

Somatostatin receptor expression on 68Ga-Dotatate imaging among patients with poorly differentiated extra-pulmonary neuroendocrine carcinomas: a prospective study

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Background

- **Poorly-Differentiated Neuroendocrine Carcinomas (NECs)** are aggressive, high-grade malignancies (Ki-67 >70%) with a typically poor prognosis.
- Somatostatin Receptor (SSTR) expression is the critical target for Peptide Receptor Radionuclide Therapy (PRRT, e.g., ¹⁷⁷Lu-Dotatate)
- Successful treatment requires **strong and uniform** SSTR expression (Krenning Grade 3 or 4, or uptake > normal liver) on **all measurable tumors**.
- Retrospective studies previously reported high SSTR positivity rates (up to 40-66%) in NEC, but these figures were potentially influenced by selection bias, necessitating a prospective evaluation

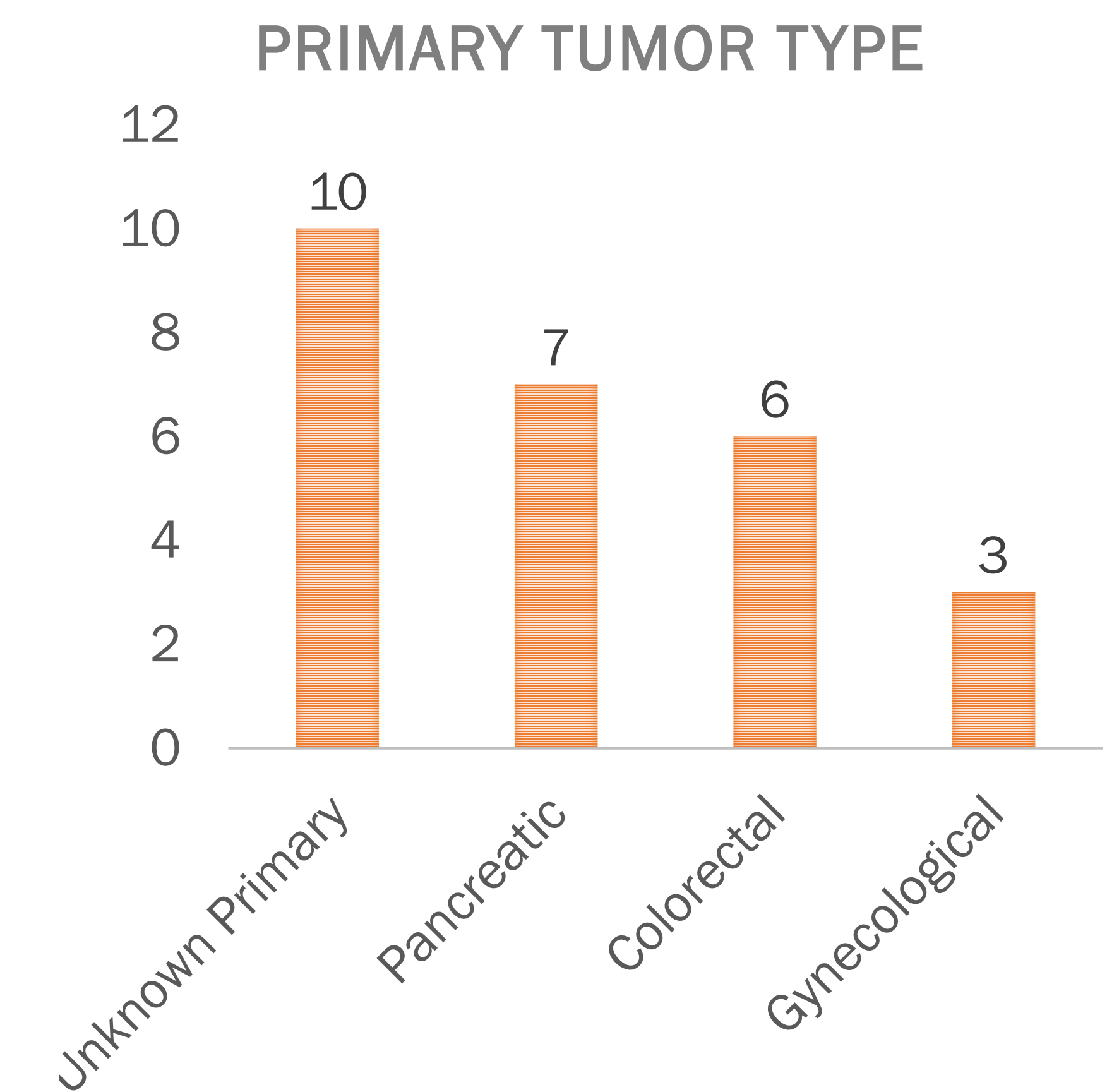
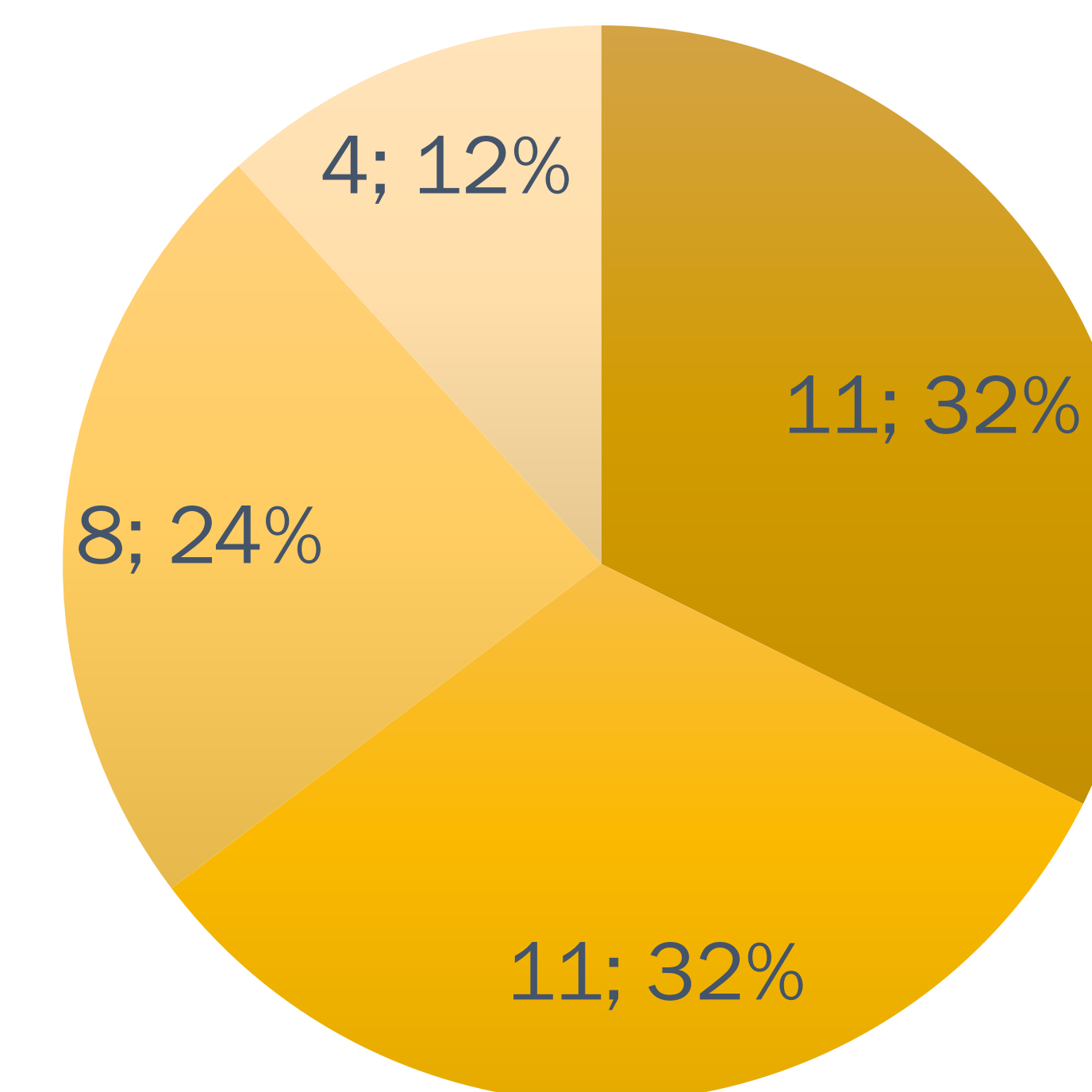
Methods

- Prospective imaging study conducted on patients with metastatic extrapulmonary (EP-NEC) comparing ⁶⁸Ga-DOTATATE PET with FDG-PET
 - Patients must have had at least 1 measurable site of disease per RECIST 1.1
- Primary Endpoint: The proportion of patients with tumors showing Dotatate-avidity (uptake > normal liver) in all measurable tumors.
- Secondary endpoint was the proportion of patients with completely negative SSTR expression or a heterogeneous pattern of expression
- MCC 19943 – IRB Approved by Advarra IRB
- All patient signed study specific consent form prior to any study protocol activity

Results

Histological Subtype	Count
Small Cell Carcinoma (SCC)	15
Large Cell Carcinoma (LCC)	6
Mixed or Unspecified	9
Total	30

- SSTR Expression**
- Avid (Any lesion)
 - Completely Absent
 - Weak/Heterogenous
 - Primary Endpoint Met (Uniformly Avid)



- Only **4 patients (13%)** had evidence of avid (Krenning grade 3 or 4) **uniform** SSTR expression across all measurable metastatic sites.
- This finding confirms that avid and uniform SSTR expression is relatively uncommon in unselected EP-NEC patients
- *All 4 patients who achieved the primary endpoint of uniform avidity had small cell carcinoma histology*
- *This correlation was statistically significant (p=0.003) when comparing SCC against LCC or mixed/unspecified subtypes.*

Conclusions

- **Uniform, avid SSTR expression is uncommon in EP-NEC, but may be somewhat enriched in small cell histology compared to large cell or mixed.**
- **SSTR-targeting PRRT is unlikely to play a major role in the broad treatment of this patient population**