



Farmaci innovativi
 e ipofrazionamento

PALACONGRESSI DI RIMINI
 30 settembre, 1-2 ottobre 2016

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IX CONGRESSO NAZIONALE AIRO GIOVANI
 Coordinatore: Daniela Greto

Disfagia tardiva riportata dal paziente dopo trattamento curativo con IMRT e chemioterapia concomitante in una serie di pazienti affetti da carcinoma dell'orofaringe: studio trasversale multicentrico

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The Authors declare no conflicts of interest



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BACKGROUND

- Long term dysphagia: 30–50% of head and neck cancer (HNC) patients treated with intensive radio-chemotherapy approaches (RT-CHT)

(Caudell JJ, Int J Radiat Oncol 2009; Trotti A, J Clin Oncol 2008; Russi EG, Cancer Treat Rev 2012)

- It is known to be one of the major detrimental effects upon health-related QOL

(Ramaerker 2012)

- No agreement regarding which tool must be adopted to assess late swallowing outcome

- Commonly scored by:

- ▣ endoscopic or radiological examination (Fiberoptic Endoscopic Evaluation of Swallowing, FEES, videofluoroscopic swallowing study, VFSS)
- ▣ PRO questionnaires
- ▣ physician assessment tools

(Russi, CRHO 2015)



BACKGROUND

- In HNC patients, the majority of studies assess adverse events as reported by physicians
- Patient-reported outcome (PRO) measures are rarely used
- Swallowing patient-reported tools are easy to administer and sensitive to change when non-surgical strategies are employed

(Wilson J, Head and Neck surgery 2011)



MDADI

MD Anderson Dysphagia Inventory (MDADI)

Chen AY, Frankowski R, Bishop-Leone J, et al.
The development and validation of a dysphagia-specific quality-of-life questionnaire for patients with head and neck cancer: the M. D. Anderson dysphagia inventory.
Arch Otolaryngol Head Neck Surg 2001;127:870-6.

The M. D. Anderson Dysphagia Inventory

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The following statements have been made by people who have problems with their swallowing. Some of the statements may apply to you.
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- My swallowing ability limits my day-to-day activities.
Strongly Agree Agree No Opinion Disagree Strongly Disagree
- E2. I am embarrassed by my eating habits.
Strongly Agree Agree No Opinion Disagree Strongly Disagree
- F1. People have difficulty cooking for me.
Strongly Agree Agree No Opinion Disagree Strongly Disagree
- P2. Swallowing is more difficult at the end of the day.
Strongly Agree Agree No Opinion Disagree Strongly Disagree
- E7. I do not feel self-conscious when I eat.
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- E4. I am upset by my swallowing problem.
Strongly Agree Agree No Opinion Disagree Strongly Disagree
- P6. Swallowing takes great effort.
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- E5. I do not go out because of my swallowing problem.
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Strongly Agree Agree No Opinion Disagree Strongly Disagree
- P8. I cough when I try to drink liquids.
Strongly Agree Agree No Opinion Disagree Strongly Disagree
- F3. My swallowing problems limit my social and personal life.
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- F2. I feel free to go out to eat with my friends, neighbors, and relatives.
Strongly Agree Agree No Opinion Disagree Strongly Disagree
- P5. I limit my food intake because of my swallowing difficulty.
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- P1. I cannot maintain my weight because of my swallowing problem.
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- E6. I have low self-esteem because of my swallowing problem.
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- P4. I feel that I am swallowing a huge amount of food.
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Thank you for completing this questionnaire!



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- 10 minutes

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Italian validation

Rev Laryngol Otol Rhinol (Bord). 2008;129(2):97-100.

Adaptation and validation of the Italian MD Anderson Dysphagia Inventory (MDADI).

Schindler A¹, Borghi E, Tiddia C, Ginocchio D, Felisati G, Ottaviani F.

+ Author information

Abstract

INTRODUCTION: Oropharyngeal dysphagia is a common symptom in patients with head and neck tumours. The MD Anderson Dysphagia Inventory (MDADI) is a questionnaire currently used in North America for the assessment of dysphagia-related disability in patients with head and neck cancer. The aim of the study is to analyze reliability and clinical validity of the Italian MDADI.

MATERIAL AND METHOD: 48 persons with no history of dysphagia and 50 head and neck cancer patients with a chronic and stable dysphagia have been included in the study. Each subject completed alone the Italian MDADI twice with a week interval between the two questionnaire completion. Intra-subject reliability was analyzed through Pearson test in both groups of subjects. Clinical validity was calculated through the non parametric Mann Whitney test of the first MDADI assessment in both groups.

RESULTS: Internal consistency and test-retest reliability were high for each MDADI subscale in subjects without dysphagia as well as in those with dysphagia. The difference between MDADI values in subjects with and without dysphagia was significant for each subscale.

DISCUSSION: The Italian MDADI is reliable and clinically valid. The application of the MDADI is recommended in clinical practice as well as in descriptive, outcome and efficacy research.



Aim of the study

The search for clinical, biological (p16 status), and treatment related factors associated with patient-reported long term dysphagia using M.D. Anderson Dysphagia Inventory (MDADI) questionnaire in a OPC pts population receiving curative Intensity Modulated Radiation Therapy (IMRT) and chemotherapy (CHT)



Methods

- Cross-sectional study
- 148 patients with OPC
- 3 Italian tertiary cancer centers:
 - ▣ National Cancer Institute (INT), Milan → 101 pts
 - ▣ European Institute of Oncology (IEO), Milan → 36 pts
 - ▣ Santa Croce and Carle Hospital, Cuneo → 11 pts
- All pts completed the MDADI questionnaire, immediately before their follow-up visit (physician-assessed dysphagia tool: CTCAE v. 4.0).



Methods

INCLUSION CRITERIA:

- OPC patients
- stage III-IV
- IMRT/VMAT (70 Gy/2-2.1 2 Gy/fr) + concomitant platinum based CHT
- with or without induction (I)-CHT
- at least 6 months after completion of treatment
- complete remission



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Methods

We analyzed MDADI total scores (MDADI TS) according to the following variables:

- pts gender
- p16 status
- T stage
- N stage
- IMRT technique
- late xerostomia and dysphagia (CTCAE v4.0)
- enteral nutrition duration
- time from treatment end
- I-CHT yes or not

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Radioterapia
Oncologica



Results

Age	Mean 59 yrs (43-78)
Sex	M=76%, F=24%
Stage	T3-T4= 51%; N2-3= 84%
I-CHT	Yes=36%, No=64%
p16	Pos = 66%, Neg=23%, not available=10%
IMRT technique	Conventional IMRT=49%, VMAT=51%
Late xerostomia	G0=22%, G1=72%, G2= 6%
Late dysphagia	G0=31.7%, G1=43.2%, G2=20.3%, G3=4.2%
Time from treatment end	Mean, median : 35, 30 months (range 6-79); ≤ 25 months = 43%; > 25 months = 57%



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Results

- Mean MDADI TS = 73 (range, 40-100)
- The median (IQR) scores of:
 - MDADI TS = 72 (63-84)
 - MDADI-G = 80 (60-80)
 - MDADI-F = 80 (68-92)
 - MDADI-P = 73 (67-84)
 - MDADI-E = 70 (58-80)
- MDADI TS <60 (poor): **17.6% of pts**



Results

- At univariate analysis MDADI TS distributions were significantly better in:
 - male vs female ($p=0.0001$)
 - p16 positive vs p16 negative ($p=0.01$).
 - late G0-1 xerostomia vs G2 xerostomia ($p<0.0001$)
 - late G0-1 dysphagia vs G2 dysphagia ($p=0.01$)
 - interval time (IT) ≥ 25 months vs IT < 25 months ($p=0.03$)

- No significant difference in MDADI TS was found analyzing pts according to T stage, N stage, enteral nutrition duration, I-CHT with or without, IMRT technique.



Results

- A multivariable analysis showed that p16 positivity and late G0-1 xerostomia were significant independent predictors for better MDADI TS



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Conclusions (1)

- PRO measures were able to identify more frankly late swallowing symptoms compared to physician assessment

(4,2% vs 17,6%)

- Late dysphagia is still a concern in IMRT era



Conclusions (2)

- Globally, treatment with IMRT and concurrent CHT was able to maintain a good level of patient-reported dysphagia, with further improvements after 25 months of follow up
- p16 status and late xerostomia are the main predictors of late dysphagia



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