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Cetuximab as third line treatment of metastatic colorectal carcinoma (mCRC) – 5-year experience from the Institute for Oncology and Radiology of Serbia

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Background

Cetuximab is a monoclonal antibody directed against the extracellular domain of the EGF receptor, and is effective in patients harbouring wild type ras genes including K-ras and N-ras, while it has no activity in patients with mutations in these genes. Its use in later lines of therapy is widely accepted, with the most promising data about its efficacy in first line treatment of mCRC.

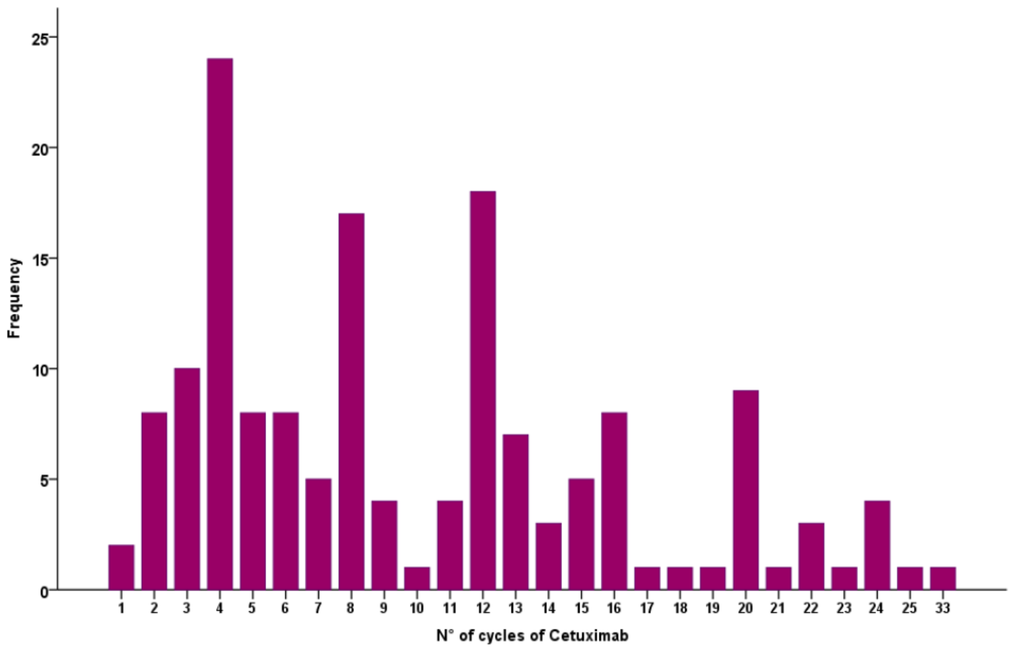
Patients and methods

K-ras testing for mutations in codons 12 and 13 has been done at the Institute for oncology and radiology of Serbia since 2009. Cetuximab has been reembursed by the Serbian Health Insurance Fund since april 2009. for the use in third line of treatment of mCRC in patients with wild type K-ras gene. We prospectively followed patients treated with cetuximab in third line therapy in a 5-year period. Data concerning demographic characteristics, previous treatment, number of cycles of cetuximab, toxicity and treatment outcome were analysed.

Cetuximab was used in combination with irinotecan or as monotherapy, in 14-day cycles, the dose given was 500mg/m².

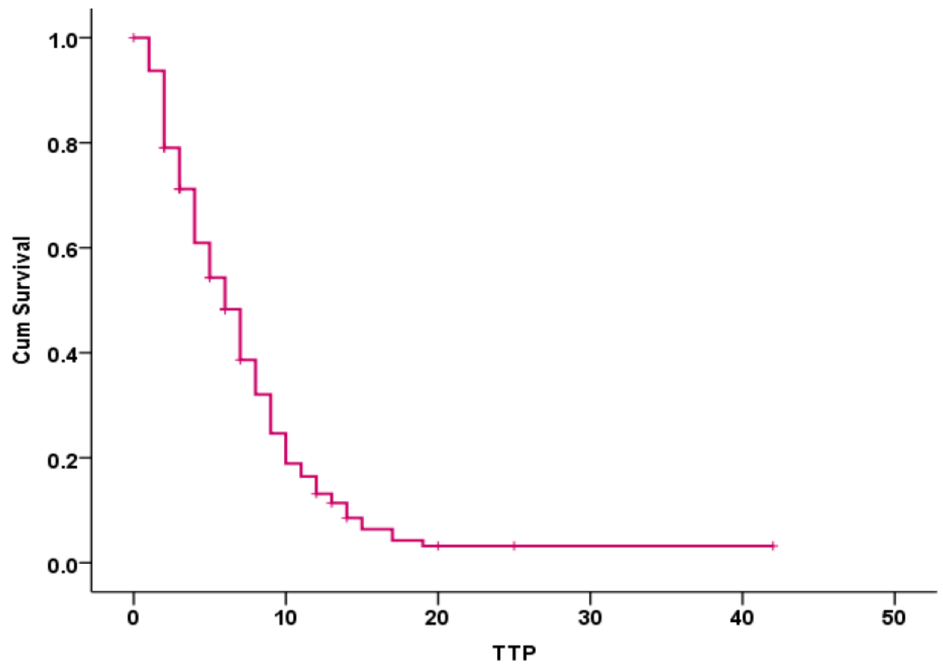
Patient characteristics	N-162
Gender	No of pts (%)
Male	95 (58,6)
Female	67 (41,4)
Age (years)	
Median (range)	60 (24-80)
Localisation of metastases at start of cetuximab therapy	
Liver	132 (81,5)
Lung	55 (34)
Lymph nodes	36 (22,2)
Peritoneum	31 (19,1)
Local recurrence	27(16,7)
Bone	10 (6,2)
Multiple metastastic sites	94 (58)

Results



Median number of cycles of cetuximab administered was 8, range 1 to 33. 44 patients received between 8 and 12 cycles, 53 patients more than 12 cycles, and 44 patients received up to and including 4 cycles.

Best response to therapy was partial response in 25 patients (15%), stable disease in 86 patients (53%), and progression in 39 patients (26%).



Median progression-free survival (PFS) was 6.01 months (4.88-7.12, CI 95%). There was no statistically significant difference in PFS between men and women, patients with primary colon or rectal tumors, nor depending on localisation of metastatic site(s). Of these patients, 22 are still on cetuximab.

Toxicity of cetuximab

	Gr.1 No of pts (%)	Gr.2 No of pts (%)	Gr.3 No of pts (%)	No toxicity
Rash	80 (52.3)	13 (8.5)	5 (3.3)	55 (35.5)
Paronichia	18 (11.8)	4 (2.6)	0	126 (81.3)
Ocular changes	9 (5.9)	2 (1.3)	0	142 (91.6)

Rash developed after median of 2 cycles of cetuximab. Paronychia was present in 36 patients, gr.I in 23 (14%), to gr.III in 6 (4%). Eye disorders appeared in 12 patients (7%). Cetuximab had to be stopped due to toxicity before progression of disease in 20 patients.

In this group of patients there was an association between grade of skin toxicity and response to treatment (Spearman's correlation coefficient 0.186, p= 0.023).

Conclusion: In our 5-year experience, cetuximab was shown to be a good treatment choice in third line for patients with wild type K-ras CRC. It showed a good response rate (17%) with PFS about 6 months and was well tolerated. Survival analysis will follow.

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