

Early Response Assessment of ¹⁷⁷Lu-DOTATATE in Neuroendocrine Tumors Using Choi (CC) versus RECIST Criteria (RC): Insights from the OZM-067 Trial



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Introduction Materials & Methods Results

- Choi criteria (CC) assess tumor response using size and density and have shown improved performance in GIST and colorectal cancer.
- Given low structural response rates in neuroendocrine tumors, we hypothesize that CC is superior in capturing treatment response than predicting long term outcomes compared with RECIST criteria (RC)
- Objective:** Compare response as defined by RC vs CC after ¹⁷⁷Lu-DOTATATE in the OZM-067 trial and their association with overall survival.

- OZM-067:** multicenter prospective trial of 4 cycles of ¹⁷⁷Lu-DOTATATE in progressive neuroendocrine tumors. RC used for primary endpoint (progression-free survival). CC assessed concurrently
- Imaging assessment:** Triphasic CT at baseline, 4 months post-treatment, then every 4–6 months for up to 5 years. Additional CTs performed as clinically indicated. Standard published definitions used for CR, PR, SD, and PD (**Figure 1**)
- Outcomes of interest:**
 - Overall concordance rate between RC and CC for response at post treatment
 - PFS & OS based on first post treatment response as defined by RC and CC

- Analysis cohort**
 - 147 patients received ≥1 cycle of ¹⁷⁷Lu-DOTATATE, paired RC and CC response assessments at first post treatment assessment serving as the analysis cohort.
 - Median time to first follow-up scan** (from 28 days pre-C1D1): 12.1 months (IQR 11.3–12.9).

Outcomes

	Choi	CR	PR	SD	PD
RECIST					
CR		1	0	0	0
PR		0	31	0	0
SD		0	56	36	2
PD		0	1	1	18

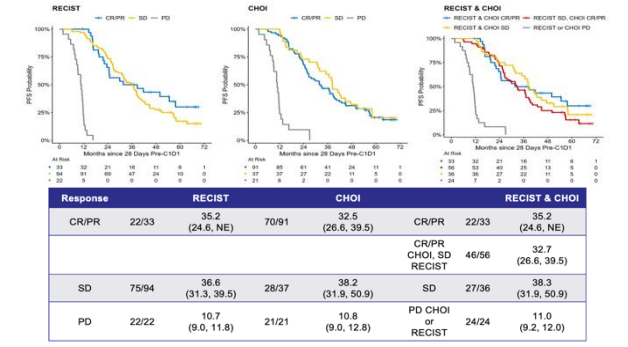


Figure 2: Progression-free survival by first response post ¹⁷⁷Lu-DOTATATE

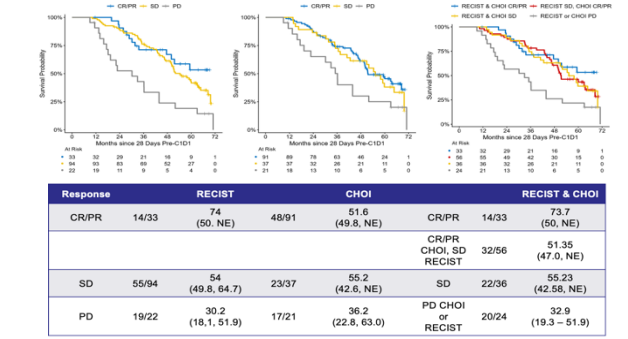


Figure 3: Overall Survival by first response post ¹⁷⁷Lu-DOTATATE

Figure 1: Summary of Choi versus RECIST Criteria

Aspect	CHOI CRITERIA (Choi et al., 2007)	RECIST CRITERIA (RECIST 1.1, 2009)
Basis of assessment	Based on both tumor size and tumor density (HU on CT)	Based only on tumor size (longest diameter)
Measurements	<ul style="list-style-type: none"> 1 target lesion (maximum diameter) Tumor attenuation (HU) on contrast-enhanced CT (arterial or portal venous phase) 	<ul style="list-style-type: none"> Up to 5 target lesions Longest diameter of each target lesion (sum of longest diameters)
Response Definitions	<ul style="list-style-type: none"> Partial Response (PR): ≥10% decrease in tumor size OR ≥15% decrease in tumor density (HU) Stable Disease (SD): Neither PR nor PD Progressive Disease (PD): ≥10% increase in tumor size AND no ≥15% decrease in density OR New lesions 	<ul style="list-style-type: none"> Partial Response (PR): ≥30% decrease in the sum of longest diameters (SLD) compared to baseline Stable Disease (SD): Neither PR nor PD Progressive Disease (PD): ≥20% increase in the SLD compared to nadir (smallest SLD recorded) AND an absolute increase of ≥5 mm OR new lesions
New lesions	Presence of new lesions = Progressive Disease	Presence of new lesions = Progressive Disease

- Overall concordance rate:** 58.5% (86/147). Largest discordance was observed in 56 patients (38%) where patients were classified as PR by Choi but SD by RECIST.

PFS and OS by response criteria

- RC response did not predict better PFS: 35.2m (95% CI 24.6–NE) vs SD 36.6m (95% CI 31.3–39.5) (**Figure 2**)
- RC response showed improved OS: CR/PR: 74.0m (95% CI 49.9–NE) vs SD: 54.8m (95% CI 50.6–65.9). (**Figure 3**)
- OS for CC responders were similar to those with SD by RC (51.6m CC CR/PR, vs 54m RC SD) (**Figure 3**)

Conclusions

- CC is more sensitive than RC in detecting response to ¹⁷⁷Lu-DOTATATE.
- However, the OS of CC responders is similar to patients classified with SD using RC