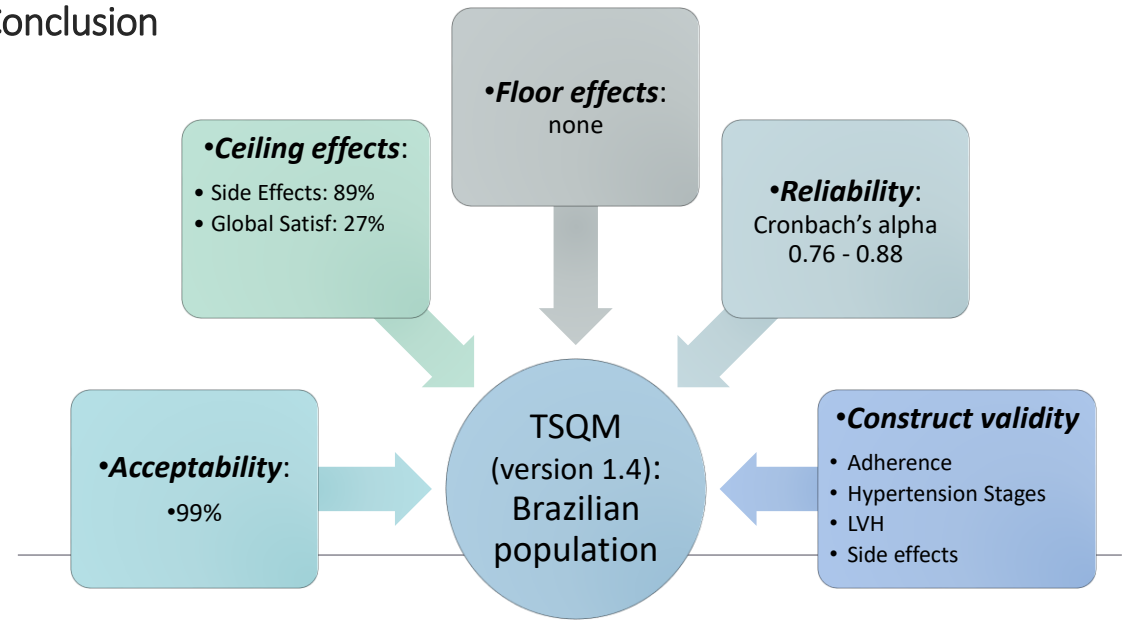
Known Group Validity: *Left Ventricle Hypertrophy*

Side Effects	Brazilian version of the TSQM					
	Effectiveness	t (p-value)	Convenience	t (p-value)	Global Satisfaction	t (p-value)
	Mean (SD)		Mean (SD)		Mean (SD)	
Yes (n=39)	71.8 (17.3)	**3.63 (0.0001)**	70.7 (16.9)	**2.58 (0.01)**	75.7 (14.9)	**5.6 (0.0001)**
No (n=261)	60.8 (19.3)		63.2 (17.1)		59.9 (24.7)	

T-test

Known Group Validity: *Side Effects*

Conclusion



Thank you!

Please share your questions or comments…

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Correlation coefficient between the scores of the Brazilian version of the TSQM (version 1.4) and Morisky Self-Reported Measure of Medication Adherence Scale and proportion of adherence

	Proportion of adherence	Morisky	TSQM - Effectiveness	TSQM Side Effects	TSQM Convenience	TSQM Global Satisfaction
Proportion of Adherence	1.0					
Morisky	-0.32†	1.0				
TSQM - Effectiveness	**0.13‡**	**-0.12‡**	1.0			
TSQM - Side Effects	**0.20†**	-0.02	0.30†	1.0		
TSQM - Convenience	0.10	**-0.21†**	0.59†	0.22†	1.0	
TSQM - Global Satisfaction	**0.19†**	**-0.15†**	0.64†	0.41†	0.60†	1.0

**r= Partial Correlation Coefficient adjusted for gender, age and education; †p<0.01; ‡p≤0.05.*