

DiSCHARGE

Charité - Universitätsmedizin Berlin

DISCHARGE

WP10

"Health-related Quality of Life"



Contact Details WP10

"Health-related Quality of Life"

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Overview

- Objectives of WP10 "Health-related Quality of Life"
- First Results of the Pilot Study
- Selection of Measures for the PRCT

Objectives

- To compare health-related quality of life (QoL) in the intervention versus control group
- **Additional:**
 - » Compare Quality of Life across European regions at baseline and over time
 - » Assess factors associated with quality of life at follow-up
 - » Evaluate patient utilities using time trade-off methodology

Quality of Life Measures

Quality of Life – Generic

SF-12 v2 (4 week)

Health-related quality of life

EQ 5D-3L (EuroQol)

Health-related quality of life
Utilities for different QoL states

HADS (Hospital Anxiety and
Depression Scale)

Depression and anxiety symptoms

WHO-5

Depression symptoms

Chest Pain

Rose Angina questionnaire – short
form

Severe and not severe exertional
chest pain

Own items

Physical activity limitation
due to chest pain

Direct time-trade off method

Chest pain utility

Pilot Phase

February – ongoing

➤ Objective of the Pilot Phase:

To test patient understanding (content), and acceptability (length and content) of different QoL questionnaires in **60** patients (30 CT, 30 ICA)

.... as a basis to select the best questionnaires for the intervention study

**SELECTED FIRST RESULTS
QOL PILOT STUDY**

Demographic Characteristics (N=169)

	Charité (N=49)	Latvia (N=60)	Romania (N=60)
Age, Mean (SD)	60.0 (12.9)	61.6 (11.5)	58.3 (11.1)
Female	41	59	48
Years of schooling	Mean Age Women: 63.75 (11.10)		
0-4	Mean Age Men: 56.13 (11.29)		
5-8	$p < 0.001$		
9-12	10	34	40
13+			
With partner	80	61	85
ICA	31	52	53
CTA	69	48	47
Angina Classification			
<i>Typical Angina Pectoris</i>	6	24	39
<i>Atypical Angina Pectoris</i>	39	28	27
<i>Non-angina chest discomfort</i>	33	48	27
<i>Other chest discomfort</i>	22	0	7

SD = Standard Deviation

Note: Numbers are % except for age. Number of missing values varies between 0 and 3

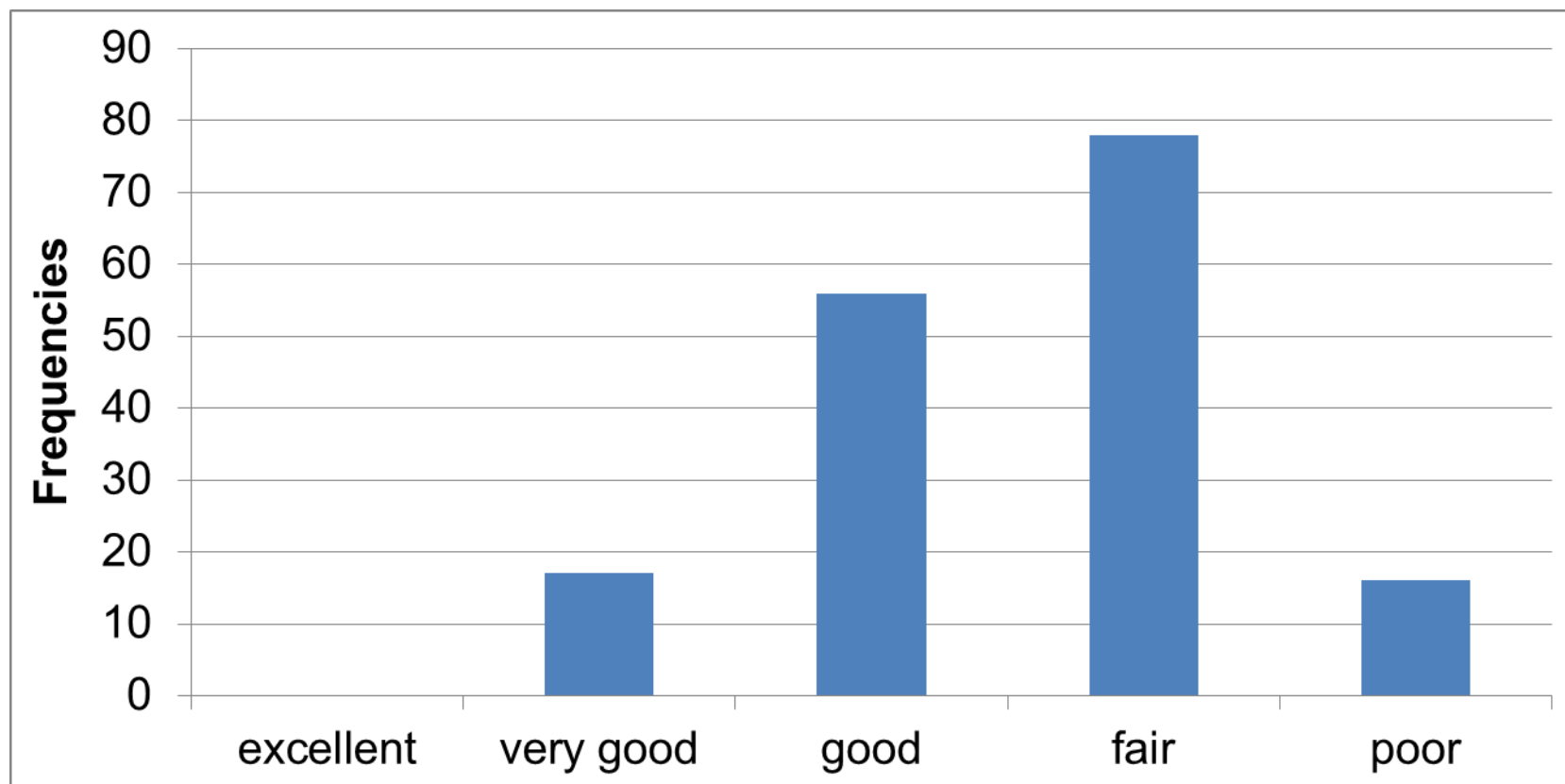
Time needed to complete Questionnaire

	Self-Completion (N=131)	Staff assistance (N=33)
5-10 minutes	32%	46%
11-20minutes	54%	33%
21-30 minutes	10%	18%
> 30 minutes	4%	3%

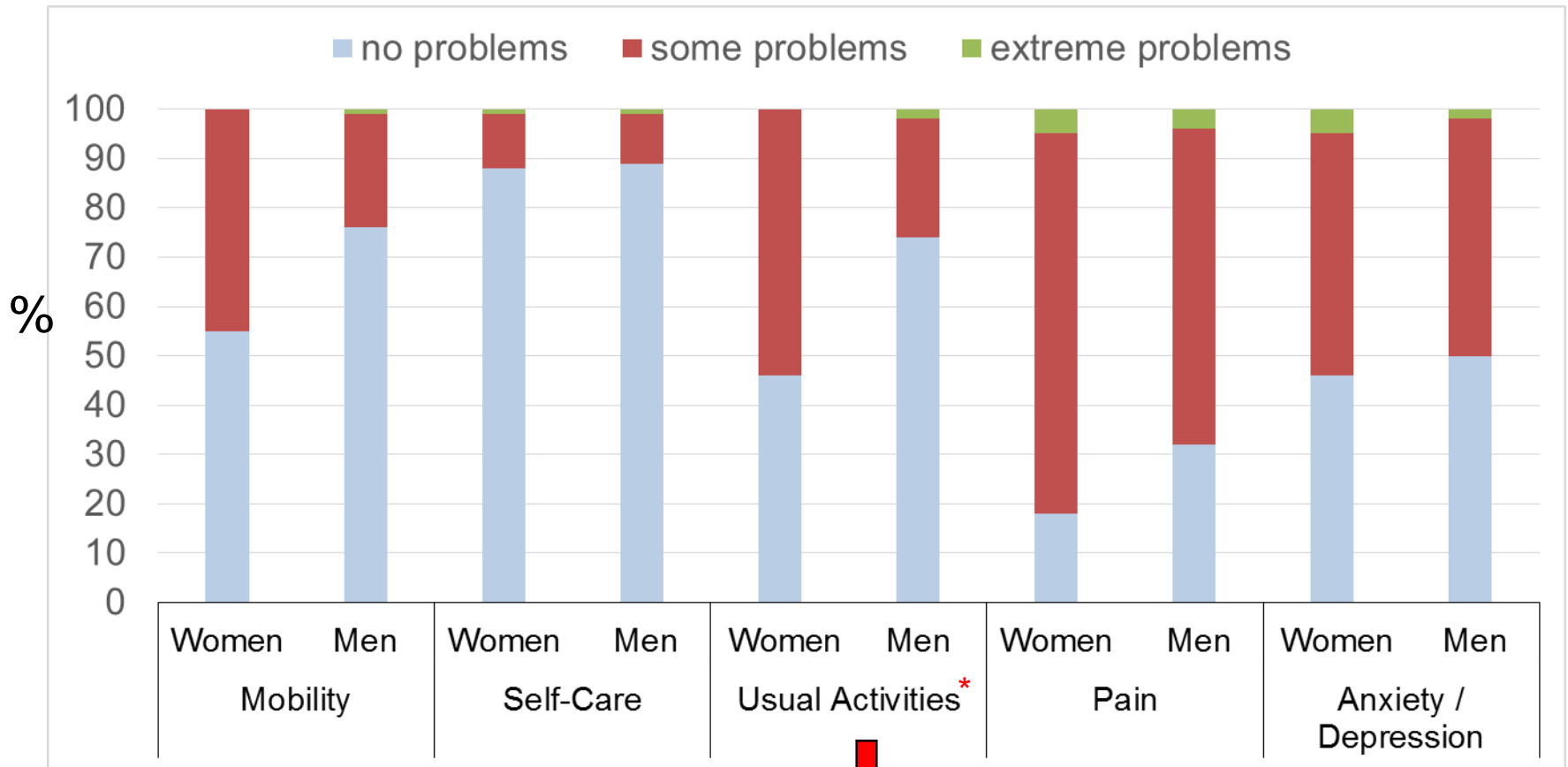
Note: N=5 missing data

SF-12 Self-Rated Health

In general, would you say your health is:



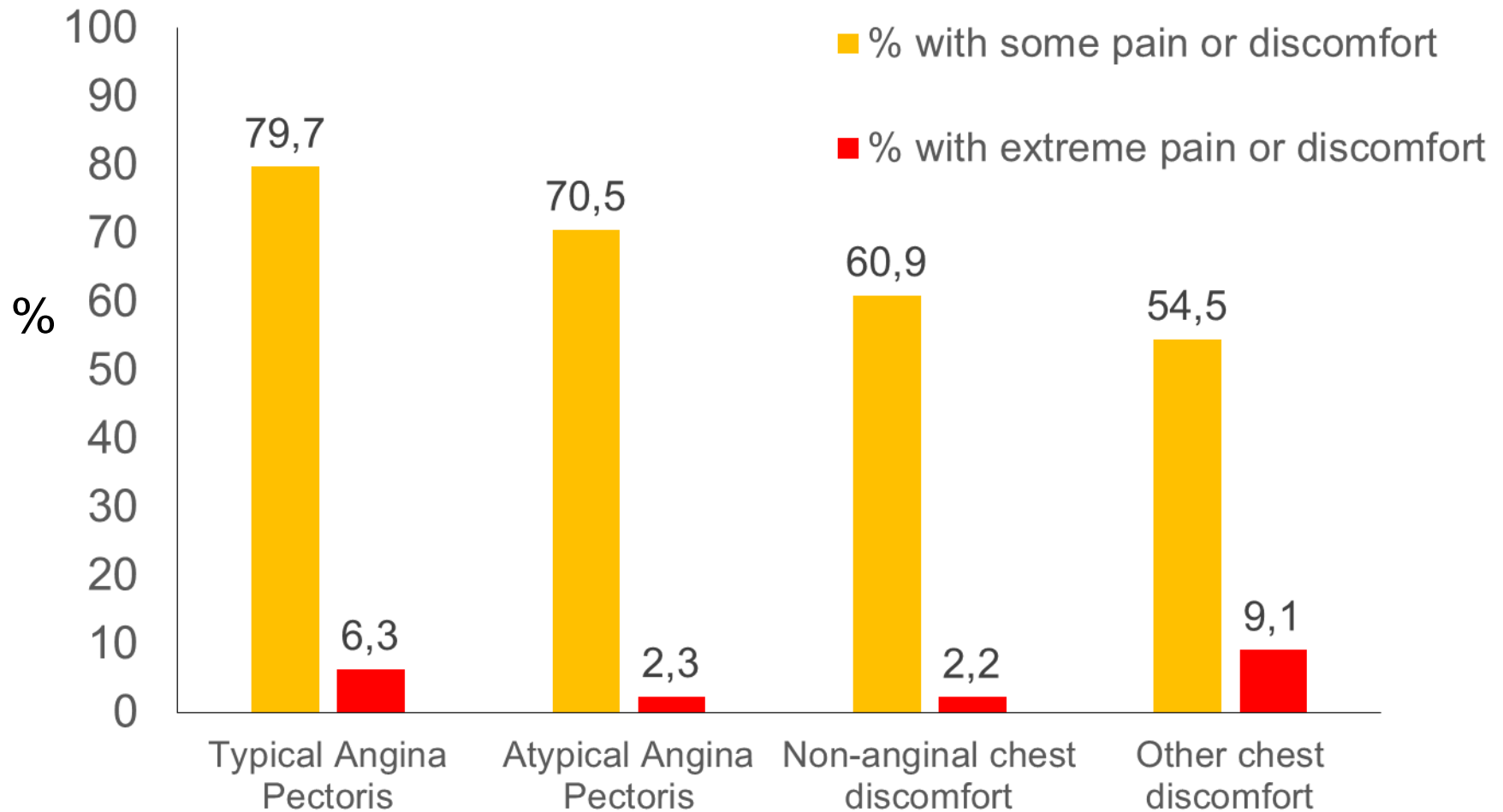
EuroQol – Functional Domains



*p < 0.05 after controlling for age

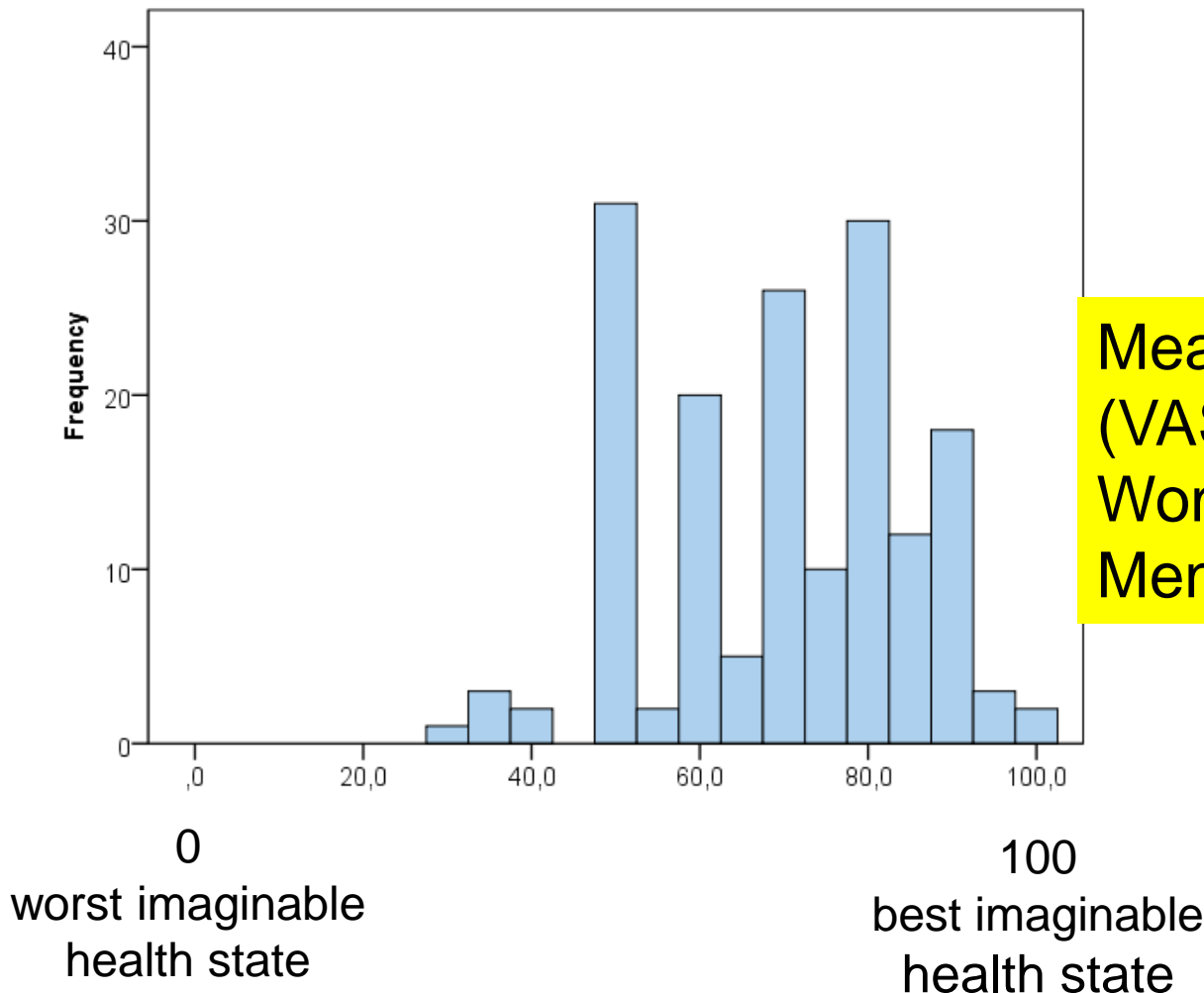
Cross-Validation

EuroQol Domain Pain/Discomfort – Angina Classification

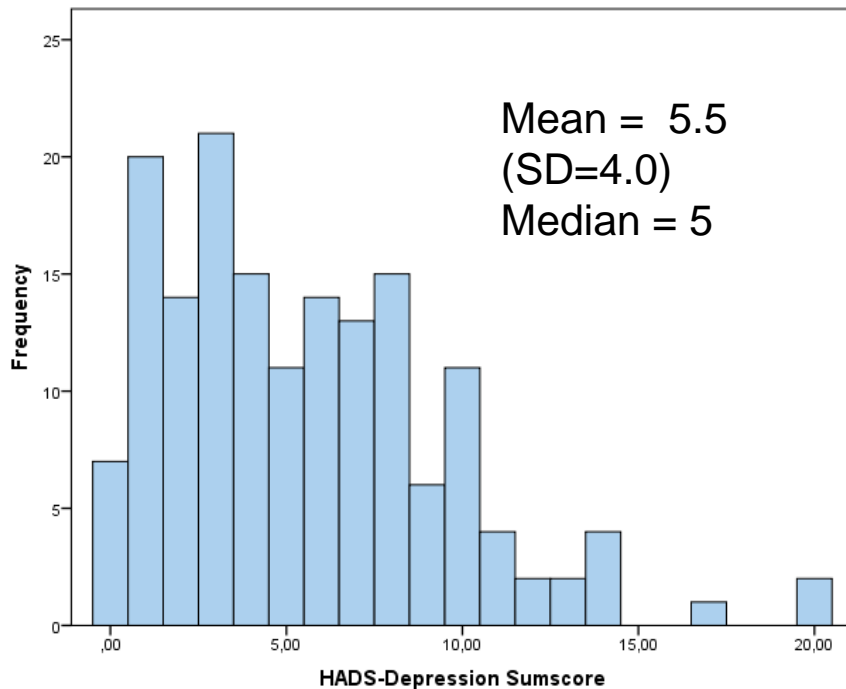


EuroQol - VAS

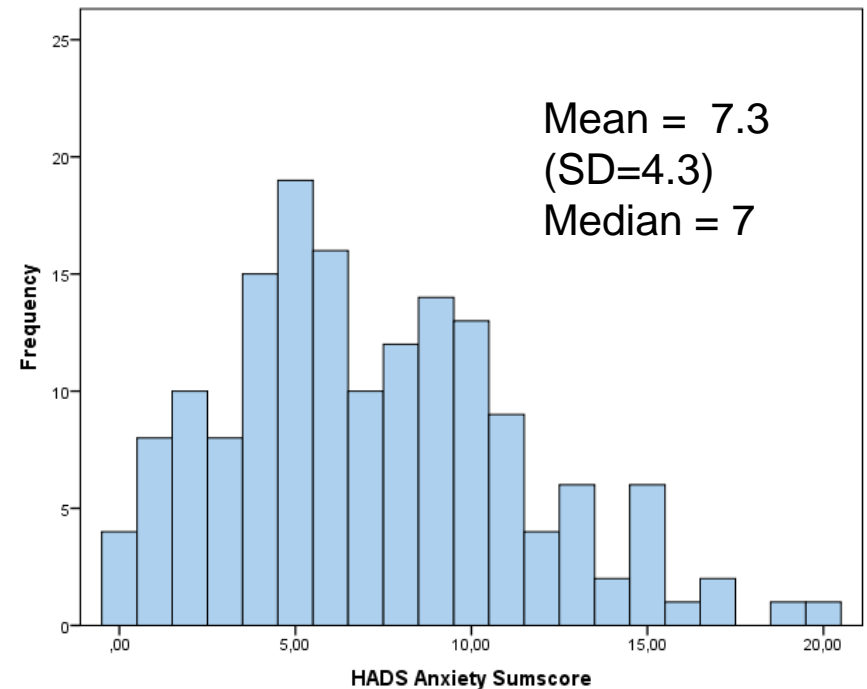
("How good or bad your health is today")



Hospital Anxiety and Depression Scale



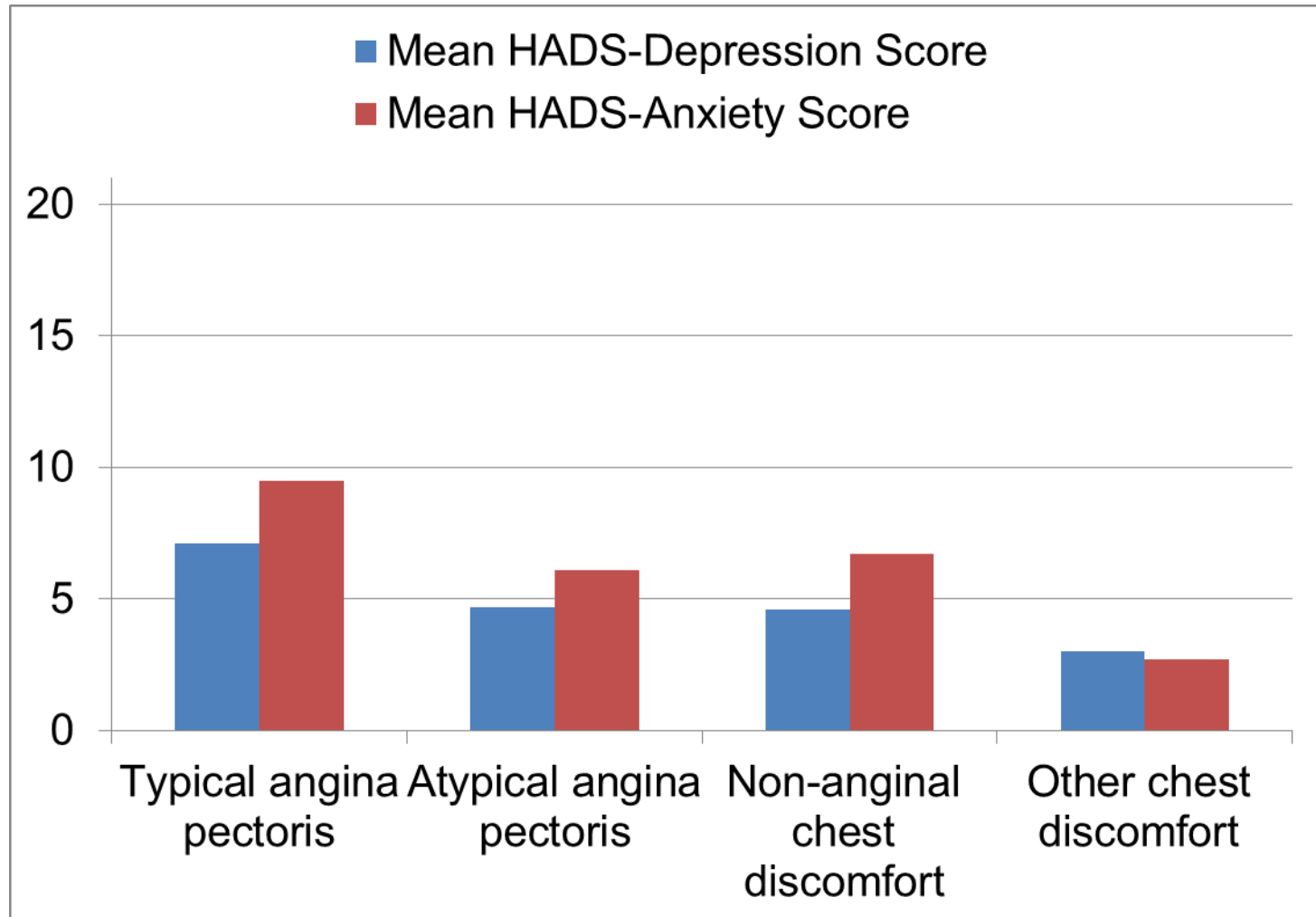
Depression



Anxiety

$r = .62$

Depression, Anxiety and Angina Classification



Rose Angina Questionnaire - Short Form

12. Do you ever have any pain or discomfort in your chest?

① Yes

① No

23.5% said NO!

2. When you walk at an ordinary pace on the level does this produce the pain?

① Yes

① No

⑧ Unable

3. When you walk uphill or hurry does this produce the pain?

① Yes

① No

⑧ Unable

Results from Cognitive Interviewing

- Questions were well understood
- Time frame often ignored
- Some had difficulties relating the terms chest pain/ chest discomfort to their current state of health => did not consider themselves to have typical chest pain
- Problems with **time-trade-off** questions:
 - "Difficult"
 - Association with suicide / euthanasia

> 20% with no or invalid data

Conclusion

- Questionnaire generally acceptable with acceptable completion time and less than 5% missing data
- About 20% will need staff assistance
- Problems with time-trade-off questions

Note....

- Answers are not always consistent! (and that's ok...)
- More than 20% reported to *not* have chest pain on Rose Angina Questionnaire
- Gender differences need to be controlled for age

QoL Measures selected for PRCT

QoL general

SF-12 v2 (4 week)	Health-related quality of life
EQ 5D-3L (EuroQol)	Health-related quality of life Utilities
HADS (Hospitals Anxiety and Depression Scale)	Depression and anxiety symptoms

Chest Pain

Rose Angina questionnaire – short form	Severe and not severe exertional chest pain
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Errors to Avoid in PRCT

- Baseline QoL questionnaire package completed after randomization
=> needs to be completed **BEFORE** randomization
- Family member or friend completes questionnaires for participant
=> participants can be assisted but need to give own answers
- Questionnaires distributed without ID or wrong version
=> useless!

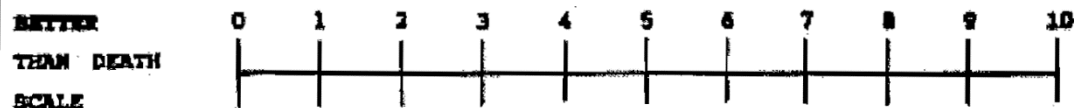


BACKUP

-
- TTO typically uses a horizontal sliding scale which allows the length of time spent in a health state to be varied
 - a new TTO board was designed so that both sides could be used – one for states considered better than death, and the other for states considered worse than death

STATE BETTER THAN DEATH

MARK 'X' UNDER 0 ON THE SCALE BELOW.



CONTINUE TO USE TIME BOARD WITH SIDE '1' UPWARDS

SET BOARD MARKER FOR LIFE A TO 5 YEARS ($t = 5$).

Now you would either live in Life A for γ years and then die, or you would live in Life B for ten years then die. Would you prefer Life A or Life B, or are they the same?

CONTINUE TO WRITE ON SCALE ABOVE ON THIS PAGE.

IF A : \checkmark UNDER γ

MOVE MARKER 1 YEAR TO THE LEFT.

REPEAT d. WITH γ 1 LESS THAN LAST TIME.

IF B : X UNDER γ

MOVE MARKER 1 YEAR TO THE RIGHT.

REPEAT d. WITH γ 1 MORE THAN LAST TIME.

IF SAME : = UNDER γ

GO TO Q.14

- Suppose you faced 20 years with chronic angina followed by death.
- Suppose you could be free of chest pain but wouldn't live as long.

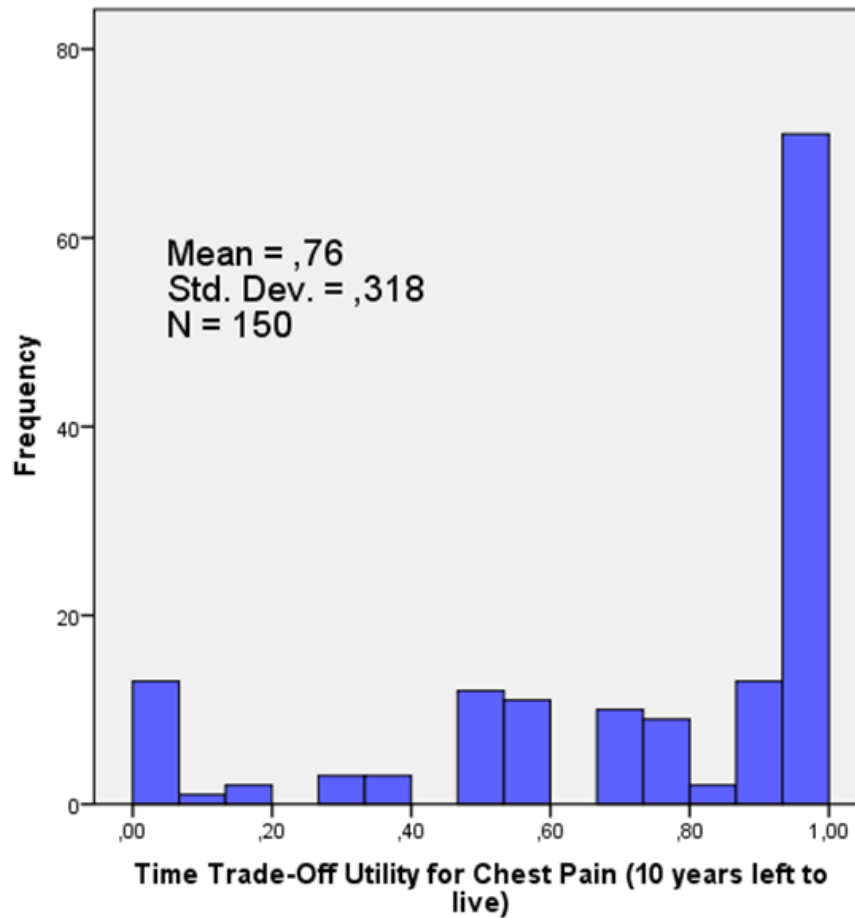
Years free of pain	Answer
20	Of course!
12	Are you kidding? No way!
19	That's easy. Sure.
16	No. Too many years lost
18	That's tough. Can't decide

Tabelle 4.3. Vergleich der TTO-Bewertungen mit dem EQ-5DIndex
Gesundheitszustand TTO (Mittelwert)

Health State	TTO	EQ-5D index
11111		
11211	,9383	,999
11112	,9340	,999
12111	,9341	,912
12211	,8872	,912
21111	,9614	,900
11121	,9417	,887
.....		

11111 = healthy = no problems in any functional domain

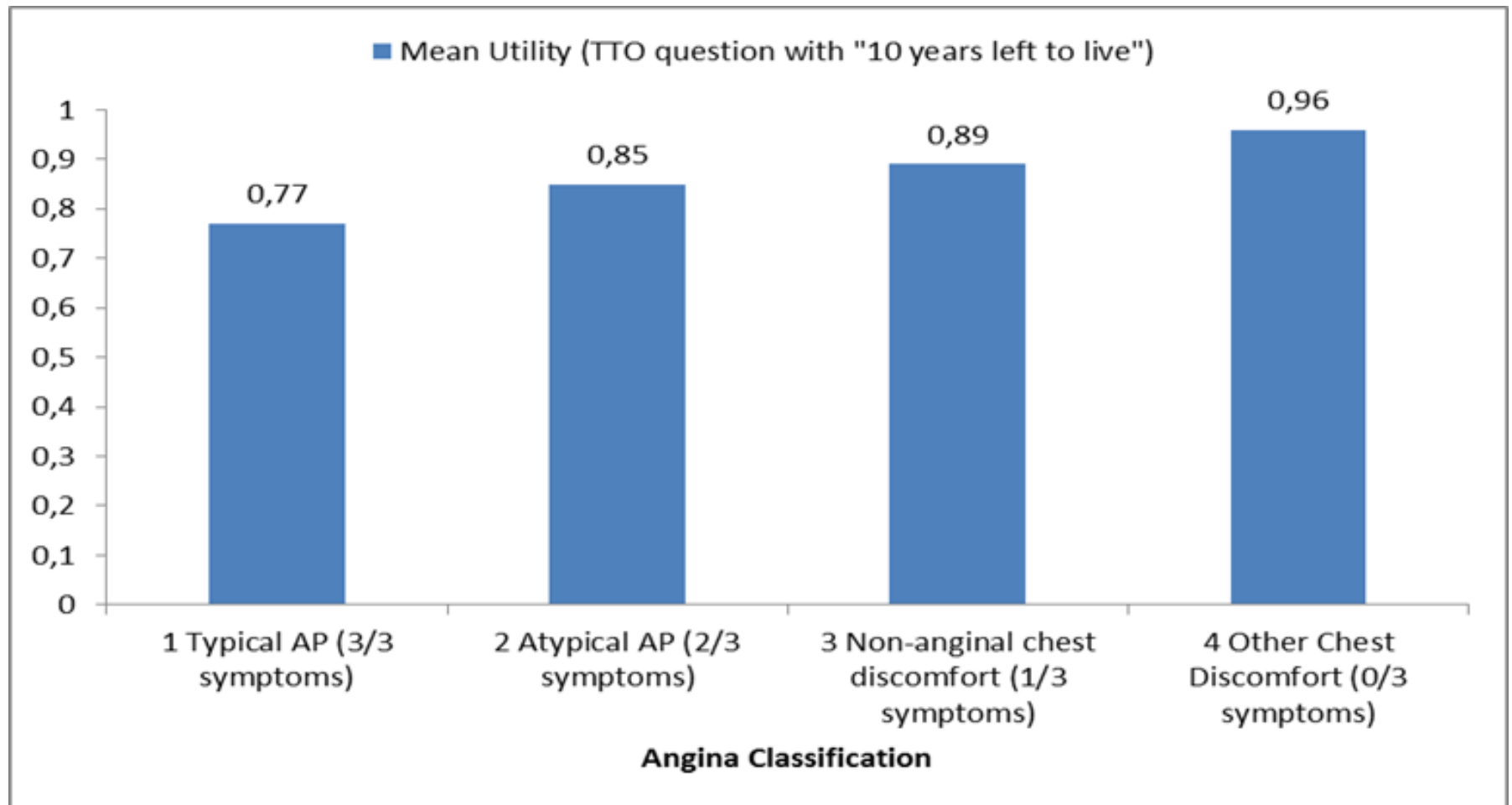
Results for time trade-off questions



Results for time trade-off questions

	# participants missing data	# participants who answered “0” (probably invalid)	Total # participants with no or invalid data	Percent participants with no or invalid data
TTO 10 years	19	13	32	19 %
TTO 20 years	20	12	32	19%

Mean utility for chest pain (patients with utility of 0 excluded, N=137)



SF-12
