A Patient-Reported Outcome Measure to screen for Symptom in the Head and Neck Cancer Population: Translation and Pilot Study on Testing Feasibility and Utility of the Vanderbilt Head and Neck Symptom Survey (VHNSS)

Valutazione dei Sintomi nei Pazienti con Neoplasia del Distretto Testa-Collo: Traduzione del Questionario Vanderbilt Head and Neck Symptom Survey (VHNSS) e Studio Pilota di Fattibilità e Utilità del suo impiego nella Pratica Clinica

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Measurement Issues

Management of symptoms and acute/late side effects of therapy is a critical issue in **Head and Neck Cancer** patients

- ✓ **Objective measures** (e.g. MBSS for swallowing function)
  - ✓ Expensive, time-consuming
  - ✓ Standards for reporting
  - ✓ Not for all symptoms
- ✓ **Patient reported outcome (PRO) measures** → subjective report on patient perception of his health status
  - ✓ Inexpensive, easy to administer, multiple time points can be assessed
  - ✓ Validity and reliability is variable
  - ✓ Most PROs have not been correlated with objective measures

The majority of PROs are not available in the Italian language

Study Design

Prospective observation trial for implement the use of a PRO measure

Primary **objectives**:

- ✓ to **translate** the Vanderbilt Head and Neck Symptom Survey (VHNSS) into Italian language.
- ✓ to conduct **preliminary tests** to validate the translation.
- ✓ to perform a **pilot test** on the translated survey to assess both the **feasibility and utility** of its administration in clinical practice.

The Protocol was approved by the local Ethical Committee: **Study 1925 – VHNSS-IT**

Why the VHNSS?

- ✓ a quick tool **for screening** (early identification) **symptom and functional problems** in patients with HNC undergoing CCR

- ✓ **tested** in a series of 5 studies involving 332 patients (2000-2007), by the Pain and Symptom Management Program Research Team of the Vanderbilt Ingram Cancer Center (Nashville, TN), **showing excellent psychometric properties**

Murphy BA. Head Neck. 2010. Reliability and validity of the Vanderbilt Head and Neck Symptom Survey

- ✓ Several studies (completed or ongoing) to **correlate items and subscales with objective measures**

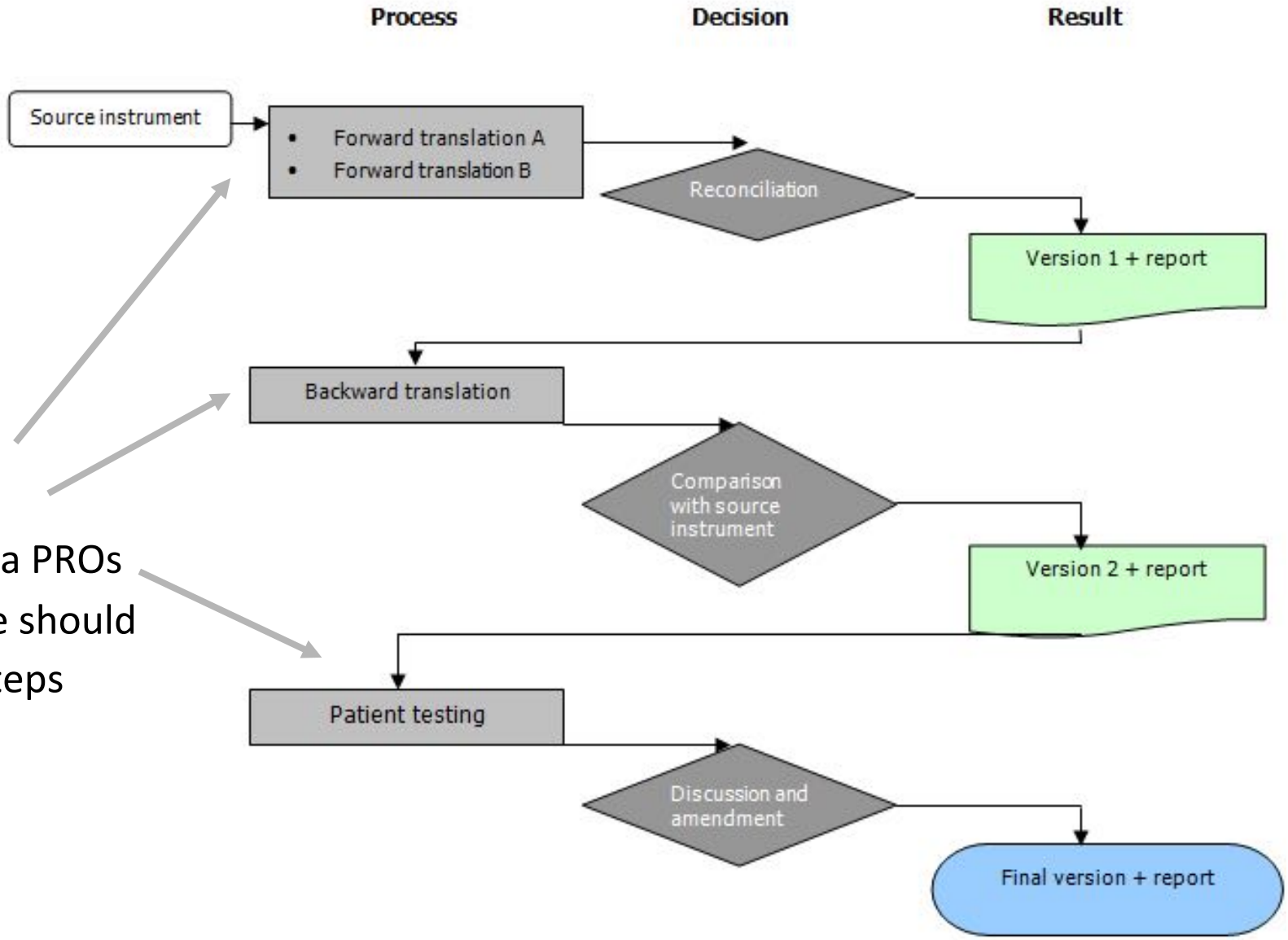
VHNSS v 2.0

The final revised version of the VHNSS 2.0 included **50 questions** ranked using a Likert scale between **0 (no symptom)** to **10 (severe symptoms).**

10 subscales and 3 single item

1. Mouth Pain
2. General Pain
3. Swallow Solid
4. Swallow Liquid
5. Nutrition
6. Mucus
7. Dry Mouth
8. Speech/Communication
9. Taste/Smell
10. Dental Health
11. Hearing (1 item)
12. Jaw ROM (1 item)
13. Neck/Shoulder ROM (1 item)

Translation & Preliminary test



The **linguistic validation** of a PROs questionnaire should consist in 3 steps

at http://www.pedsql.org

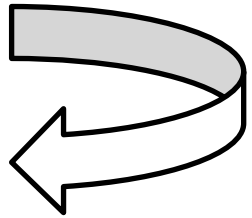
Aim1: Translation

Phase 1: Forward translation step

Translation of a questionnaire into a foreign language

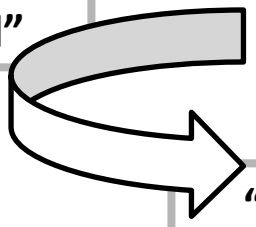
- ✓ Three forward translations of the original items, instructions and response choices, independently produced by the PI and 2 other colleagues

Single reconciled version **(VHNSS-IT v.1)**



The PI and the *forward translators* found the survey **easy to translate**

“I choke or strangle on solid food”



“I cibi solidi mi vanno di traverso”

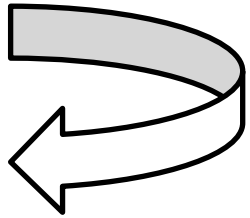
Aim1: Translation

Phase 2: Backward translation step

Translation of the first reconciled version back into the source language

- ✓ A Italian pro skilled in teaching English (*bt*) translated the VHNSS-IT v.1 back in English
- ✓ The backward version was compared with the original source

Changes to the 1st version → 2nd version **(VHNSS-IT v.2)**



The PI and the *bt* agreed that **the meaning of the original source was maintained**. The translator was concerned that **the verbiage was still scholarly**: the discussion centered on making the items easier to understand.

"My taste is altered" → **"Il gusto è alterato"** → **"I sapori sono alterati"**

Aim2: Preliminary Test of the Translated Version

To determine whether the translation (instructions, items and response choices), **was clear simple and appropriate**.

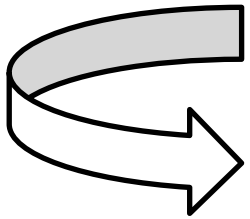
Sample size = $n = Z^2 \times P (1 - P)/d^2$
$= 1.962 \times 0.1 (1 - 0.1)/0.01 = 35$

Z = Z statistic for a level of confidence = 1.962
d = precision = 0,1
P = expected prevalence of comprehension problems
→ a low prevalence was estimated (< 10%).

Inclusion criteria:

- ✓ Age > 18 years
- ✓ Diagnosis of HNC
- ✓ Italian native speakers

- ✓ 2 patients reported **problems of comprehension** (5,7%) in 1 and 16 items, respectively
- ✓ All other patients did not have problems understanding the survey; 15 of them suggested **minor revision** to the PI



Changes to the 2nd version → final version **(VHNSS-IT)**

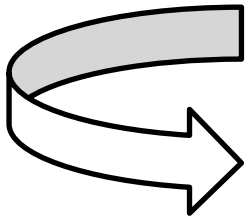
Aim3: Pilot Test on Feasibility and Utility

for clinicians
for patients

At least 35 patients

(P = expected prevalence of adherence → a refusal rate < 10% was estimated)

6 clinicians → 6 patients for each clinician



38 patients screened: 1 denied consent → refusal rate **2,6%**.

Section 1: The clinic visit was conducted per standard of care for the first three patients. After the clinic visit was completed, clinician reviewed the patient's questionnaire and reported:

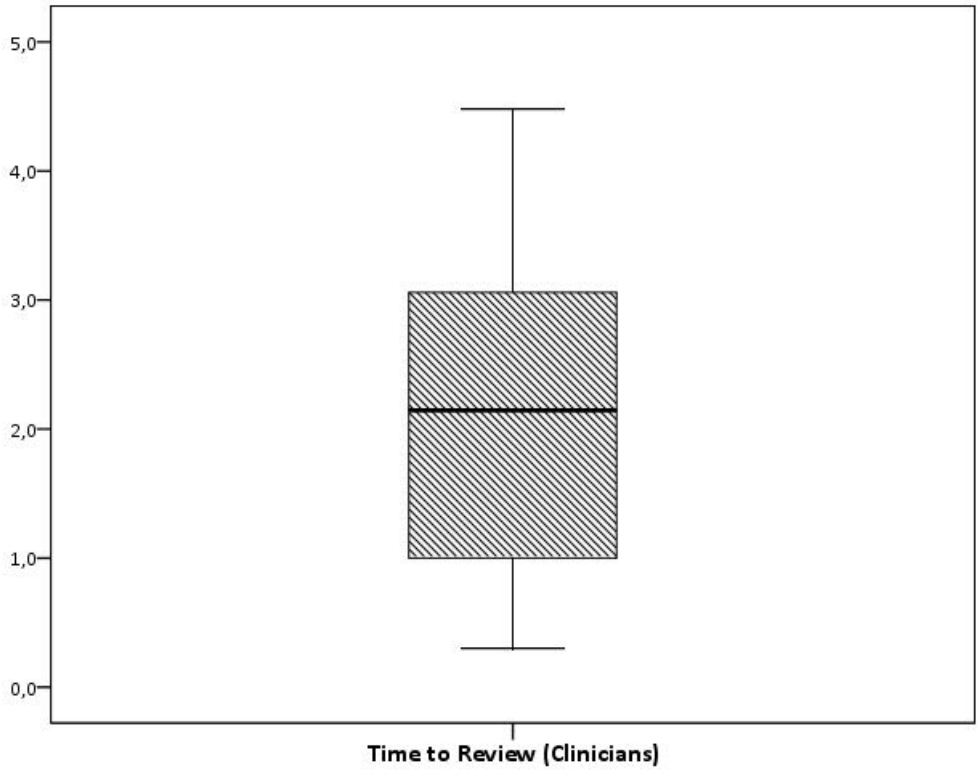
- ✓ Review time
- ✓ Acceptability of time burden
- ✓ Ease of use
- ✓ Identification of unrecognized symptoms

Section 2: For the last three patients clinicians were allowed to review the questionnaire during the visit.

- ✓ global perceived utility

Clinicians outcomes

Time to review:
Median → 2’15’’
Minimum → 0’30’’
Maximum → 4’50’’
IQR → 1’00’’-3’08’’



- ✓ **Time burden** was perceived to be acceptable for all clinicians
- ✓ All clinicians found the questionnaire **easy to use**
- ✓ Rates of global **perceived utility** was 100%

Unaddressed symptoms

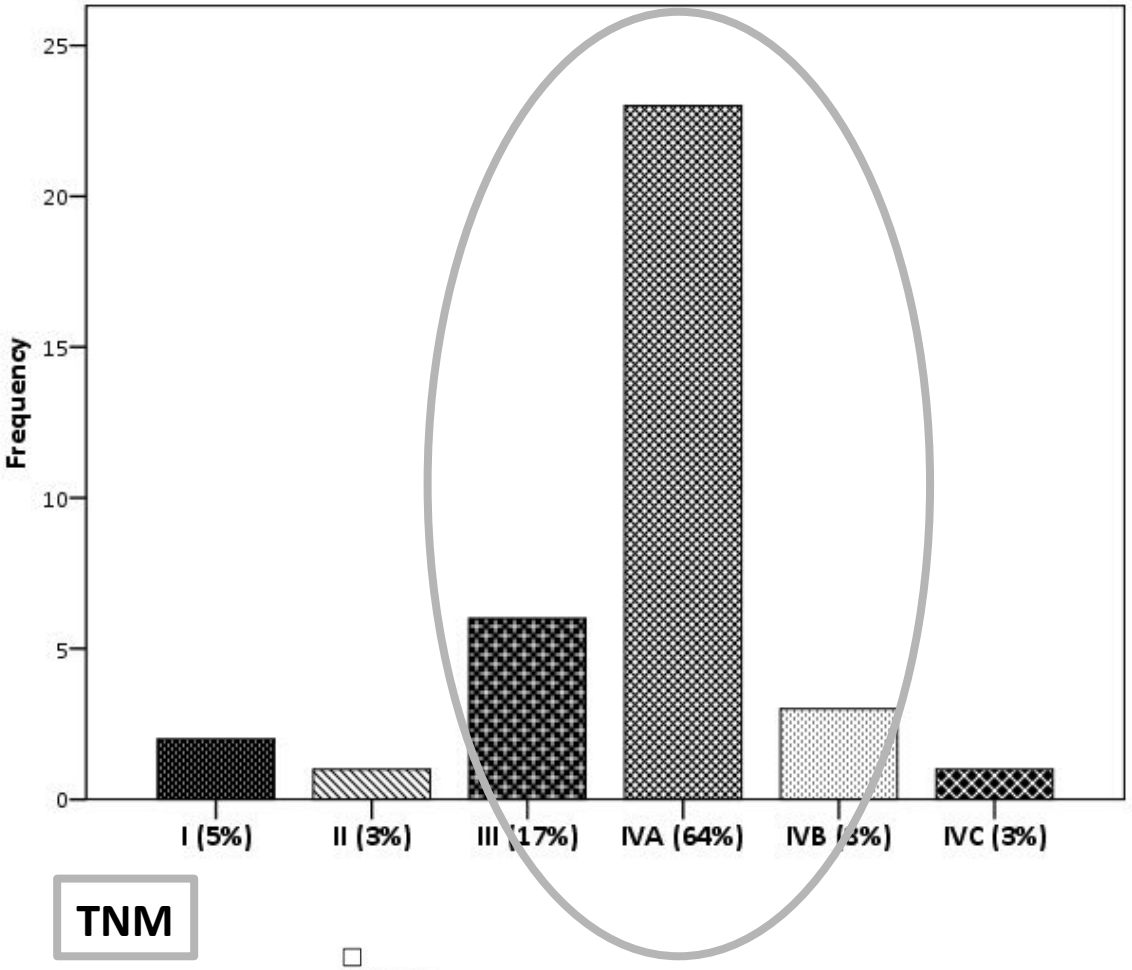
- ✓ 4/6 clinicians (67%) referred identification of problems that went unrecognized during the visit in at least 1 of their 3 patients in section 1.

Item	Relevance Rate(s)
Swallowing	
13. It takes me longer to eat because of my swallowing problem	3,8
Dry Mouth	
16. Problems with dry mouth affect my ability to sleep	3,4,7
17. Problems with dry mouth affect my ability to talk	3,4,8
Mucus	
18. I have thick mucous or phlegm	1,7
19. Mucous causes me to choke or gag	7
21. Mucous causes difficulty sleeping	3,4,7
Mouth Pain	
22. I have sores in my mouth or throat that cause pain	7
23. Mouth or throat pain causes difficulty swallowing	7
24. Mouth or throat pain causes difficulty speaking	3,7
45. The lining of my mouth and throat is sensitive to spicy, hot or acidic foods	2,7,9
47. Burning pain in the lining of my mouth and throat changes what I eat	7
General Pain	
25. My average pain level over the last week has been…..	7
26. My worst pain level over the last week has been….	7
27. The average relief from my pain medication is….	7
28. Pain causes difficulty sleeping	3,7
Voice	
29. I have trouble speaking	5
Hearing	
32. I have trouble with my hearing	3,5,10

Patients characteristics

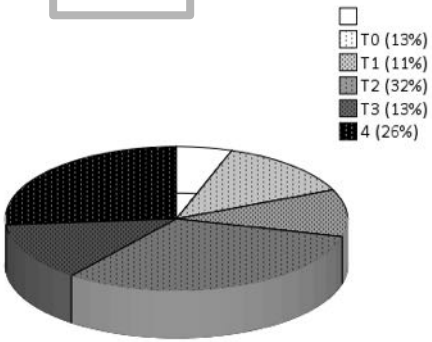
Gender	Men Women	29 (78%) 8 (22%)
KPS	60 70 80 90	1 (3%) 10 (27%) 17 (46%) 9 (24%)
Age	Median [range]	68 [45-87]
Smoke	Yes, current Yes, past No	4 (11%) 23 (62%) 10 (27%)
Alcohol	Yes, current Yes, past No	1 (3%) 4 (11%) 32 (86%)
Highest grade of education	Primary school Middle school High school University	12 (32%) 11 (30%) 11 (30%) 3 (8%)
Employment status	Full time Part-time Unemployed Retired	6 (16%) 1 (3%) 3 (8%) 27 (73%)

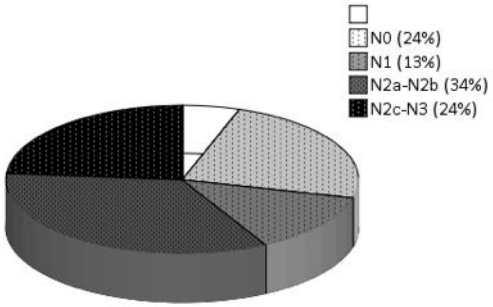
Disease & treatment characteristics

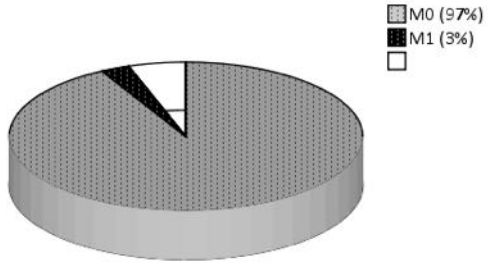


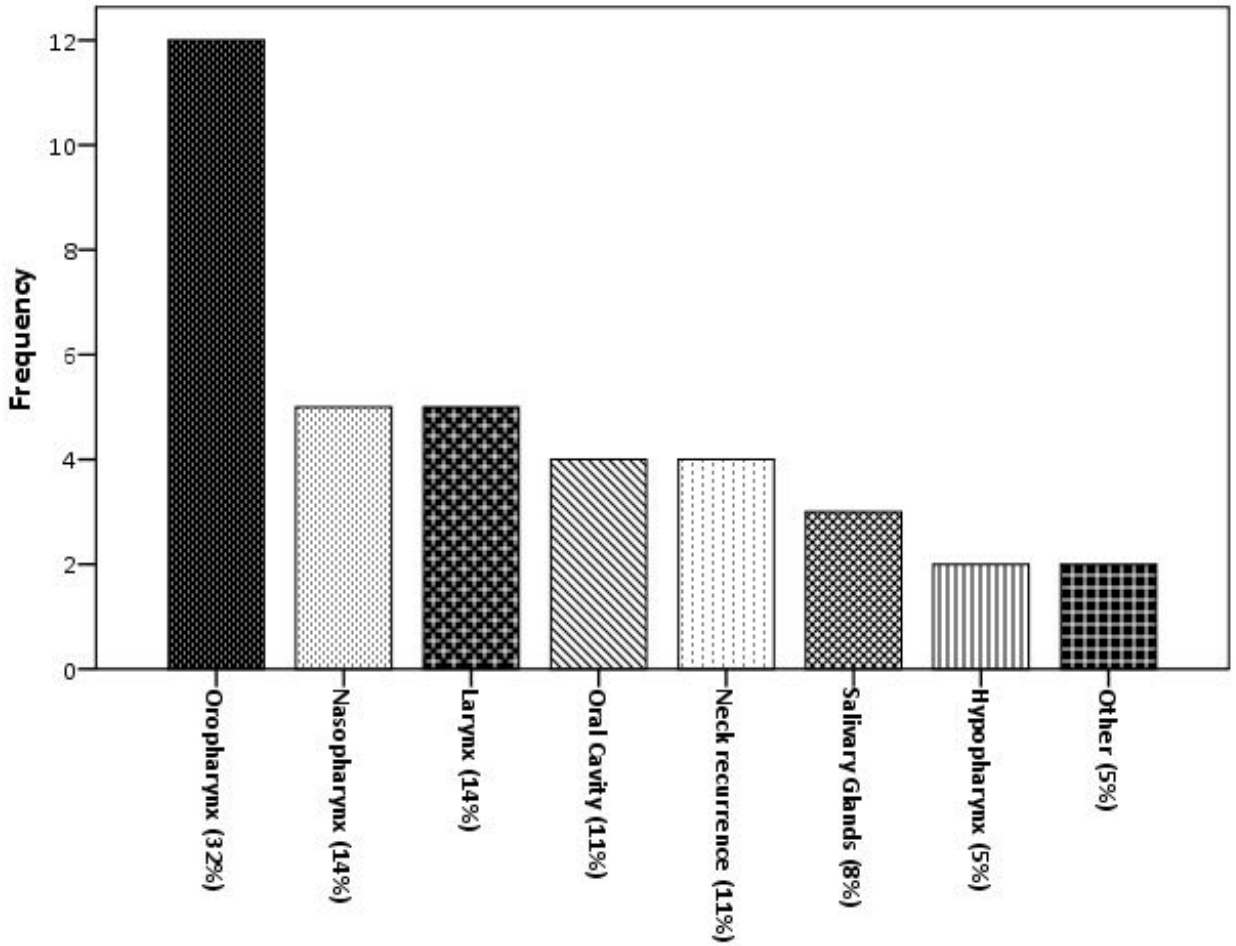
STAGE

TNM





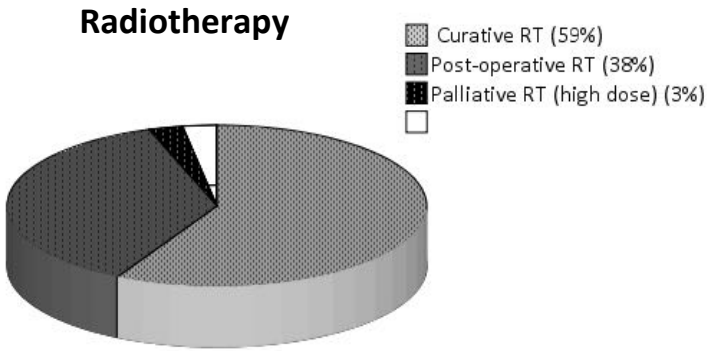




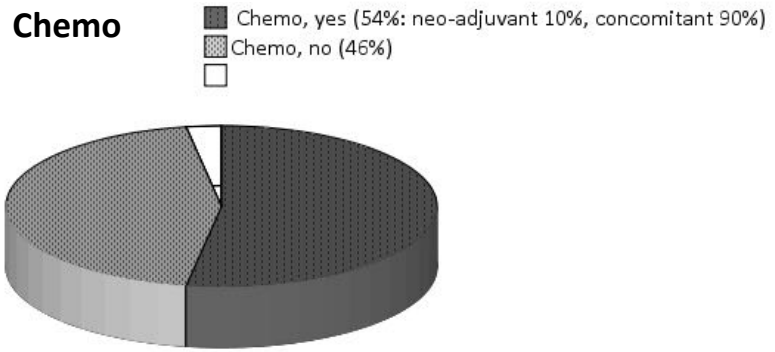
DISEASE SITE

TREATMENT MODALITY

Radiotherapy



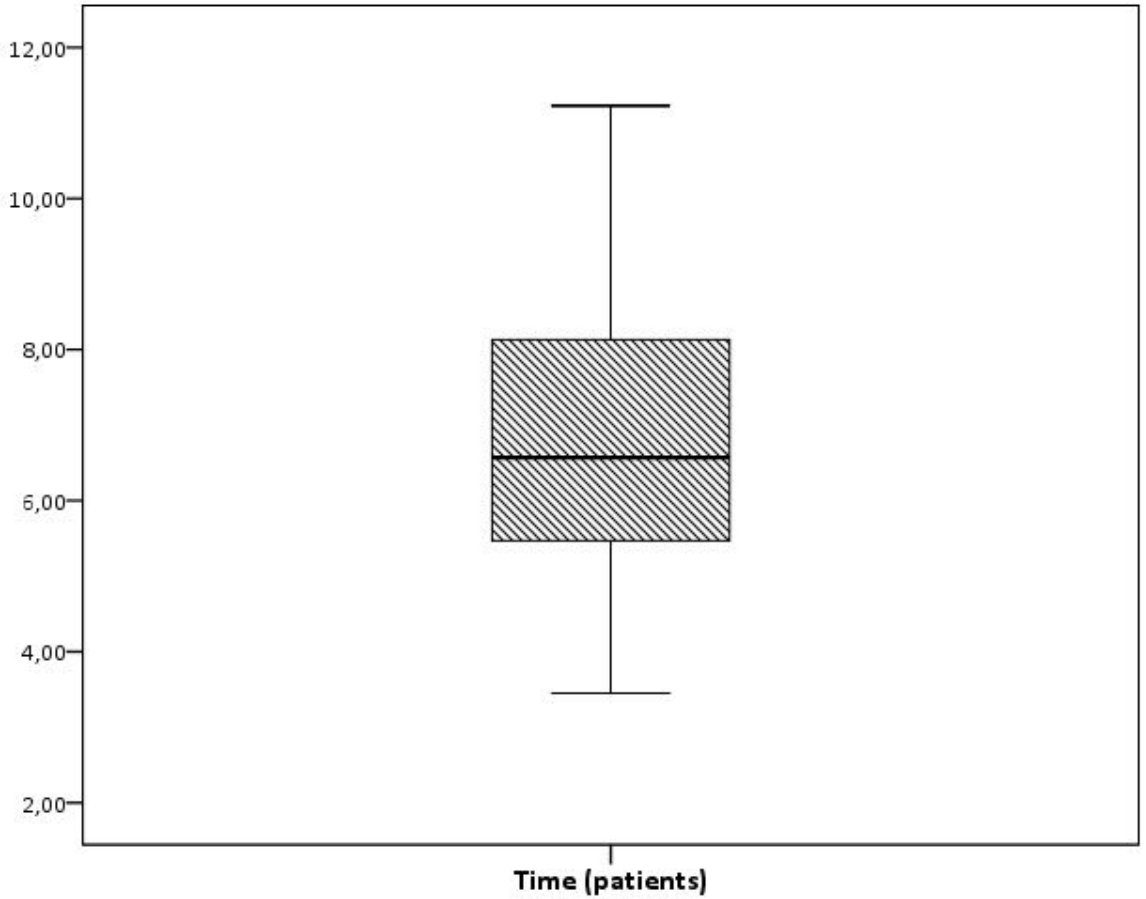
Chemo



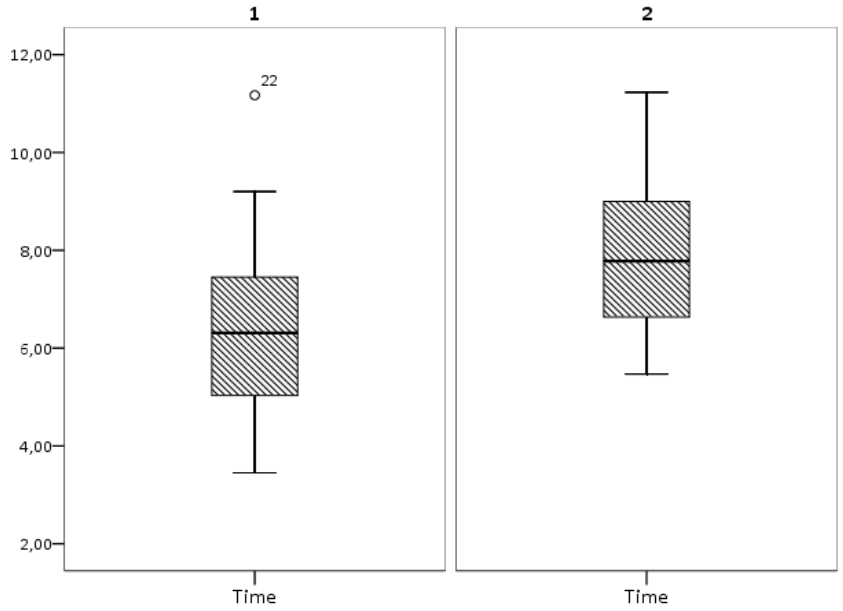
VHNSS-IT caregiver help and time of completion

p < 0,001 (Anova)	**Caregiver help**	
	Yes (30%)	No (70%)
Median age [range]	77,4 [66-87]	65,6 [45-83]

Median time → 6’57’’
Minimum → 3’45’’
Maximum → 11’23’’
IQR → 5’44’’ - 8’14’’

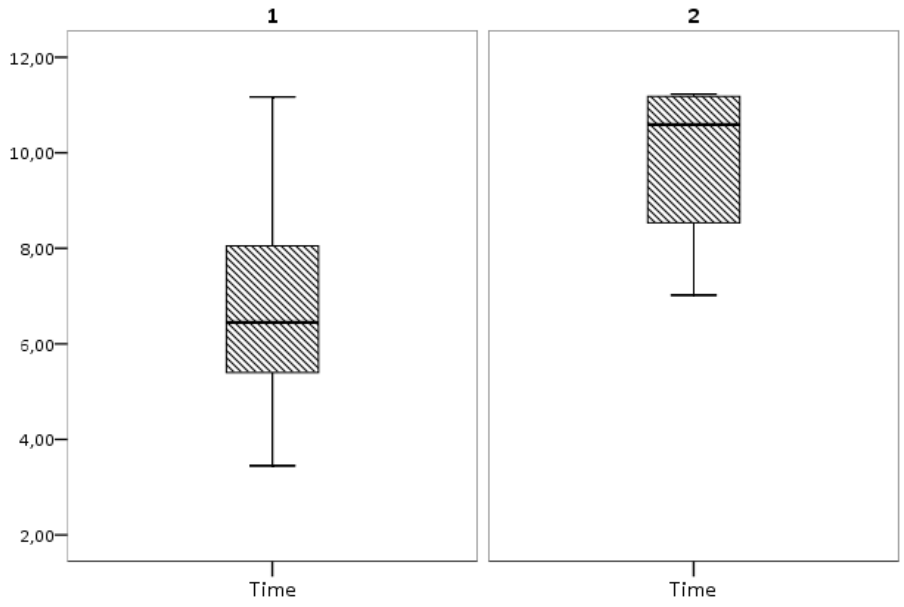


1 = Age < 70
2 = Age > 70



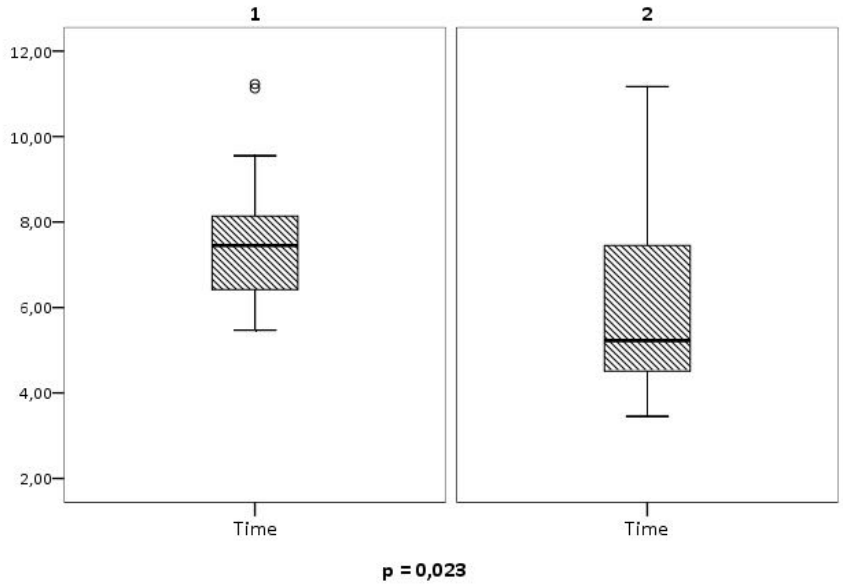
p = 0,009

1 = Age < 80
2 = Age > 80



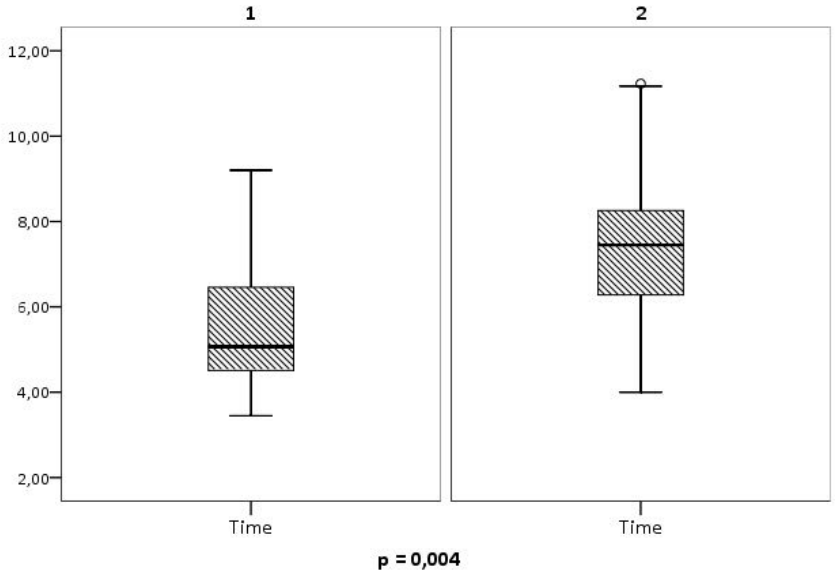
p = 0,002

Education
1 = primary - middle school
2 = high school - university



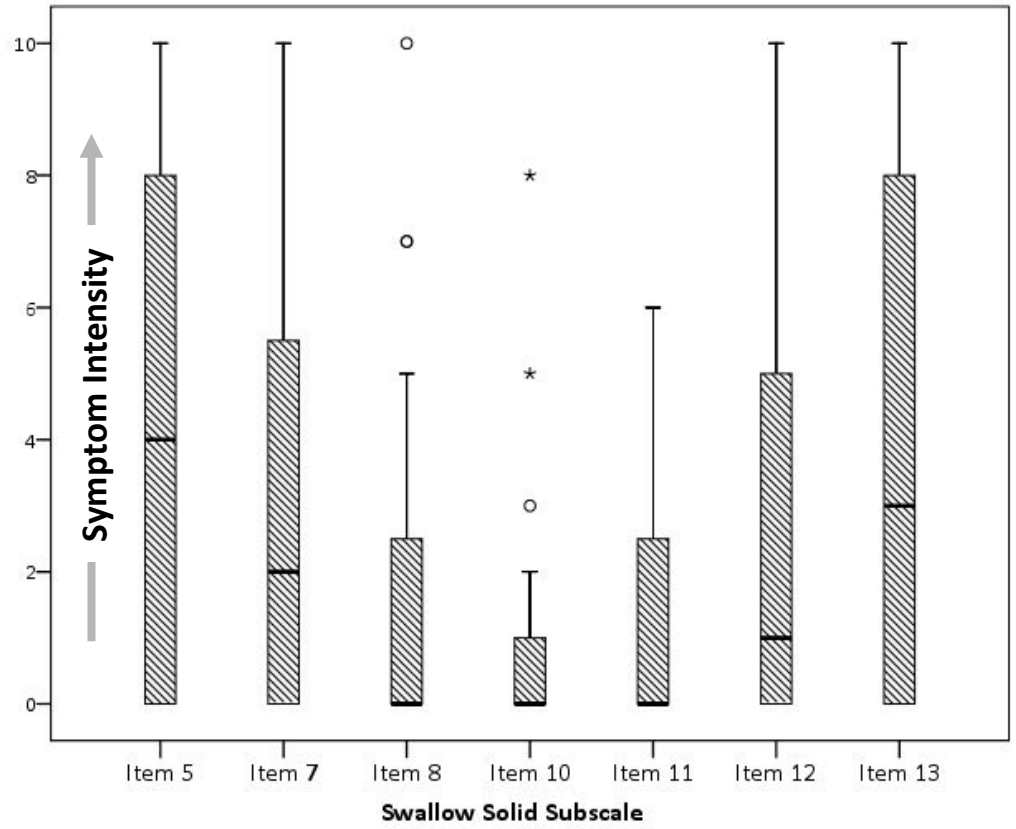
p = 0,023

Employment status
1 = employed - unemployed
2 = retired

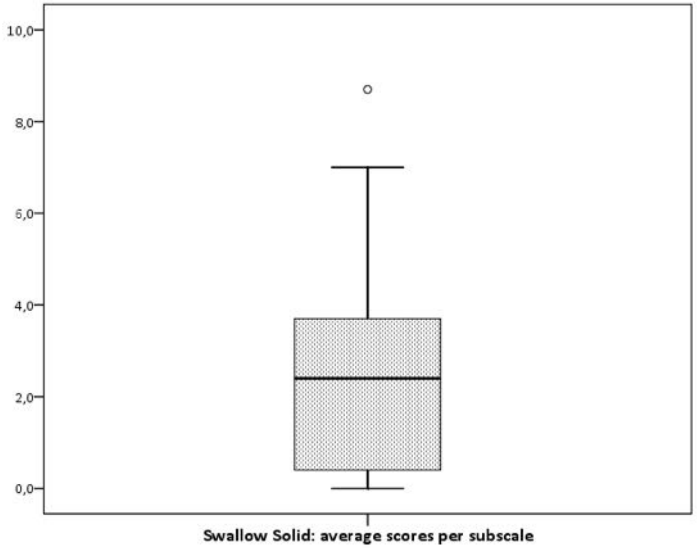


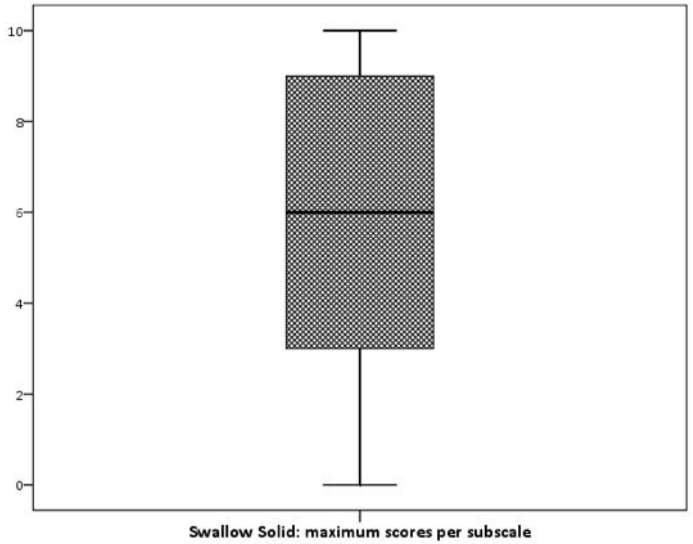
p = 0,004

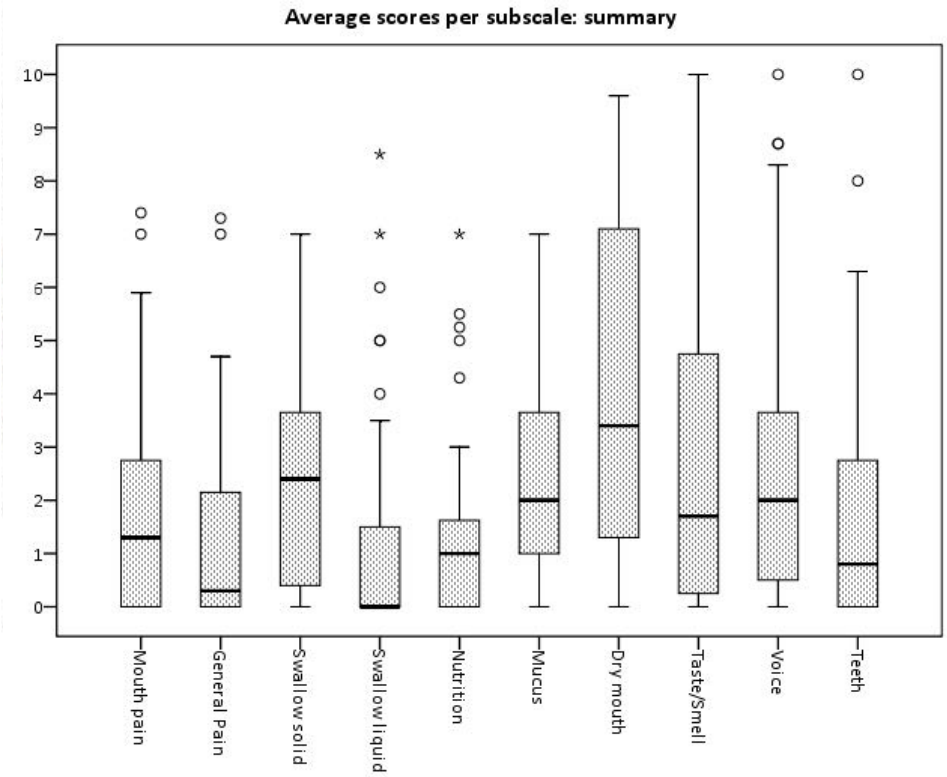
VHNSS-IT scores distributions (symptom intensity)

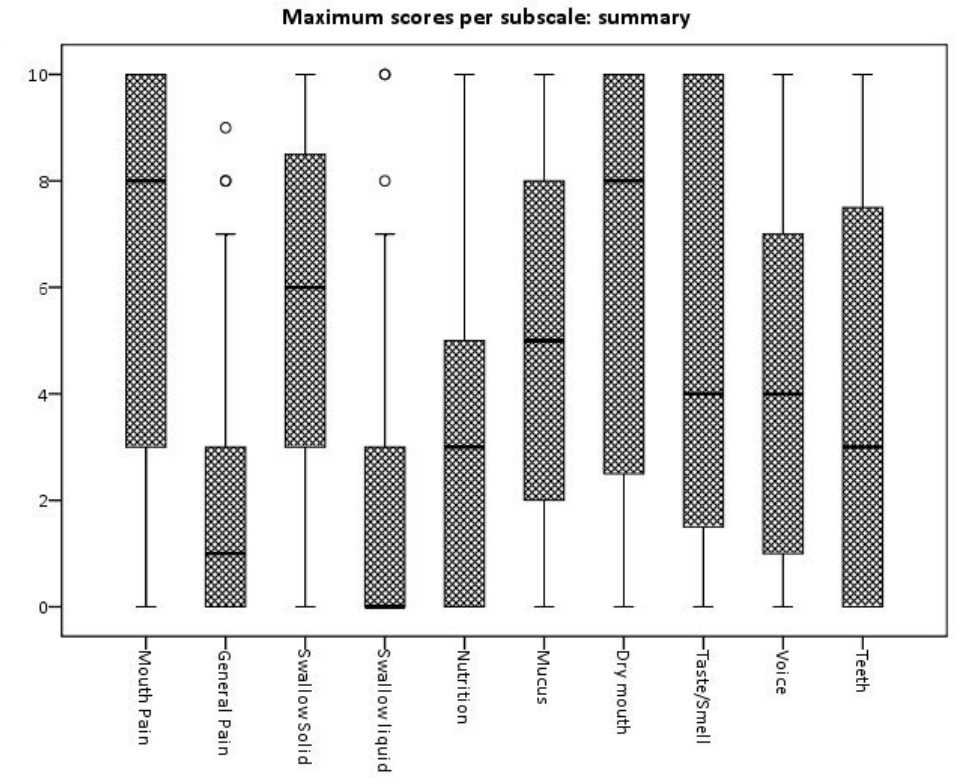


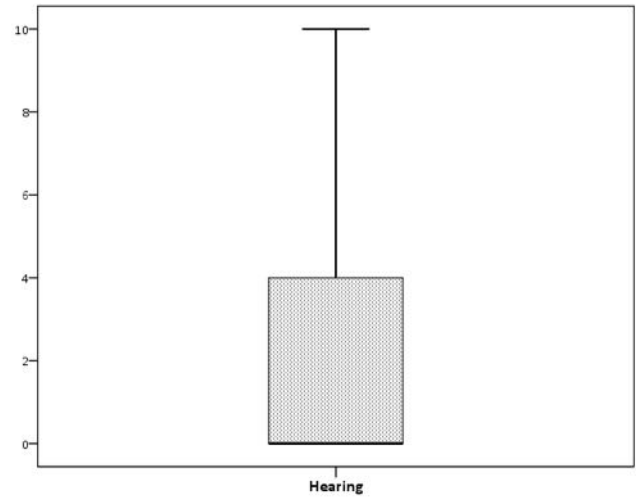
Described grouping items in **subscales**, with **average and maximum scores** per subscale (eg. Swallow solid subscale)

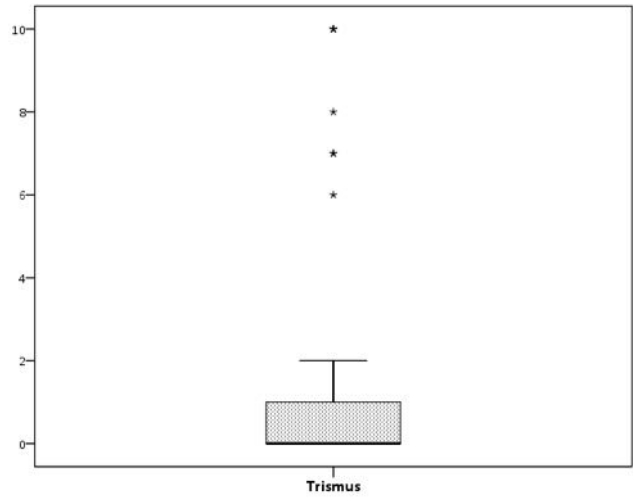


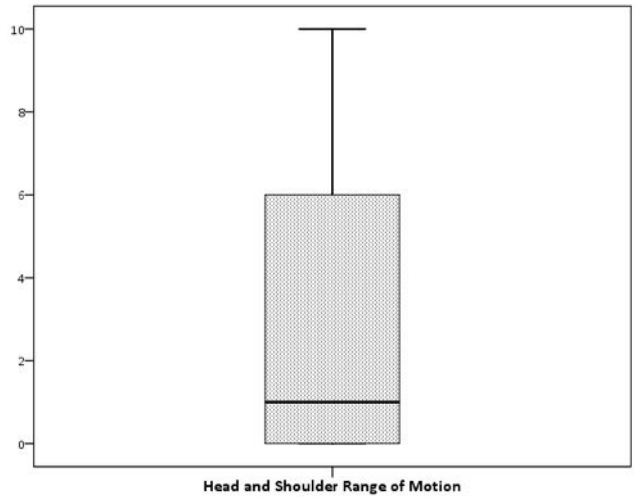



Average scores per subscale: summary
10
9
8
7
6
5
4
3
2
1
0
Mouth pain
General Pain
Swallow solid
Swallow liquid
Nutrition
Mucus
Dry mouth
Taste/Smell
Voice
Teeth


Maximum scores per subscale: summary
10
8
6
4
2
0
Mouth Pain
General Pain
Swallow Solid
Swallow liquid
Nutrition
Mucus
Dry mouth
Taste/Smell
Voice
Teeth

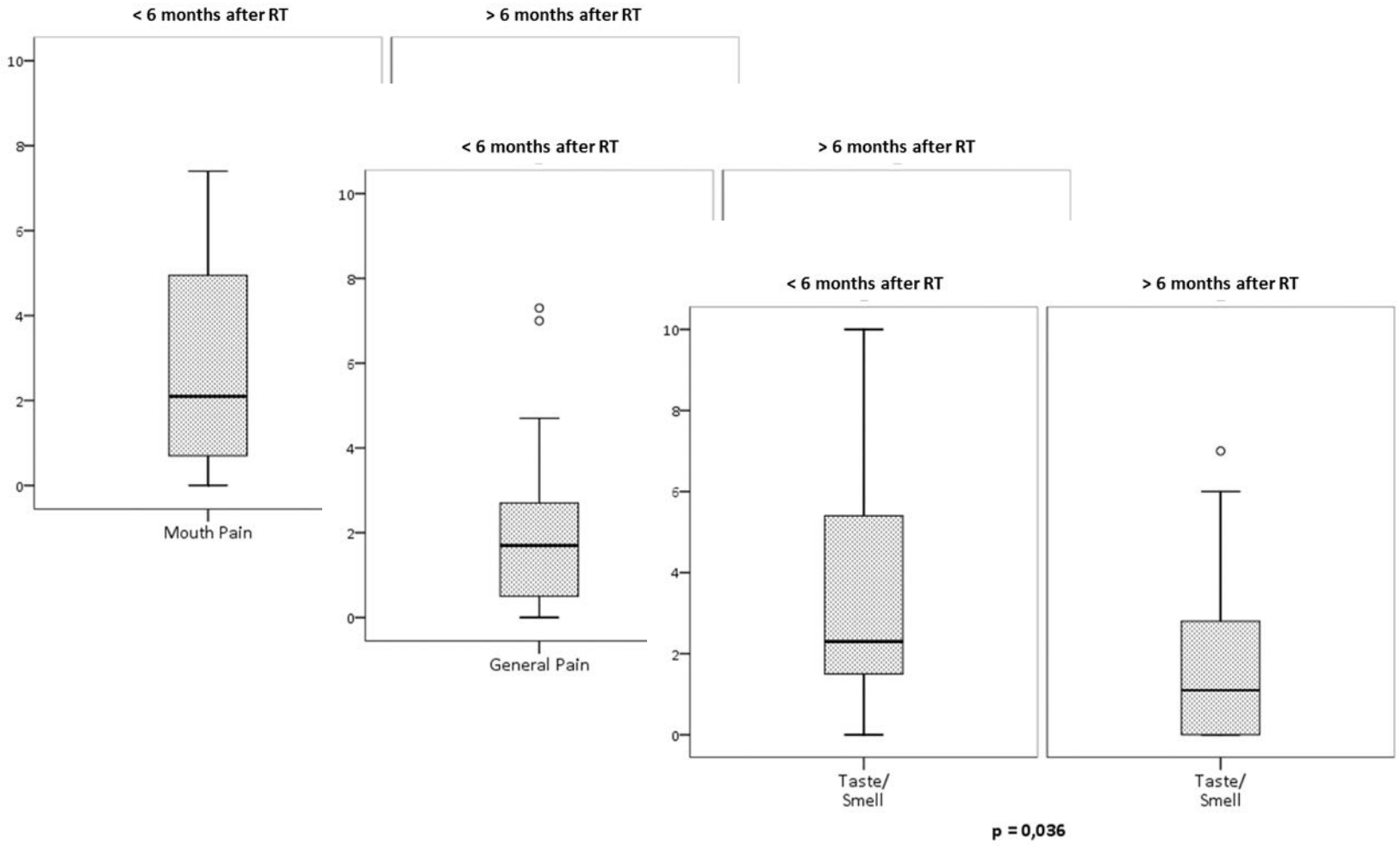

10
8
6
4
2
0
Hearing


10
8
6
4
2
0
Trismus


10
8
6
4
2
0
Head and Shoulder Range of Motion

Variables influencing symptom's intensity

- ✓ Time after the start of the radiotherapy course (< vs > 6 months)
- ✓ Surgery



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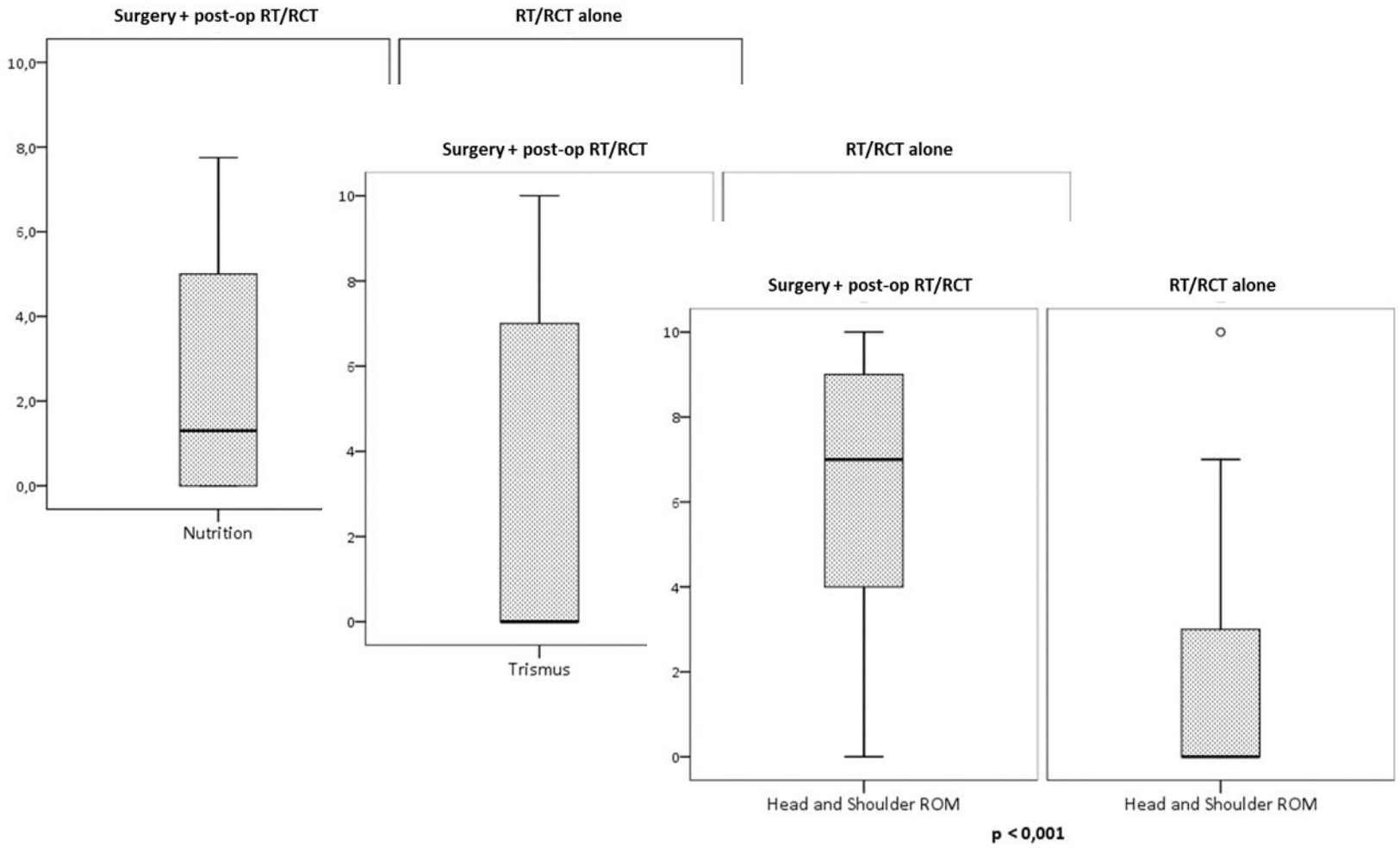

Conclusions

- ✓ The linguistic validation process allowed to optimize a instrument, the VHNSS-IT, **clear** for patients and **easy to use** for clinicians.

- ✓ **Time to review** (clinician) was perceived to be acceptable. **Average completion time** (patients) was similar to the average completion time reported for other PRO measures. Age, educational level and employment status influenced the time of completion: however, none of the patients asked to interrupt the survey and the rate of missing answer was random.

- ✓ Results on **symptoms' intensity** and correlations with **treatment modality** are consistent with data previusly reported in literature.

- ✓ The VHNSS-IT has demonstrated to be a **useful and suitable measurement** to screen for symptoms that require further evaluations or intervention in Italian HNC patients treated with surgery and radio-chemotherapy.