Current Status on the Management of Recurrent Head/Neck Cancer

Nancy Lee, M.D.
April 30, 2010

Results of treatment recurrence of advanced head and neck cancers, S/P Surgery + PORT

• Cooney et al Arch of Oto 1999

Actuarial 5 year survival after recurrence

Survival is horrible, surgical salvage is difficult. The best chance for the patient is the FIRST chance

IMRT Head and Neck Cancer: What have we learned from published literature?

• IMRT allows preservation of salivary function: mean dose ≤ 26 Gy

• More importantly, IMRT does not compromise loco-regional control in published series

• Importance of accurate target volume delineation
T2N1 oral Tongue Cancer

Treated Ipsilateral oral cavity, levels I-II

Post-treatment

Contralateral Neck Failure

Omission of level III

Submental Failure
Recurrent NPC failed at skull base. Patient received 70 Gy using IMRT and chemo. Coverage superiorly at skull base of tight.

Skull base marginal failure

After couple days of treatment, no longer with any pain. At 3 weeks, can move his left eye.

Background

- Recurrent head and neck cancer: great challenge particularly in the setting of prior head and neck radiotherapy where most patients already received around 70 Gy.

- For operable patients, salvage surgery +/- 2nd course of post-operative radiotherapy +/- chemotherapy is the treatment of choice.

- For inoperable disease, chemotherapy has traditionally been the standard of care, with response rates between 10 to 40% and dismal median OS of around 5 to 9 months. The only exception is nasopharyngeal cancer.
Background

- Combination chemotherapy including targeted therapy has been used. Despite improved RR (67-77%), there is only slight increase in 2-3 year OS of around 5 to 10%.
- However, results are suboptimal because majority die of active loco-regional disease.

EGFr inhibitors in recurrent/metastatic disease:

<table>
<thead>
<tr>
<th>No.pts</th>
<th>Agent</th>
<th>CR/PR</th>
<th>CR/PR/NC</th>
<th>Med Surv</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trigo</td>
<td>2004</td>
<td>103</td>
<td>13%</td>
<td>46%</td>
</tr>
<tr>
<td>Baselga</td>
<td>2002</td>
<td>96</td>
<td>10%</td>
<td>53%</td>
</tr>
<tr>
<td>Kies</td>
<td>2002</td>
<td>79</td>
<td>10%</td>
<td>56%</td>
</tr>
<tr>
<td>Cohen</td>
<td>2003</td>
<td>52</td>
<td>11%</td>
<td>53%</td>
</tr>
<tr>
<td>Kane</td>
<td>2004</td>
<td>65</td>
<td>4%</td>
<td>38%</td>
</tr>
<tr>
<td>Soulieres</td>
<td>2004</td>
<td>115</td>
<td>4%</td>
<td>43%</td>
</tr>
</tbody>
</table>

EGFr inhibitors in recurrent/metastatic disease:

E1395
Cisplatin/Paclitaxel vs Cisplatin/5-FU

Median OS
CF 8.7 mos (CI 7, 12)
CP 8.1 mos (CI 6, 10)
Still within 5-9 months

Gefitinib vs Methotrexate RCT

<table>
<thead>
<tr>
<th># pts</th>
<th>ORR (%)*</th>
<th>SD (%)*</th>
<th>OS (mo)*</th>
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<tbody>
<tr>
<td>Gefitinib 250mg daily</td>
<td>158</td>
<td>2.7</td>
<td>47.6</td>
</tr>
<tr>
<td>Gefitinib 500mg daily</td>
<td>167</td>
<td>7.6</td>
<td>45.2</td>
</tr>
<tr>
<td>Methotrexate 40mg weekly</td>
<td>161</td>
<td>3.9</td>
<td>44.1</td>
</tr>
</tbody>
</table>

* There were no statistically significant differences between the three treatment arms - more tumor hemorrhage in gefitinib arms.
**Extreme Study**

Patients included were those who were ineligible for local therapy.

**EXTREME: Overall Survival**

<table>
<thead>
<tr>
<th></th>
<th>C225+Platinum+5-FU</th>
<th>Platinum+5-FU</th>
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<tbody>
<tr>
<td>n</td>
<td>222</td>
<td>220</td>
</tr>
<tr>
<td>10.1 months</td>
<td>7.4 months</td>
<td>0.80</td>
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</table>

**Conclusion:** Addition of cetuximab to standard first-line platinum-based chemotherapy improves overall survival.

**Recurrent Head Neck Cancer**

Importance of Local Therapy

Even among patients who die with DM, a large portion still harbor uncontrolled disease at the primary site and suffer from intractable pain, bleeding, and infection.
Recurrent NPC with DM

Background

- A local modality is needed to improve loco-regional control and thus the rationale of re-RT. Data on re-irradiation is largely retrospective studies from single institutions.

- Due to fear of unacceptable late complications, different centers have limited their re-RT to brachytherapy (Interstitial or IORT) or SRS

- For NPC, intracavitary brachytherapy has resulted in 5 year LC of 85%
Improved Outcomes of HDR IORT for Recurrent and LA Head Neck Cancer

- N= 18 (16 recurrent and 2 locally advanced)
- 2001-2006
- Ir-192
- Median dose: 15Gy (10Gy to 20 Gy)
- Median F/U of 18 months
- In-field control rate: 95%
- 2 year DM rate: 39%
- 2 year OS: 67%
- 9% wound complications

HDR Interstitial Brachytherapy for Recurrent HNC

- N= 30 where 18 underwent surgery followed by HDR
- Typical prescription dose: 3.4 Gy BID to 34 Gy
- If combined with EBRT (40-50 Gy): 4 Gy BID to 20 Gy
- HDRBT was initiated 5 days after catheter placement
- Median F/U: 12 months
- 2 year LC and OS were 71% and 63%, respectively
- Patients who had surgery had better LC (88% vs 40%)
- 4 Grade 3 complications→ mainly bleeding events

Narayana et al. Brachytherapy 2007
Background: Re-RT

- Brachytherapy is a great option in selected patients. However, some patients’ underlying medical condition preclude them from anesthesia. And, most recurrences are large, irregularly shaped and situated in a region that are not amenable to brachytherapy.

- Emergence of data recently on SRS or SBRT using the Cyberknife system. Typically a hypofractionated regimen is used which can potentially result in higher late complications. May not be the best option for a very large irregularly-shaped recurrence.

- Alternative methods using EBRT using conventional, 3D conformal, or IMRT have been implemented.

Caveats: Re-RT

- Study population is therefore heterogeneous.

- Most of these studies included various techniques within the study ranging from brachy, SRS, to EBRT. Sometimes brachy and SRS used as a boost.

- Most of these studies included both operable and inoperable patients.

- For operable patients: 3-4 year OS ranges from 40 to 60% versus unresectable patients with 4-5 year OS between 10 to 17%)

- Nasopharyngeal has the best outcome among all other sites within the head and neck and OS has been reported with re-RT over 90%

Background: Re-RT

- Overall, single institution results have been promising when compared to chemotherapy alone with a median OS of around 12-14 months. [An improvement from chemotherapy alone of only 6-9 months.]

- 2 year loco-regional control up to 40 to 50%

- 2 year OS of up to 30-40%.
Re-RT for NPC

<table>
<thead>
<tr>
<th>Author</th>
<th>Median F/U</th>
<th>5 year LC</th>
<th>5 year OS</th>
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<tbody>
<tr>
<td>Koutcher (29)</td>
<td>45</td>
<td>52</td>
<td>60</td>
</tr>
<tr>
<td>Huang(74)</td>
<td>20</td>
<td>49</td>
<td>37</td>
</tr>
<tr>
<td>Teo(104)</td>
<td>20</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Leung(91)</td>
<td>55</td>
<td>38</td>
<td>30</td>
</tr>
<tr>
<td>Lee(654)</td>
<td>17</td>
<td>23</td>
<td>16</td>
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</tbody>
</table>

Re-RT for IMRT

<table>
<thead>
<tr>
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<th>N</th>
<th>Median F/U</th>
<th>LC</th>
<th>OS</th>
</tr>
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<tbody>
<tr>
<td>Lu</td>
<td>49</td>
<td>9</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Chua</td>
<td>31</td>
<td>11</td>
<td>65</td>
<td>63</td>
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</table>

Re-RT + Chemo: U Chicago

- Seven prospective phase I and II trials for recurrent or met head and neck SCC
- N= 115
- Sites: Oral Cavity, Oropharynx, Nasopharynx, Hypopharynx, Larynx, Maxillary Sinus
- Hydroxyurea + 5FU or CDDP and Taxol
- Median Re-RT dose was 65 Gy with previous median RT dose of 68 Gy

Re-RT + Chemo: U Chicago

- Median follow up of surviving patients was 67 months
- Median OS and PFS was 11 months and 7 months
- 3 year OS, PFS, LR Control, freedom from DM were: 22%, 33%, 51%, 61%, respectively
- MVA showed that re-RT dose, triple agent chemo (CDDP, Taxol, Gemcitabine), surgery were independent prognostic factor for OS, PFS, LR control
**Re-RT + Chemo: FCCC**

- Two prospective trials on unresectable SCC recurrent head and neck cancer
- Re-RT began as early as 3 months since first course of RT with prior median dose of 64.2 Gy.
- N= 38
- Sites: Oral Cavity, Larynx, Nasopharynx, Oropharynx, Paranasal sinuses, hypopharynx, salivary gland, skin

**Re-RT + Chemo: FCCC**

- CDDP + Taxol and 1.5 Gy BID to 60 Gy in a split course fashion: weeks 1, 3, 5, 7 with treatment and other weeks with GCSF support.
- Median follow-up of 10 months
- Median OS of 12 months with 1 and 2 year OS of 50% and 35%, respectively
- 63% experienced local progression of disease all within RT field with 1 year PFS of 33%

**Re-RT + Chemo: Michigan**

- N= 40
- Median prior RT dose: 70 Gy
- Median re-RT dose: 60 Gy
- 78% re-RT with curative intent while 9 patients underwent palliative re-RT
- Patients were treated with conformal techniques
- Chemotherapy given concurrently in 14 patients

**Re-RT + Chemo: Michigan**

- Median OS was 12.5 months
- 1 and 2 year actuarial survival were 51% and 33%, respectively
- MVA showed that palliative intent, tumor bulk, tumor site other than NPX or larynx had worse OS
- Median time to Relapse-Free and LR recurrence-free survival were 4 and 8 months.
Cooperative Trials

- RTOG conducted Phase I and II studies on re-RT and chemo using a split course.
- Re-RT: 1.5 Gy BID x 5 days with chemo (Hydroxyurea + 5FU; CDDP and Taxol) weeks 1, 3, 5, 7 and GCSF support during the weeks with no treatment.
- 2 year OS of up to 26% have been reported.
- Based on the results of single institutional as well as multi-institutional trials, RTOG opened a phase III randomized trial comparing re-RT + chemotherapy versus chemotherapy alone.

re-RT Toxicities

- Can result in life-threatening treatment-related toxicities
- Can result in poor quality of life

Late Complications of re-RT

- Fortunately, life-threatening toxicities caused by re-RT occur infrequently.
- Carotid rupture results in death in nearly all the patients.
- De Crevoisier (France): 5 cases
- Salama (U Chicago): 6 cases and one survived
- RTOG 99-11: 2 cases

Cranial Neuropathy with re-RT

- Mostly in Nasopharyngeal cancer
- Chua (Hong Kong using IMRT): 20% with one year actuarial rates of Late toxicities of 25% for grade 3 and 70% for all grades
- Shin (Korea using 3D conformal): 24% grade IV or V toxicities. Brainstem necrosis (2); temporal lobe necrosis (1); mucosal necrosis (1); massive epistaxis (1)
Late Complications of re-RT

- Vascular stenosis and thromboembolism are potential complications of re-RT and can manifest as TIA or stroke. This has not been reported perhaps because this entity is under-appreciated and under-reported.
- Myelitis have been reported when tumors are close to spinal cord.

Quality of Life with re-RT

- Not well studied
- U Chicago reported long-term speech and swallowing.
- Intelligible speech in 85% of the patients and ability to swallow solids without PEG dependence in 25%
- Most patients already can’t swallow prior to re-RT

RTOG Phase III Trial on Chemo +/- re RT

- Recurrent SCC of Head and Neck
- Received prior full Course RT
- Unresectable

Randomize

CDDP + Taxol
Re-RT: 60 Gy (Split course)

CDDP + Taxol

Study closed due to poor patient accrual

Phase III Trial on Postoperative Re-RT with Chemotherapy after Salvage Surgery vs Surgery Alone

- Recurrent SCC of Head and Neck
- Received prior full Course RT
- Resected

Randomize

RT to 60 Gy
5FU + Hydroxyurea

N= 65
No imbalance

Observation

Janot et al. JCO, 2010
Results

Late Complications: 26% versus 9% in the surgery alone arm

At 2 years after randomization: 39% versus 10% had grade 3 or 4 late complications.

Sclerosis, trismus, ORN, feeding tube dependence.

Late Toxicities

Re-RT and chemotherapy after salvage surgery improved locoregional control and disease-free survival but not overall survival

There were deaths related to treatment and caution should be used when considering re-RT in all recurrent head and neck cancer.

Conclusion
Salvage Re-irradiation for Recurrent Head and Neck Cancer


*Department of Radiation Oncology
**Department of Medical Physics
***Department of Biostatistics
****Department of Medicine: Head & Neck Service
*****Department of Surgery: Head & Neck Service

Purpose

- Retrospective study is to review MSKCC experience in treating recurrent head and neck cancer with re-irradiation.

Materials and Methods

- From 7/1996 to 9/2005, 155 recurrent head and neck cancer patients who had prior full course head and neck radiation therapy presented to our medical center.
- The following patients were excluded from this study:
  - KPS ≤ 60%
  - Use of salvage brachytherapy
  - Patients with melanoma, RT-induced sarcoma
  - Presence of distant metastases at presentation
- This present cohort consists of 105 patients who underwent external beam radiotherapy for their recurrent head and neck cancer.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Male</td>
<td>69</td>
<td><strong>66%</strong></td>
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<tr>
<td>Female</td>
<td>36</td>
<td><strong>34%</strong></td>
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<tr>
<td>Median Age</td>
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<td>31-84</td>
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<table>
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<tr>
<th>Site of Recurrence</th>
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<tbody>
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<td>Nasopharynx</td>
<td>21</td>
<td><strong>20%</strong></td>
</tr>
<tr>
<td>Neck</td>
<td>21</td>
<td><strong>20%</strong></td>
</tr>
<tr>
<td>Paranasal Sinus</td>
<td>18</td>
<td>17%</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>16</td>
<td>15%</td>
</tr>
<tr>
<td>Larynx</td>
<td>10</td>
<td>10%</td>
</tr>
<tr>
<td>Oral Cavity</td>
<td>9</td>
<td>9%</td>
</tr>
<tr>
<td>Parotid</td>
<td>6</td>
<td>6%</td>
</tr>
<tr>
<td>Hypopharynx</td>
<td>4</td>
<td>4%</td>
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<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N</th>
<th>% or Range</th>
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<td>69</td>
<td><strong>66%</strong></td>
</tr>
<tr>
<td>Female</td>
<td>36</td>
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<tr>
<td>Median Age</td>
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<tr>
<td>Site of Recurrence</td>
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<td>Nasopharynx</td>
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<td>6%</td>
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<td>Hypopharynx</td>
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<td>4%</td>
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<table>
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<tr>
<th>Recurrent Histology</th>
<th>N</th>
<th>% or Range</th>
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<tbody>
<tr>
<td>Recurrent Tumor in RT Field</td>
<td>63</td>
<td>60%</td>
</tr>
<tr>
<td>Primary site only</td>
<td>20</td>
<td>19%</td>
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<tr>
<td>Neck only</td>
<td>22</td>
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<tr>
<td>Both primary and neck</td>
<td>22</td>
<td>21%</td>
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<tr>
<td>Squamous Cell Carcinoma</td>
<td>91</td>
<td>87%</td>
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<td>5%</td>
</tr>
<tr>
<td>Mucopidermoid Carcinoma</td>
<td>5</td>
<td>5%</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>4</td>
<td>4%</td>
</tr>
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</table>
**Materials and Methods**

- **Radiation Therapy**
  - Treatment N
  - Prior radiotherapy median dose 62 Gy (28 - 78)
  - Interval between prior RT and re-irradiation 38 months (5 - 380)
  - Re-irradiation median dose 59.4 Gy (30 - 70)
  - Median range of dose per fraction 1.8 - 2.0 Gy
  - Re-irradiation Technique
    - Conventional 15
    - Simple 3D Conformal 10
    - Complex 3D Conformal 6
    - IMRT 74

- **Surgery**
  - Surgery was performed on 36 patients (34%) immediately prior to re-irradiation.
  - Because of high suspicion of microscopic residual disease at the time of surgery, these patients underwent post-operative radiation therapy.

- **Chemotherapy**
  - Given at Discretion of Med Onc with Various Agents
  - Treatment N
    - Prior chemotherapy only 4
    - Concurrent chemotherapy only 45
    - Prior + concurrent chemotherapy 14
    - Concurrent + adjuvant chemotherapy 10
    - Prior + concurrent + adjuvant chemotherapy 2

**Target Volumes**

- **Unresectable Tumors**
  - GTV was defined as any visible evidence of disease on PE or any available imaging modalities such as CT, MRI and/or PET scans
  - Fusion of MRI or PET was done when possible
  - Subclinical sites not included
  - PTV included 1 to 2 cm margin
**Target Volumes**

Resectable Tumors

- CTV included at least the preoperative GTV and the postoperative bed
- Subclinical sites of disease not included
- PTV included 1 to 2 cm margin

**Results**

- Median F/U of surviving patients: 35 months (2.4 months to 80 months)
- 5 patients did not complete prescribed re-RT due to progression of disease during treatment
- 4/5 had local progression and died shortly after discontinuation of re-RT
- 1/5 developed lung mets and received palliative chemotherapy only

**Results**

- Median cumulative RT dose was 121.4 (range: 88 to 137 Gy)
- Median cumulative spinal cord dose was 50 Gy and brain stem was 60 Gy

**Locoregional Progression-Free Probability**
Overall Survival Probability

Patterns of Failure

- Failures occurred within the re-irradiated GTV volume

- University of Michigan: Popovtzer et al. IJROBP, 2009. Almost all loco-regional failures occurred within the re-irradiated GTV volume despite avoiding prophylactic RT of tissue at risk for subclinical disease.

Results

- Prognostic factors of LRPFS (UVA):
  - Re-irradiation doses ≥ 50 Gy
    [HR: 0.36, 95% CI 0.20 - 0.65, p = 0.001]
  - Use of IMRT:
    2-year LRPFS +/- IMRT = 52% vs. 20%
    [HR: 0.36, 95% CI 0.21 - 0.61, p <0.001]
  - MVA: IMRT remained associated with LRPFS
    [HR 0.37, 95% CI 0.19 - 0.76, p = 0.006]
  - Dose was no longer sig, p<0.13

Local-Regional Progression-Free Probability - IMRT vs. Non-IMRT
Summary of Literature on Recent Experience with IMRT

- Doses up to 72.6 Gy have been used
- 2 year locoregional control up to 65%
- 2 year overall survival around 60%
- 5 year locoregional control around 40%
- 5 year overall survival around 20%
- Late effects: 20% of the patients

Locoregional Progression-Free Probability - +/- Surgery (Subset = SCC, non-NPC patients)

Results

Severe Complications

N

Grade 3 neck fibrosis

Common

Grade 3 dysphagia/stricture

5

Grade 3 hearing loss

4

Grade 3 trismus

4

Grade 3 cranial neuropathy

1

Grade 3/4 temporal lobe necrosis

4

Grade 4 unilateral blindness

1
Recurrent NPC with Retropharyngeal Lymph Nodes

Recurrent NPC with Retropharyngeal Lymph Node Involvement

Plan: 7000

Recurrent NPC with DM

Red: 70 Gy
1 week  
2 weeks  

3 weeks
Mask No Longer Fits properly Remasked and Replanned

4 weeks

5 weeks 6 weeks 7 weeks
Prior to Treatment

Patient from Upstate NY. Had two full courses of RT

SNUC Recurrence Orbital Extent. Was Recommended Try re-RT

Treatment Plan: 800 cGy x 3
2D OBI Does not show rotation well

Prior to Treatment

Post-Treatment

4 months post re-RT
**Conclusions**

- Achieving locoregional control is crucial for improved overall survival in patients with recurrent head and neck cancer who has received prior head and neck radiation.
  - Patients who achieved loco-regional control of disease had better OS. RT dose also predicted for better OS.
  - Subset analysis showed that non-nasopharyngeal SCC patients had better LRPFS and OS with the addition of surgery prior to re-irradiation.
  - Nasopharyngeal tumors and the use of IMRT predicted for better tumor control.

**Conclusions**

- Aggressive efforts to maximize tumor control for recurrent head and neck cancer including dose escalation with the use of IMRT and improved chemotherapy are warranted.

- Patient selection for re-RT? Development of a nomogram.
**08-050: Phase II Study of Docetaxel + Cetuximab + Concurrent Re-RT (IMRT) for Patients with Locoregionally Recurrent Head and Neck Cancer**

Dose escalate to 70 Gy
Treating GTV + Margin: no prophylactic subclinical treatment

Trial closed due to lack of funding

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**Prognostic Factors for Survival After Salvage Reirradiation of HNC**

- **N= 103**
- Salvage surgery in 46 patients prior to re-RT
- Median PFS and OS were 12.1 months and 19.3 months
- Median OS was 5.5 months among those who had significant comorbidity and organ dysfunction and 4.9 months per Adult Comorbidity Evaluation vs. 59.6 and 44.2 months if none of the above existed.
- Developed a nomogram to predict the probability of death within 24 months after re-RT was developed. (concordance index = 0.75)

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**Nomogram Predicting for Survival**

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<thead>
<tr>
<th>Prognostic Factor</th>
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<th>No</th>
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<tbody>
<tr>
<td>Comorbidity</td>
<td>Normal</td>
<td>Increased</td>
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<tr>
<td>Organ Dysfunction</td>
<td>Normal</td>
<td>Decreased</td>
</tr>
<tr>
<td>Intent of New Treatment</td>
<td>Relief</td>
<td>No Relief</td>
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<tr>
<td>Tumor Bulks (cm)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Time from initial to re-RT (months)</td>
<td>0</td>
<td>5</td>
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<td>Tumor Ranges (cm)</td>
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<td>12-Month Survival Probability</td>
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<td>0.7</td>
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</table>
On-Going Research Project
Sicar, Koutcher et al.

- Based on our own re-RT population:
- Validate the nomogram
- Additional factors, i.e., dose of RT, site, RT technique
- Develop nomogram for locoregional control

Who should we radiate?

Other Research Projects

- Examination of tumor expression of various biomarkers, i.e., EGFR, RAD51, K-RAS in patients at presentation and at recurrence to see if there is any correlation in a given tumor.
- Select treatment based on the findings.