Concurrent preoperative chemotherapy and three-dimensional conformal radiotherapy followed by surgery for oral squamous cell carcinoma: a retrospective analysis of 104 cases

SUPPLEMENTARY MATERIALS

1 Case Selection Criteria
2 Exclusion criteria
3 Clinical characteristics and curative effect of the 104 patients. See Supplementary_Table_1
4 Chemotherapy toxicity and side effects of the 104 patients. See Supplementary_Table_2
5 Radiotherapy complications of 104 patients. See Supplementary_Table_3
6 The follow-up duration, time for local recurrence, distant metastasis and postoperative survival of all 104 cases. See Supplementary_Table_4
7 Kaplan-Meier analysis of the local recurrence rate
8 Kaplan-Meier analysis of distant metastasis rate
9 Kaplan-Meier analysis of restriction of mouth opening
10 Kaplan-Meier analysis of the postoperative survival rate

1 Case Selection Criteria

1. Age: 21 to 88 years old.
2. Sex: both males and females.
3. All patients were diagnosed with primary OSCC by a pathological examination. Patients were excluded if they had a history of systemic chemotherapy or radiotherapy, concomitant malignancy, active inflammatory bowel disease, active gastric/duodenal ulcer, active infection, severe heart disease, mental disorder, or other severe concurrent disease. Pregnant or lactating women were also excluded;
4. The local range of the tumor invasion was too large to cure radically by simple surgery or there was a large wound that could not be repaired and affected the functional reconstruction after surgery;
5. Distant metastasis in imaging examinations was not found in all of the patients;
6. There were no treatment-related contraindications; and
7. Before treatment, patients had an Eastern Cooperative Oncology Group performance status of 0 or 1, a life expectancy ≥3 months, and adequate organ functions (leukocytes 4,000/mm3, platelets ≥100,000/mm3, hemoglobin ≥9.0 g/dl, aspartate aminotransferase (AST) ≤2 times the upper normal limit (UNL), alanine aminotransferase (ALT) ≤2 times the UNL, alkaline phosphatase (ALP) ≤2 times the UNL, serum bilirubin ≤1.5 mg/dl, and serum creatinine ≤UNL).

All study protocols were approved by the Fuzhou General Hospital institutional review board at each participating center. All patients provided written informed consent before entry into this study.

2 Exclusion criteria

• Previous radiotherapy or chemotherapy.
• Can not tolerate the treatment protocol with systematic diseases such as history of severe pulmonary or cardiac diseases.
• Pregnancy (confirmed by serum or urine β-HCG) or lactation period.
• Legal incapacity or limited legal capacity.
• Other previous malignancies within 5 years.
• Evidence of distant metastatic disease and other cancers.
• Kaplan-Meier analysis of the local recurrence rate
Locoregional recurrence was uncommon. The 5-year local recurrence rate was 1.92% (2/104). A patient with a floor of the mouth cancer failed regionally at 6 months. Another patient with oral tongue cancer demonstrated persistent disease at post-therapy biopsy and succumbed at 24 months. There were no significant clinical or disease variables found to influence locoregional control.

8 Kaplan-Meier analysis of distant metastasis rate
Distant metastasis rate was also uncommon. The 5-year local recurrence rate was 2.88% (3/104). At the 12, 24, and 48 month timepoints, no distant metastases had occurred during follow-up.

9 Kaplan-Meier analysis of restriction of mouth opening

| Case Processing Summary |
|-------------------------|
| **Total** N | **N of Events** | **Censored** |
| 104 | 3 | 101 |

| Mean³ |
|-------|
| **Estimate** | **Std. Error** | **95% Confidence Interval** |
| 58.904 | .657 | 57.617, 60.191 |

The 5-year restriction of mouth opening was 2.88% (3/104). At the 6, 24, and 36 month timepoints, no restrictions of mouth opening during follow-up had occurred.

10 Kaplan-Meier analysis of the postoperative survival rate

| Case Processing Summary |
|-------------------------|
| **Total** N | **N of Events** | **Censored** |
| 104 | 9 | 95 |

| Mean³ |
|-------|
| **Estimate** | **Std. Error** | **95% Confidence Interval** |
| 57.462 | .904 | 55.690, 59.233 |

The 5-year restriction of mouth opening was 2.88% (3/104). At the 6, 24, and 36 month timepoints, no restrictions of mouth opening during follow-up had occurred.
The 5-year postoperative survival rate was 91.35% (95/104). At the 12, 36, and 48 month timepoints, 5 cases had succumbed during follow-up. After the follow-up of the 104 cases of patients, four cases were lost, and these four were counted as deaths.

For Supplementary Tables see in Supplementary Files