

ACUPUNCTURE FOR (CHEMO)RADIOTHERAPY-RELATED DYSPHAGIA IN PATIENTS WITH HEAD AND NECK SQUAMOUS CELL CARCINOMA (HNSCC): A RANDOMIZED PHASE 2 STUDY

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BACKGROUND

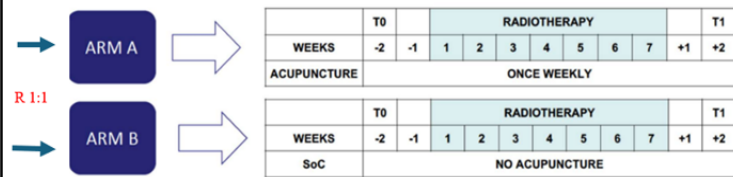
- For HNSCC patients dysphagia (DYS) during (chemo)radiotherapy (CRT) can lead to severe malnutrition
- A multicenter randomized, phase II trial (NCT05143268) evaluated the impact of acupuncture (ACP) in the mitigation of patient-reported DYS in patients undergoing curatively-intended CRT for HNSCC

MATERIALS AND METHODS

- Randomization 1:1 to experimental (A) or standard (B) arm (study design in **Figure 1**)
- Primary endpoint: severity of acute DYS 2 weeks after CRT according to MDADI composite score
- Assuming a mean MDADI composite score of 58, based on the results of the De-ESCALaTE randomized phase 3 trial, the use of ACP was hypothesized to yield a >10 point difference compared with arm B. Assuming a standard deviation (SD) of 18 in both arms, with $\alpha=0.05$ and 0.80 power, a total of 90 patients were required (accounting for 10% drop-out)

INCLUSION CRITERIA

- Histologically confirmed, locally advanced HNSCC
- Curatively-intended non surgical treatment
- Stage I-III for oropharyngeal cancer (OPC) HPV+, stage II-IVB for non-OPC HPV- carcinoma (TNM/AJCC 8th edition)
- Age ≥ 18 y
- ECOG PS 0-1



Stratification according to: - Unilateral vs bilateral neck irradiation
- Concurrent vs no systemic therapy

| CHARACTERISTICS | N (%) |
|--------------------------|---------|
| Total patients | 91 |
| Males | 60 (66) |
| Females | 31 (34) |
| Age (years) | |
| Median | 69 |
| Range | 48-84 |
| Tobacco exposure | |
| Never smoker | 36 (40) |
| <10 p/y | 6 (7) |
| 10-20 p/y | 19 (21) |
| > 20 p/y | 30 (33) |
| Tumor primary | |
| Larynx | 11 (12) |
| Nasopharynx | 8 (9) |
| Oropharynx | 70 (77) |
| Hypopharynx | 2 (2) |
| HPV status | |
| Positive | 51 (56) |
| Negative | 25 (27) |
| Not Assessed | 15 (16) |
| Type of treatment | |
| RT alone | 20 (22) |
| RT + platinum based CT | 69 (76) |
| RT + cetuximab | 2 (2) |
| Neck Irradiation | |
| Unilateral | 12 (13) |
| Bilateral | 79 (87) |

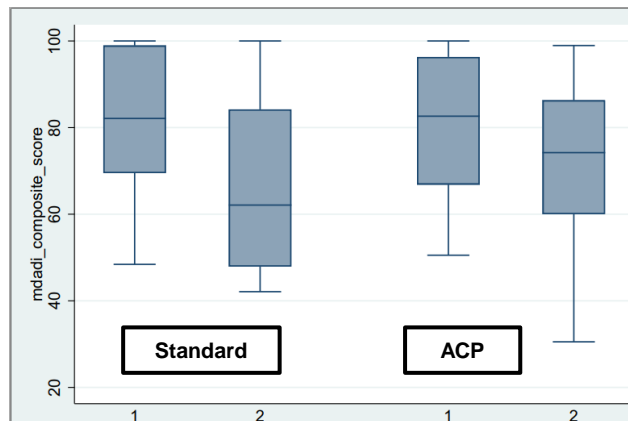


Figure 2. No difference was observed 2 weeks after CRT between the two arms. 1, pre-treatment (-2weeks) mean MDADI score; 2 timepoint +2weeks after CRT mean MDADI composite score, $p=0.446$

Table 1. Patients and treatment characteristics

RESULTS

PATIENT POPULATION

From 06/21 to 11/23, 91 patients (Arm A, 44; arm B, 47) enrolled from 6 centres (**Table 1**)

PRIMARY ENDPOINT

No difference was observed 2 weeks after CRT between the two arms (mean MDADI composite score of 72.1, SD 17.2, and 67.4, SD 20.7, in arms A and B, respectively; $p=0.446$) (**Figure 2**)

SECONDARY OUTCOMES

- A higher proportion of MDADI global score of 4-5 was observed in arm A (56.4%) compared with arm B (29.7%; $p=0.023$).
- Over time, patient-reported change in severity of QLQ-HN43 domains such as dry mouth, social eating and swallowing favoured arm A vs arm B ($p=0.091$, 0.002 and 0.052, respectively).

CONCLUSIONS

The results of our study suggest that ACP is feasible and may safely contribute to mitigate patient-reported swallowing dysfunction during CRT. Further studies are needed to confirm the clinical relevance and generalizability of our findings.