

XXXIII CONGRESSO NAZIONALE AIRO

AIRO2023

BOLOGNA,
27-29 OTTOBRE 2023

PALAZZO DEI CONGRESSI

Radioterapia Oncologica: l'evoluzione al servizio dei pazienti



Associazione Italiana
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Impact of acupuncture on acute dysphagia in patients treated with radio-chemotherapy for head and neck squamous cell carcinoma: preliminary results from a randomized phase 2 study (NCT 05143268)



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BACKGROUND

In HNSCC patients undergoing primary radio-chemotherapy (RCT), dysphagia is a frequent side effect. Acupuncture (ACP) impact on its management is still unclear. An Italian, multicentric, randomized phase 2 study is currently ongoing with the primary aim to compare the effect of ACP and standard treatment on swallowing function assessed with MDADI scale (MD Anderson Dysphagia Inventory) 2 weeks after the end of RT. Here, we report a preliminary analysis on ACP compliance in the experimental arm

MATERIALS AND METHODS**Inclusion criteria:**

- Histological diagnosis HNSCC

- Eligibility to radical non surgical treatment (RT alone, platinum-based CRT, RT+ cetuximab)

- Age \geq 18

- ECOG PS 0-2

- Stage I-III for oropharyngeal cancer (OPC) HPV+, stage II-IVB for non-OPC HPV- carcinoma and accessibility to ACP service with oncological experience.

Randomization in a 1:1 ratio

Arm A (experimental): weekly ACP from 2 weeks before the beginning of RT up to 2 weeks after the end of treatment (total of 11 sessions)

Arm B (standard): standard treatment

Dysphagia evaluation: EORTC QLQ-C30, QLQ-HN43 and MDADI questionnaires at baseline and 2, 12 and 24 weeks after treatment

ACP is hypothesized to yield a 10 point improvement in mean MDADI composite score compared with historical data (from 58 to 68; $\alpha=0.05$, $\beta=0.80$, sample size=90)

TOTAL PATIENTS	
Male	27(73)
Females	10(27)
AGE (years)	
Mean	65.07
Range	50-80
CHARLSON COMORBIDITY INDEX (CCI)	
Mean	4.8
Range	2-8
WEIGHT (kg)	
Mean	73.32
Range	47.7-117
TOBACCO EXPOSURE	
Never smoker	13(35)
< 10 p/y	2(5)
10-20 p/y	7(19)
> 20 p/y	15(41)
ALCOHOL EXPOSURE	
No/light drinking	31(84)
Moderate drinking	4(11)
Heavy drinking	2(5)
CAREGIVER	
Yes	25(68)
No	12(32)
PRIMARY TUMOR	
Larynx	9(24)
Nasopharynx	4(11)
Oropharynx	24(65)
Hypopharynx	0(0)
HPV STATUS	
Positive	20(54)
Negative	4(11)
Not Assessed	13(35)
STAGE GROUPING	
I	10(27)
II	13(35)
III	12(32)
IVA	2(5)
IVB	0(0)

Tab. 1: Patients 'characteristics (Florence cohort, n=37)**RESULTS**

June 2021-May 2023

- ✓ **78** patients enrolled (ACP, n=39; standard arm, n=39).
- ✓ All treated with IMRT and 59 with concomitant systemic therapy.
- ✓ In the Florence cohort (**Tab.1**) 10 pts underwent RT alone, 25 RT + platinum-based CT and 2 RT+ cetuximab
 - ✓ 68 bilateral neck irradiation.

ACP arm compliance among those who completed treatment:

- excellent (100%): 17
- very good (99-75%): 4
- good (74-50%): 4
- poor (49-25%): 1
- very poor (<25%): 3

Reasons for APC discontinuation: **worsening of clinical conditions requiring hospitalization** (n=2) or **supportive care** (n= 2). None had side effects from ACP

CONCLUSIONS

Our preliminary results showed that **weekly ACP is feasible and well tolerated in patients undergoing radiation-based treatment for locally advanced HNSCC**. Its impact on acute dysphagia is still under investigation.



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