

Characteristics and prognostic factors in 455 elderly pts over 70 with metastatic renal cell carcinoma treated with target therapies in the community setting: an Italian survey

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1 Oncologia Casa di Cura Pederzoli Peschiera, 2 Oncologia Rovigo, 3 Oncologia IOV Padova, 4 Oncologia AOUI Verona, 5 Oncologia Trento, 6 Oncologia Pordenone, 7 Oncologia Bolzano, 8 Oncologia Treviso, 9 Oncologia CRO Aviano, 10 Oncologia Mira-Dolo, 11 Oncologia Poliambulanza Brescia, 12 Oncologia Catanzaro, 13 Oncologia Castelfranco Veneto, 14 Oncologia Montecchio Maggiore, 15 Oncologia Santorso, 16 Oncologia Belluno, 17 Oncologia Este, 18 Oncologia Feltre, 19 Oncologia Mestre

PATIENTS & METHODS

Individual data of 1238 patients treated with TT from mid 2007 to December 2012 were obtained from 35 Italian Institutions; this study reports about the 455 pts over 70 (36.7%).

RESULTS

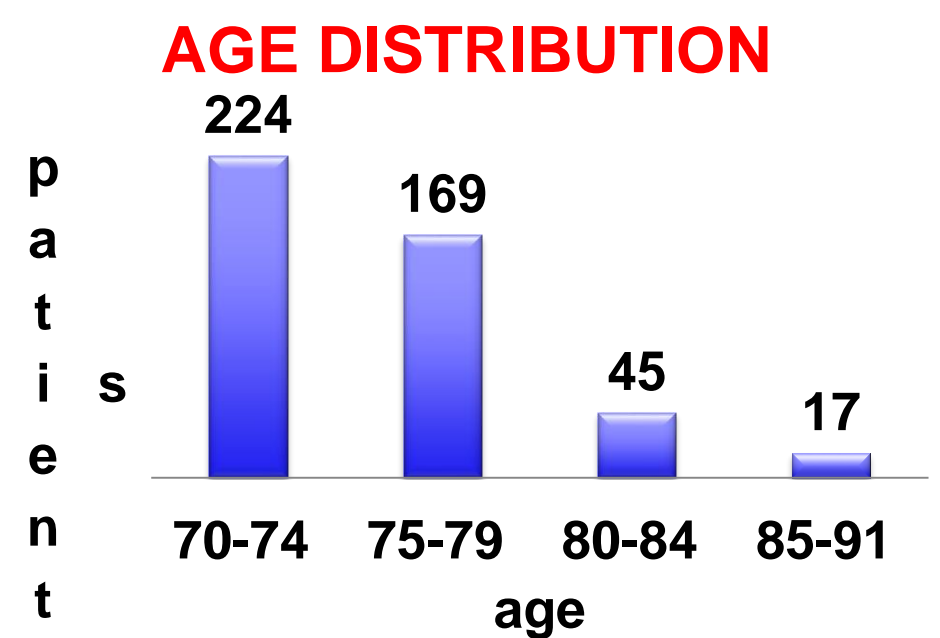
Median age was 75 yrs (range 70-91). **Comorbidities** were 0-1 in 49%, 2 in 23%, 3 in 11%, >4 in 12% of the patients, the most frequent being hypertension (48%), cardiac (25%), metabolic (16%), diabetes (15%), gastrointestinal (11%), other malignancy (9%). Median overall survival (**mOS**) was 22 mo.

1st line treatment was: sunitinib (su) 74%, sorafenib (so) 15.5%, temsirolimus (tem) 5%, others (5.5%). mOS was 26.7 for sunitinib, 21 for sorafenib (p= NS) and 4 for temsirolimus. Median 1st line PFS was 9.8 mo: sunitinib 12.3, sorafenib 7.2 (su vs so: p= 0.02), temsirolimus 1.9 (so vs tem: p>0.001). Disease control rate was 64% (293 pts). **Toxicities** for sunitinib/sorafenib (% of all grades) were as follows: mucosites (42/31), hypertension (41/25), haematological (54/4), diarrhea (14/25), fatigue (50/53), rash (10.5/24), HFS (17/39). Main G3 toxicities were hypertension (11%) and fatigue (8%); G4 were< 1%. **Dose reduction** and **treatment interruption** were required in 60%-65% and 32%-38% of the patients on sunitinib and sorafenib, respectively, mostly for toxicity (44%) or prudential reasons/declining PS (21%).

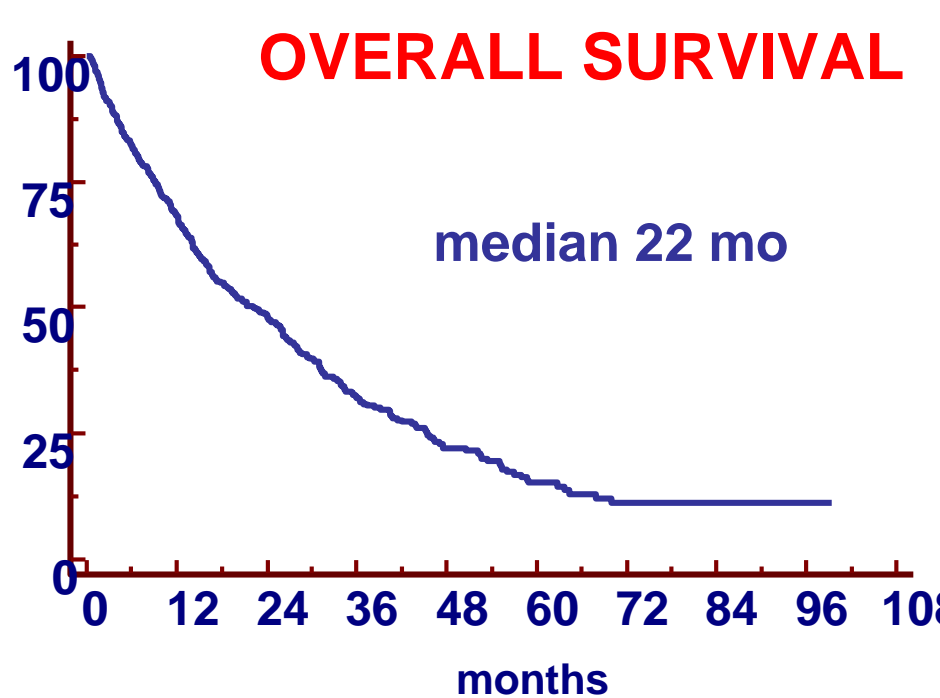
206 patients (45%) received **2nd line therapy**. OS from starting 2nd line therapy was 15.4 mo. mPFS of 2nd line was 3.3 mo: sunitinib 4.5, everolimus (eve) 4, sorafenib 3, other 2.7 (eve vs so: p= 0.02; su vs so: p= 0.045).

Good PS, nephrectomy, duration of 1st line therapy > 6 mo were statistically related to execution of 2nd line therapy at logistic regression. At **Cox multivariate analysis**, CC histology, nephrectomy, good PS, response, duration of 1st line therapy >6 mo, execution of 2nd line therapy were favourable prognostic factors for OS.

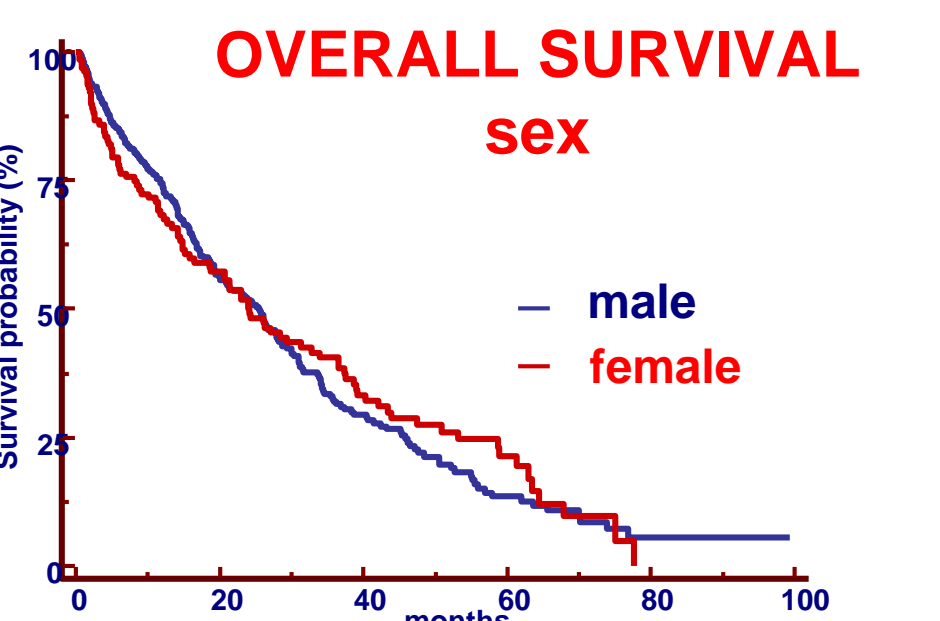
73 patients (16%) received **3 or more lines of therapy**: mOS of this group was 39 mo.



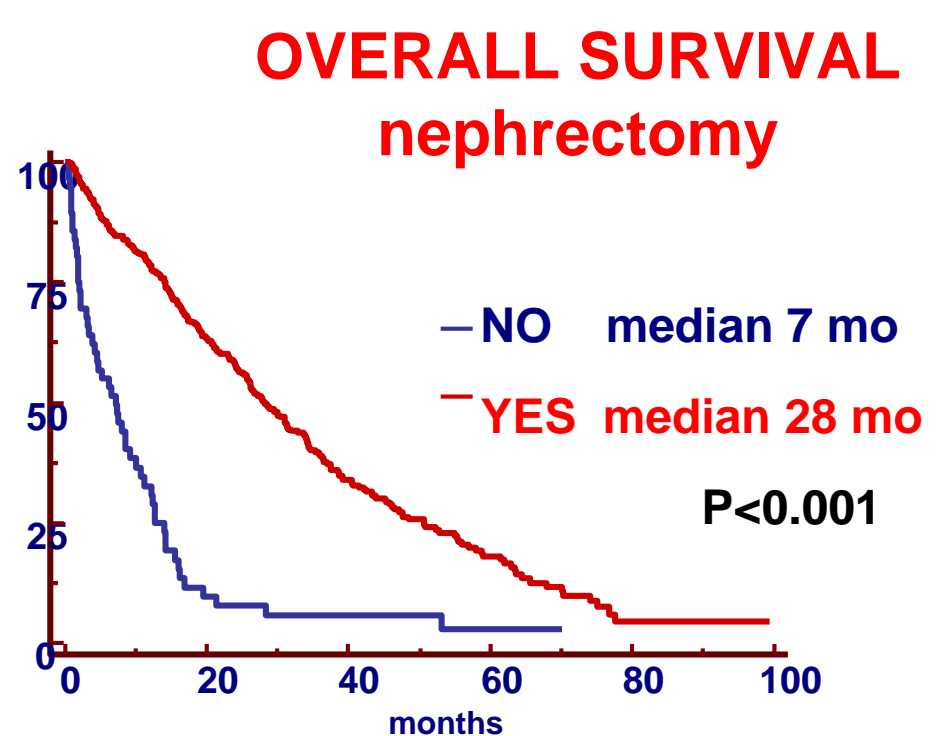
Median age 75 yrs (range 70-91)



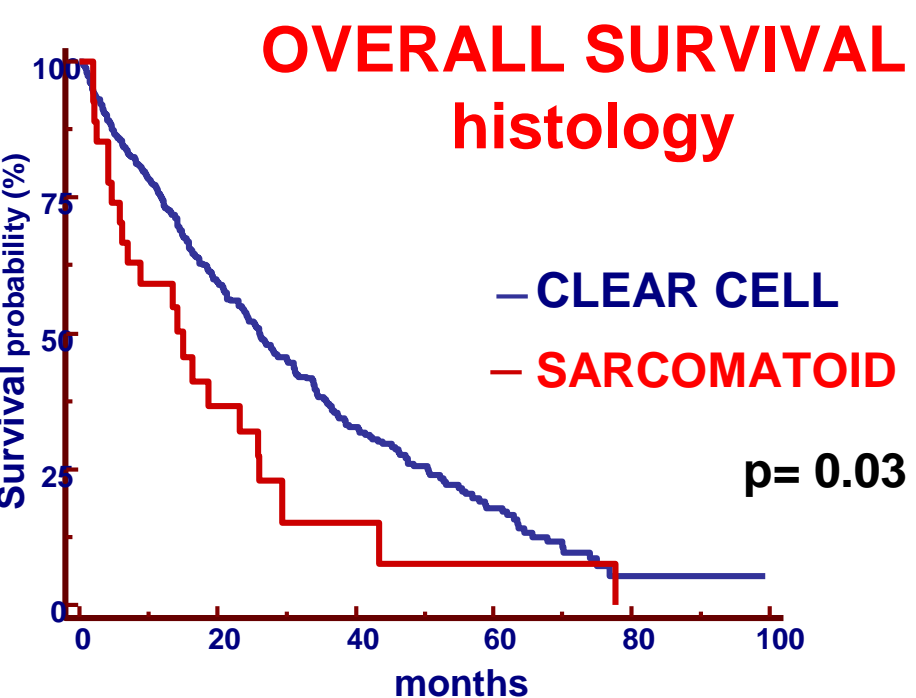
GENERAL CHARACTERISTICS	%
Male	72
Female	28



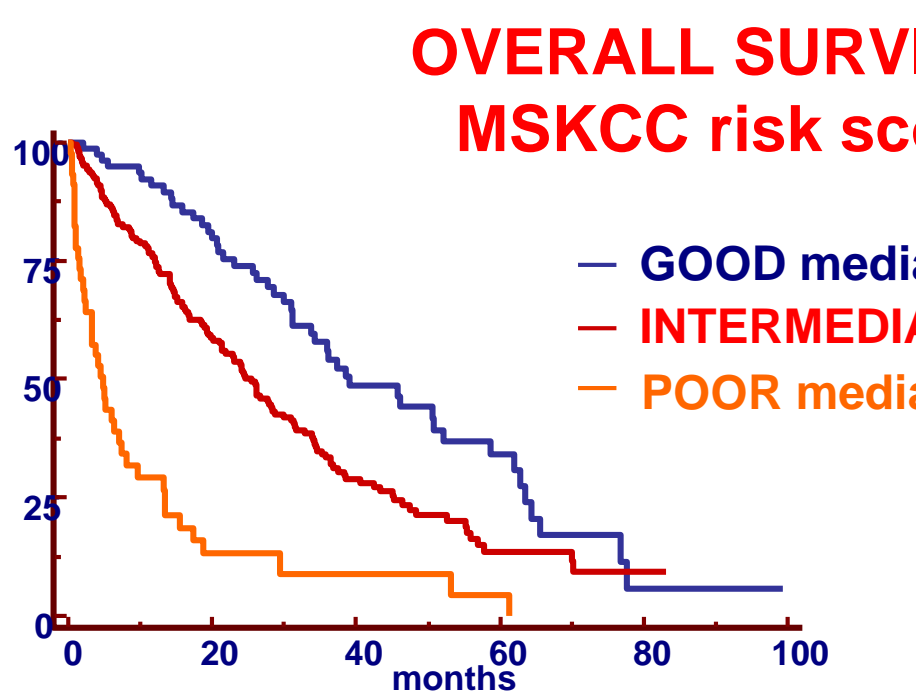
Nephrectomy	%
Yes	87
No	13



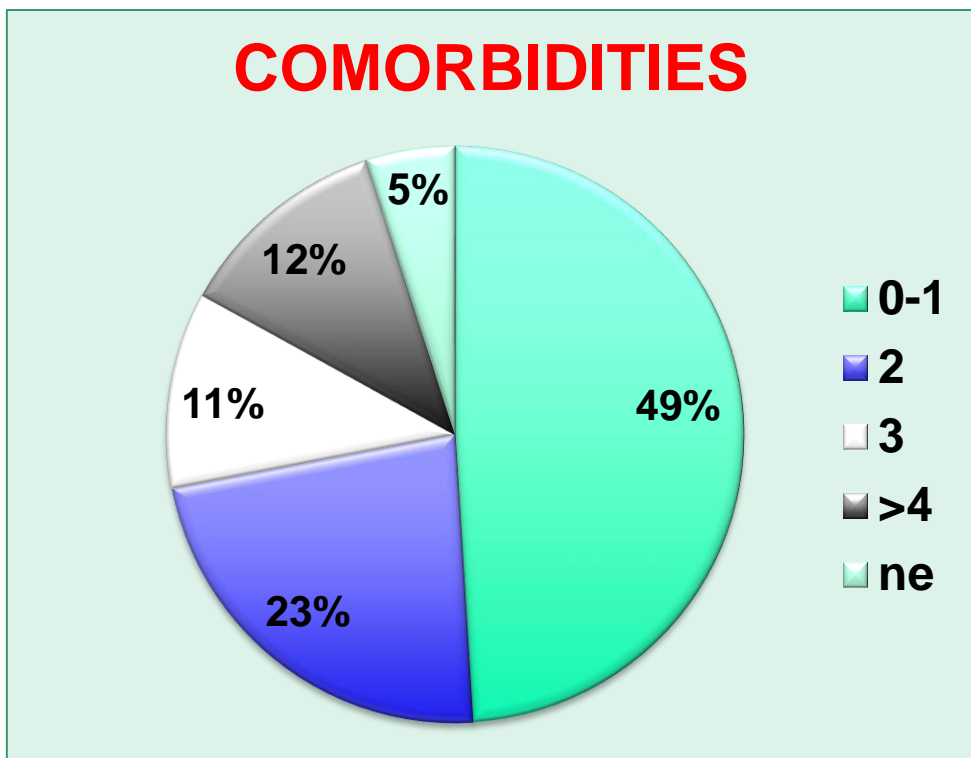
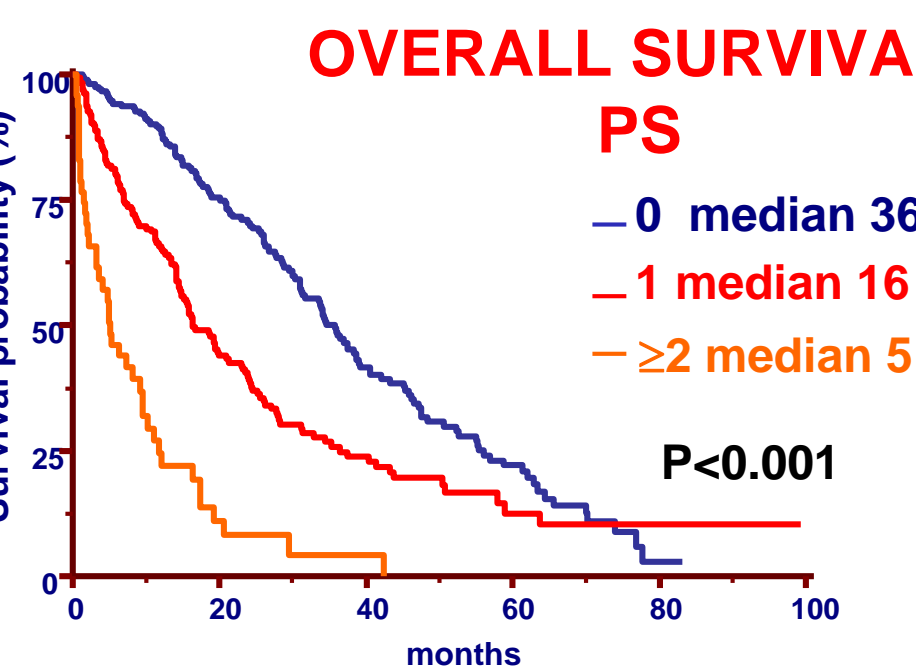
Hystology (436 pts)	%
Clear cell	85
With sarcomatoid component	6
others	5



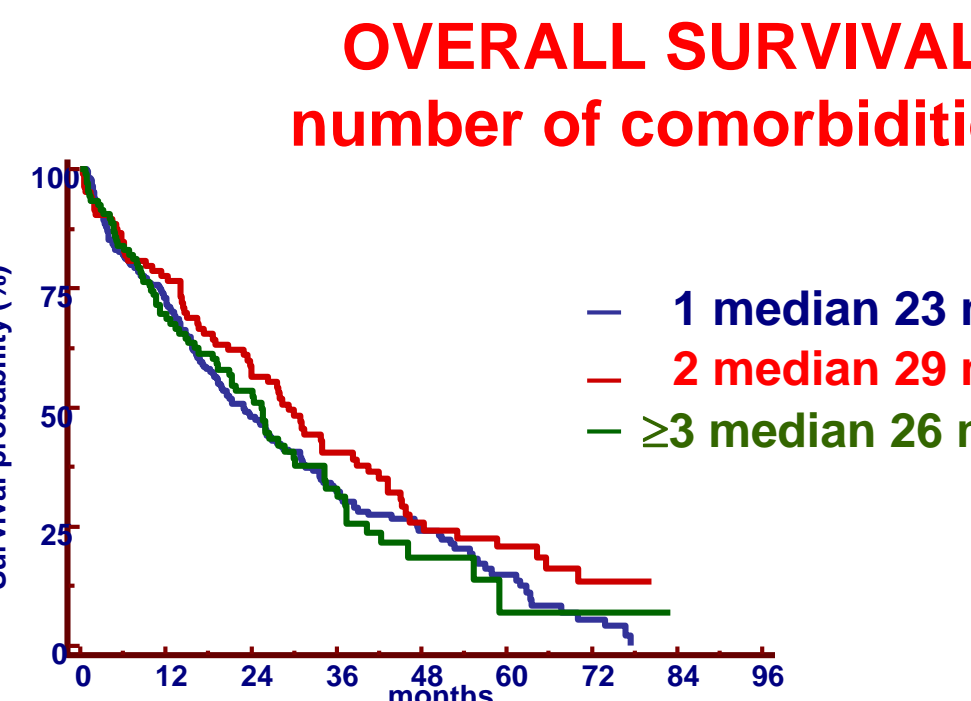
MSKCC risk score (335 pts)	%
Poor	10
Intermediate	48
Good	15



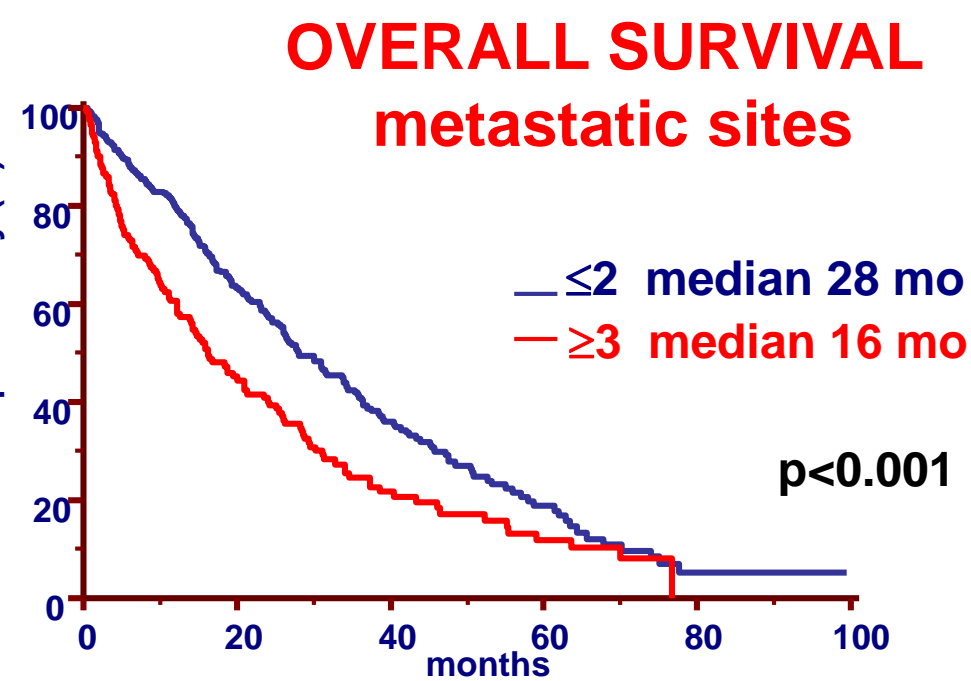
ECOG PS (439 pts)	%
0	45
1	41
≥2	10



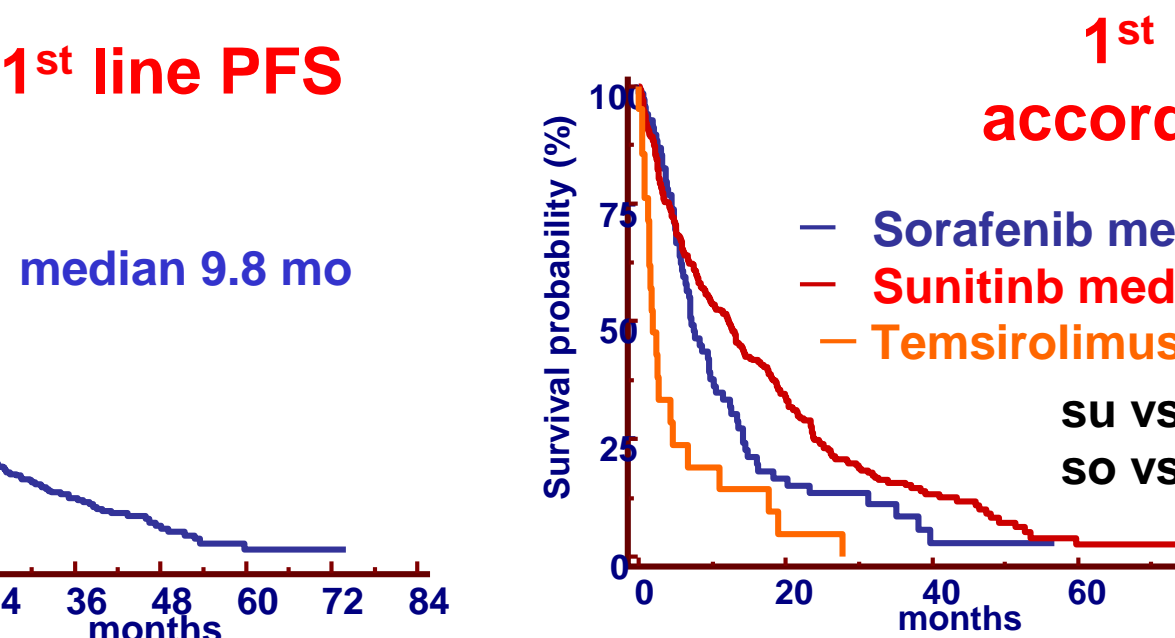
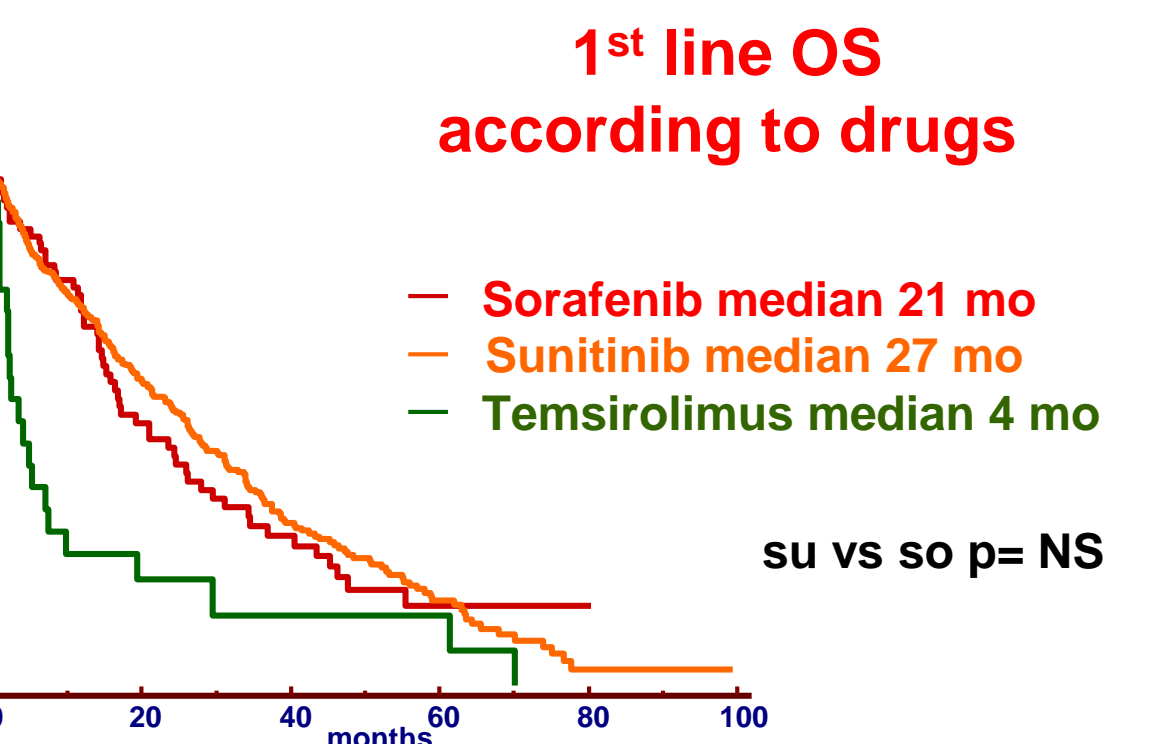
Type of comorbidities	%
hypertension	48
cardiac	25
metabolic	16
diabetes	15
gastrointestinal	11
other malignancy	9
renal failure	7
vascular	7
neurologic	7
pulmonary	3.5



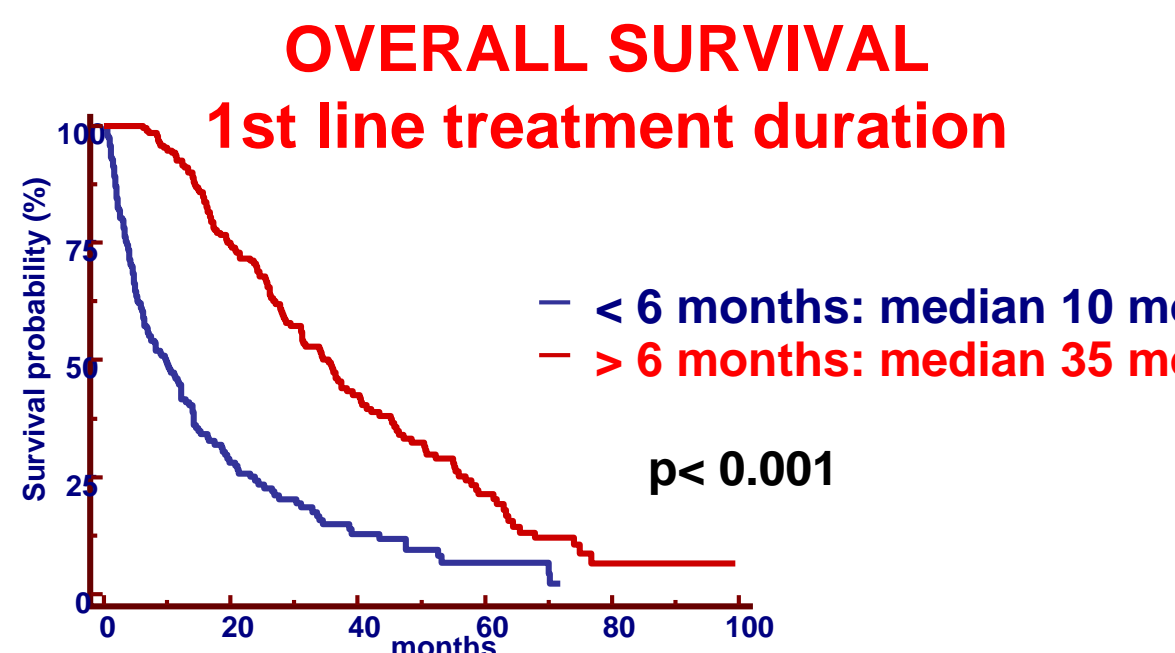
Number of Metastatic sites	%
1	28
2	34
≥3	38



1 st line therapy	%
sunitinib	74
sorafenib	15.5
temsirolimus	5.0
others	5.5

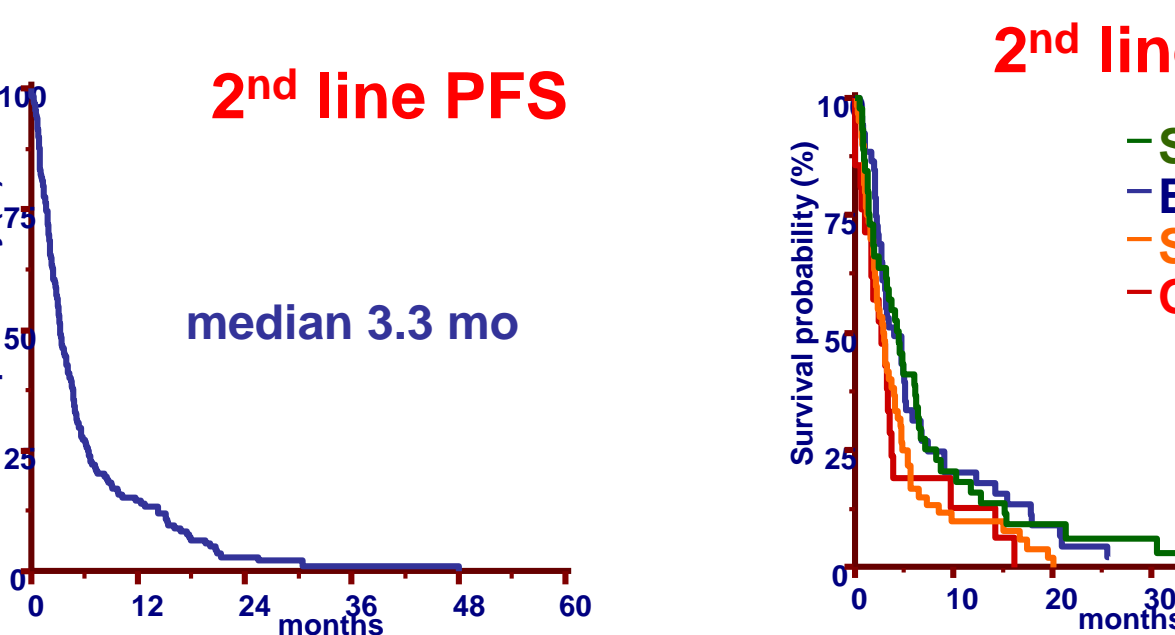
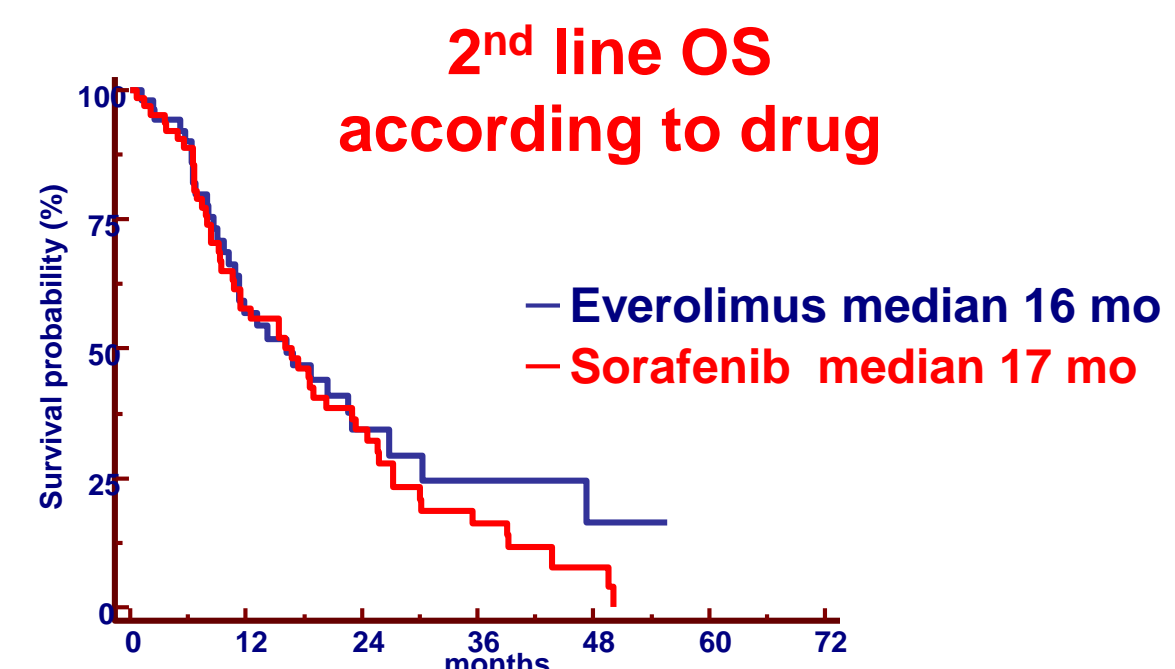


Toxicity	All grades (%)	≥ 3 (%)
Diarrhea	14.3	25.2
Nausea/vomiting	10.3	7.0
Mucositis	42.2	30.8
Rash	10.5	23.8
HFS	17.2	39.3
Fatigue	49.8	53.4
Hypertension/cardiotox	40.6	25.2
Hematological	53.6	4.2



2 nd line therapy (206 pts)	%
sorafenib	14
everolimus	11.6
sunitinib	10.3
chemo-immunotherapy	2.8
others	1.7
No for PD	38.5

92 pts not evaluable for 2nd line (1st line ongoing, persisting response, insufficient data)



COX MUTIVARIATE ANALYSIS			
Covariate	P	Exp(b)	95% CI of Exp(b)
2 nd line therapy	0.0000	0.40	0.30 to 0.53
1 st line therapy duration	0.0011	1.70	1.24 to 2.35
Histology	0.0325	1.35	1.03 to 1.78
Nephrectomy	0.0000	0.42	0.28 to 0.64
PS	0.0000	1.82	1.48 to 2.25
Response to 1 st line therapy	0.0000	0.29	0.21 to 0.42

CONCLUSIONS

This survey shows that:

- ✓ targeted therapies were feasible in elderly,
- ✓ outcome and toxicities were comparable to those of younger patients,
- ✓ CC histology, nephrectomy, good PS, response to 1st line therapy , duration of 1st line therapy >6 mo, execution of 2nd line therapy were favourable prognostic factors for OS.