Two Year Results for MC1273, a Phase II Evaluation of Aggressive Dose De-escalation for Adjuvant Chemoradiation in HPV+ Oropharynx Squamous Cell Carcinoma (OPSCC)

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Background: HPV-related oropharynx cancer

- Although cure rates for HPV-OPC are high, standard treatment can have serious and potentially life-altering side effects.

- Multiple research groups are currently exploring incremental reductions in radiation dose for HPV-OPC.

- MC1273 explored an aggressive course of treatment reduction by halving the dose of radiation after surgery.
Methods

p16+ oropharynx patients
<10 pack-year smoking history
margin clearing surgery

Cohort A: n= 37
≥T3, ≥N2, lymphovascular invasion,
or perineural invasion

30 Gy (1.5 Gy bid x 10 days)
+ weekly docetaxel (15 mg/m²) x 2

Cohort B: n=43
Extracapsular extension

36 Gy (1.8 Gy bid x 10 days)
+ weekly docetaxel (15 mg/m²) x 2

Follow-up
Swallow Studies
Quality of Life Assessment

Standard Treatment:
60 - 66 Gy over six weeks
± cisplatin
Patients

- **Median age:** 60.5 years (range: 25-77 years)
- **Gender:** 73 Male, 7 Female
- **Median follow-up:** 23.6 months (12 – 46)

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Results: Progression Free Survival

- 2-yr PFS: 91.3%
- RTOG 0234: 2-yr PFS 86.4%
- Distant Recurrence: n = 4
- Locoregional Recurrence: n = 3
Results: Locoregional Control

- 2-yr LRC: 96.3%
- Local Recurrence: n = 2
- Nodal Recurrence: n = 1
Results: Toxicity and Swallowing

• Grade ≥2 toxicity rate at two years post-treatment was 10%
  \( \rightarrow \) RTOG 0234 rate was 55%

• No patients required a feeding tube placed during treatment.

• Swallowing function improved between pre-radiation and 12 month follow-up. (MBSImp Oral: 1.5±1.9 vs 1.5±1.8 p=n.s., Pharyngeal 5.8±3.9 vs 4.7±3.6 p = 0.02.)

• Quality of life (EORTC-HN, FACT-HN and Eq-5D) remained essentially unchanged between pre and post-treatment.
Conclusions

• Aggressive treatment de-escalation resulted in disease control rates comparable to historical controls.

• De-escalated therapy led to significantly improved post-treatment side effects, improved long-term swallowing function and improved quality of life.

• A multi-institutional, phase III study (NCT02908477: “DART-HPV”) is currently open for accrual.