

EFFICACY AND SAFETY OF NIVOLUMAB MONOTHERAPY VS NIVOLUMAB PLUS IPILIMUMAB IN RENAL CELL CARCINOMA IN CLINICAL PRACTICE

M.D. ZAMBRANO CROCHE, A. ROJAS ALBARRÁN, Á. GIL GARCÍA, M. GRAGERA GÓMEZ, H. VELÁZQUEZ VÁZQUEZ.
UNIVERSITY HOSPITAL COMPLEX OF BADAJOZ, PHARMACY DEPARTMENT, BADAJOZ, SPAIN.

BACKGROUND AND IMPORTANCE



- Nivolumab is indicated for advanced renal cell carcinoma (RCC) as monotherapy (second line) and in combination with Ipilimumab (first line).



- It's unknown the benefit to add Ipilimumab to Nivolumab, also it must be taken the possible worse security profile.

AIM AND OBJECTIVES

- Determine the efficacy and security of Nivolumab plus Ipilimumab vs Nivolumab monotherapy in the clinical practice.



MATERIAL AND METHODS

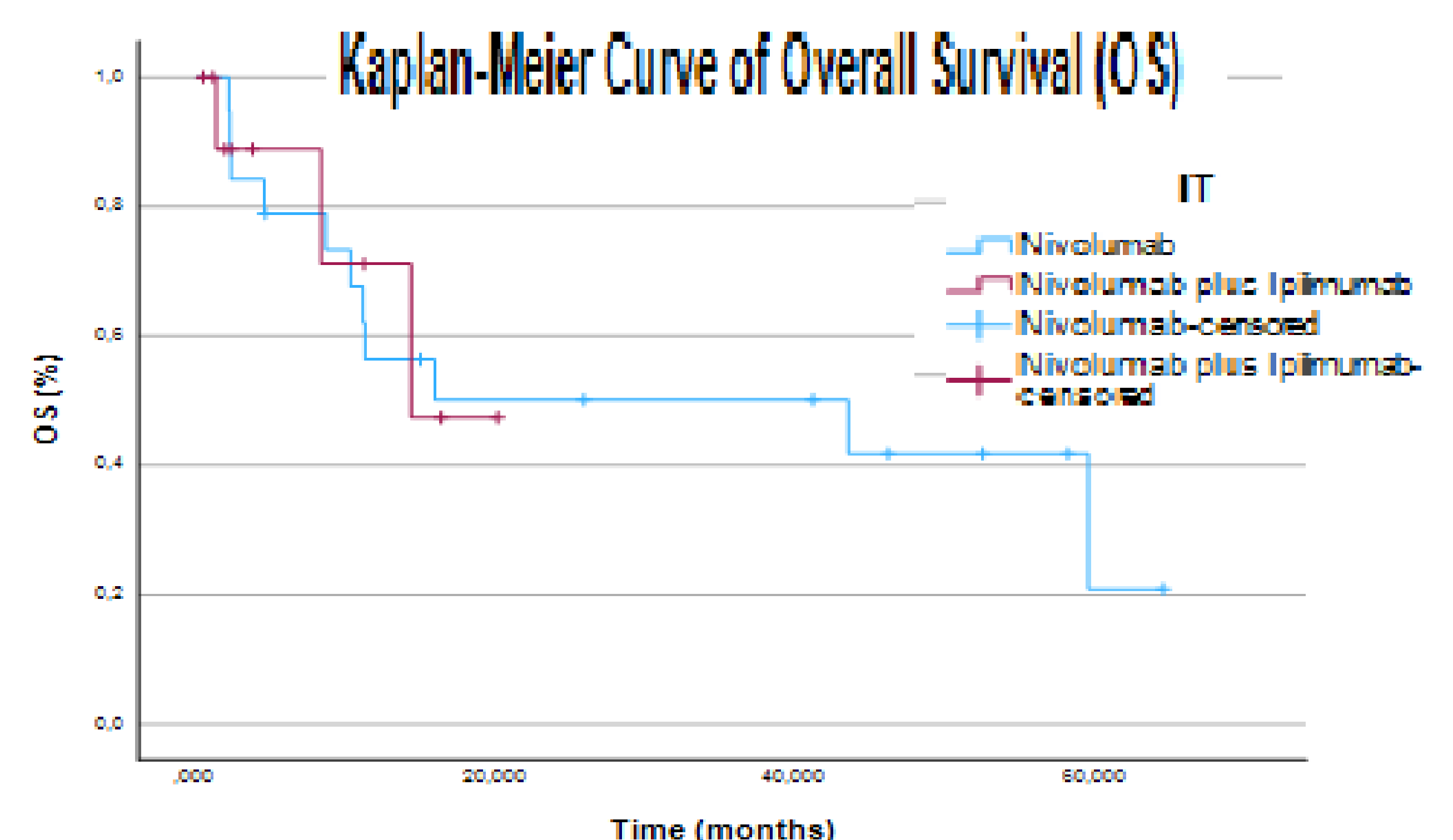
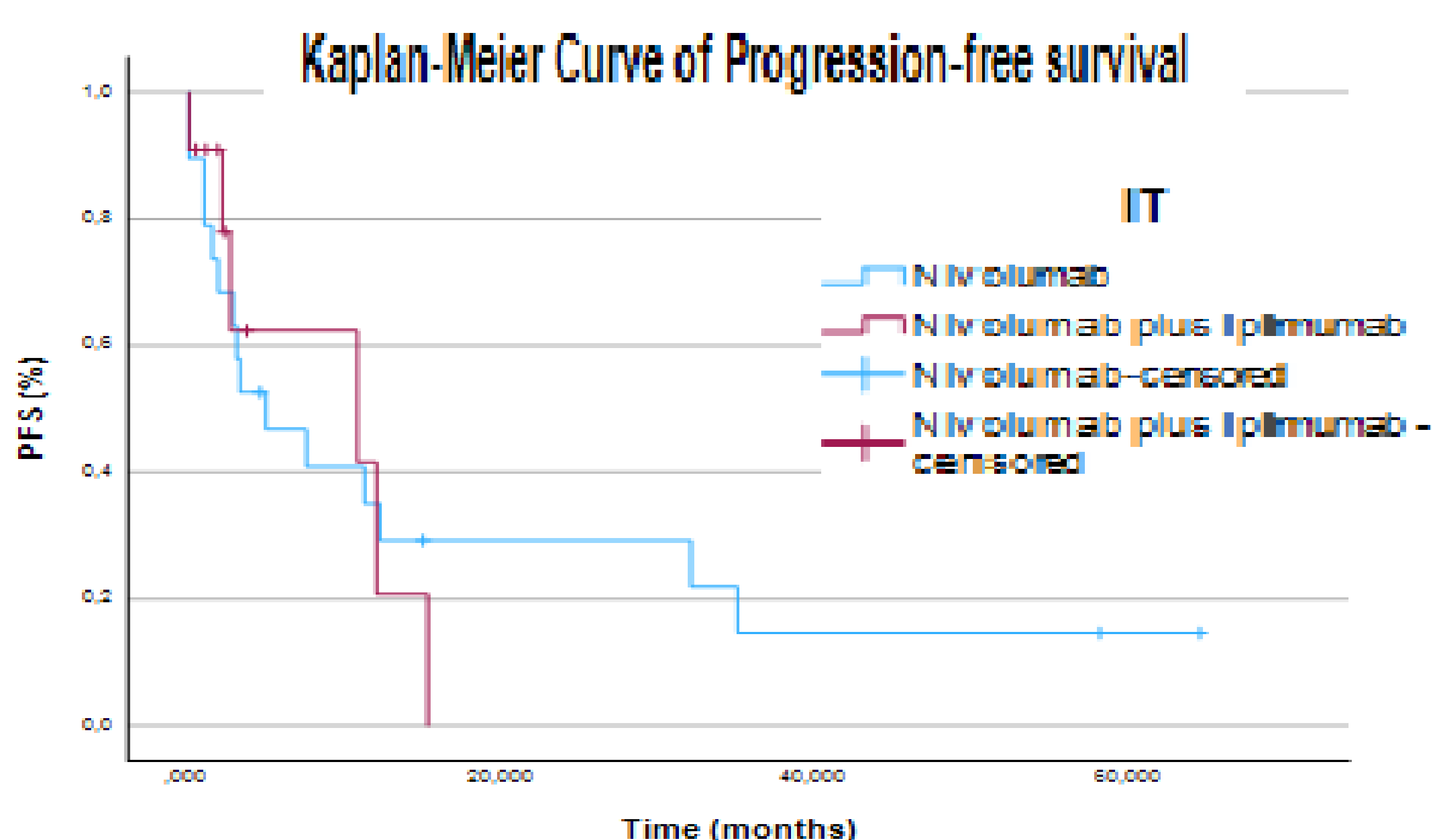
- Descriptive, observational and retrospective study (Jan 2016- Sep 2023) of 30 patients treated with Nivolumab or Nivolumab plus Ipilimumab in a third level hospital. Data were processed by Microsoft Excel and SPSS software.

RESULTS

- Median progression-free survival was 4.9 months (95% CI: 0-10.8) for Nivolumab and 10.7 months (95% CI: 0-26.5) for the combination therapy. The p-value was 0.799.
- Median overall survival was 43.4 months (95% CI: 0-97.4) for nivolumab, not reached for the combination treatment.
- Adverse reactions in monotherapy vs dual therapy group:
 - hepatic (5.3% vs 45.5%),
 - endocrine (36.8 vs 63.6)
 - and skin (57.9 vs 36.4).
 - one patient with combination therapy had immune related adverse events. Finally died.

Characteristic	Nivolumab plus Ipilimumab (n=11)	Nivolumab (n=19)
Age, median (range), years	62 (44-74)	57 (37-83)
Male	6 (54.5)	16 (84.2)
Histology		
Clear cell RCR	9 (47.4)	10 (90.9)
Papillary RCR	4 (21)	0 (0)
ECOG PS		
0	5 (45.5)	11 (57.9)
1	5 (45.5)	3 (15.8)
Not specified	1 (9.1)	5 (26.3)
Lung metastases	8 (72.7)	16 (84.2)
Liver metastases	2 (18.2)	6 (31.6)
Previously treated	4 (36.4)	19 (100)

Table 1. Patient Demographics and Disease Characteristics. NOTE: Data are No. (%) unless otherwise indicated. ECOG: Eastern Cooperative Oncology Group. PS: performance status.



CONCLUSION AND RELEVANCE

- No differences were observed in efficacy, but there were in safety. However, our study is limited since it involves few patients.

