

Author(s):

Question: Preoperative chemotherapy compared to no chemotherapy in advanced resectable Oral cancer

Setting:

Bibliography:

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Preoperative chemotherapy	no chemotherapy	Relative (95% CI)	Absolute (95% CI)		
long term mortality (follow up: median 30 months)												
2	randomised trials	serious ^a	not serious	serious ^b	very serious ^c	none	227 participants	227 participants	HR 0.96 (0.68 to 1.33) [long term mortality]	12 fewer per 1,000 (from 107 fewer to 93 more)	⊕○○○ VERY LOW	CRITICAL
							-	40.0%		12 fewer per 1,000 (from 107 fewer to 93 more)		
local recurrence												
2	randomised trials	serious ^a	not serious	serious ^b	very serious ^b	none	227 participants	227 participants	HR 0.94 (0.64 to 1.38) [local recurrence]	17 fewer per 1,000 (from 109 fewer to 98 more)	⊕○○○ VERY LOW	CRITICAL
							-	35.0%		17 fewer per 1,000 (from 109 fewer to 98 more)		
distal recurrence												
2	randomised trials	serious ^a	not serious	serious ^b	very serious ^c	none	227 participants	227 participants	HR 0.91 (0.64 to 1.30) [distal recurrence]	9 fewer per 1,000 (from 35 fewer to 28 more)	⊕○○○ VERY LOW	CRITICAL
							-	10.0%		9 fewer per 1,000 (from 35 fewer to 28 more)		
SAE (Grade >=3)												
2	randomised trials	serious ^a	not serious	not serious	very serious ^{c,d}	none	36/227 (15.9%)	1/228 (0.4%) ^e	RR 20.50 (1.49 to 282.60)	86 more per 1,000 (from 2 more to 1,000 more)	⊕○○○ VERY LOW	CRITICAL

CI: Confidence interval; HR: Hazard Ratio; RR: Risk ratio

Explanations

a. bias due to deviations from intended interventions. Sixty-three (64%) of 98 patients in the chemotherapy arm received three full-dose cycles in Licitra study, while two cycles in Zhong study.

b. not only limited to surgery but cointervention with radiotherapy; imbalance of post-operation radiotherapy in two arms

c. very wide CI and small sample size

d. few event and small sample size

e. zero event studies were adjusted by addition of 0.5 to all cells of 2x2 table. Meta-analysis using Bayesian method.