Acute gastrointestinal and genitourinary toxicity after whole-pelvis irradiation: is dietary supplement with Cis 400 of clinical benefit? Preliminary results of a monoistitutional clinical trial

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Purpose

Whole pelvic radiotherapy irradiation (WPRT) is used for the treatment of prostate cancer, rectal cancer and gynecological cancer. The aim of our prospective study was to evaluate gastrointestinal (GI) and genitourinary (GU) toxicity in patients (pts) underwent WPRT and receiving dietary supplement with Cis 400.

Matherials and Methods

From November 2019 to June 2020, 9 pts (4 male and 5 female) received WPRT with or without concomitant chemotherapy (CT) were analyzed. Of them, 4 patients were affected by prostate cancer (44 %), 2 pts by rectal cancer (22 %), 2 pts by uterine cancer (22%) and 1 by cancer of vagina (12 %). WPRT was delivered using an Elekta LINAC and a VMAT technique. The total doses prescribed to the pelvis was 45-50 Gy given in 25-28 daily fractions, 5 fractions at week. In pts receiving adjuvant CT, RT treatment was performed three weeks after CT. All pts were evaluated at the the beginning of RT treatment by a radiation oncologist and (if not contraindications) dietary supplement with Cis 400 daily was prescribe for whole duration of RT. According to CTACE vs 5 acute GI and GU toxicity was evaluated by radiation oncologist at baseline (star of RT treatment) and weekly during the RT treatment .

Results

At the data analyses the median age was 63 years old with a range wide from 28-75 years old. Overall three patients (33%) received concomitant chemotherapy. According to CTACE vs 5, four patients reported G1 GU or GI toxicity at the moment of radiotherapy beginning (4 patients reported cystitis and two patient abdominal swelling). A benefit of dietary supplement with Cis 400 one week after the treatment was observed in all cases of cystitis (100%) and in 1 patients with abdominal swelling (50 %). At the doses of 45 Gy only 2 patients (22 %) had G1 acute GI/GU toxicity that consisted in dysuria, nocturia, anal pain, proctites diarrhea and abdominal swelling. All patients completed radiotherapy treatment without temporary of definitive RT treatment interrupt. Finally, at the end of radiotherapy treatment there were not observed G2 or higher acute GI or GU toxicity

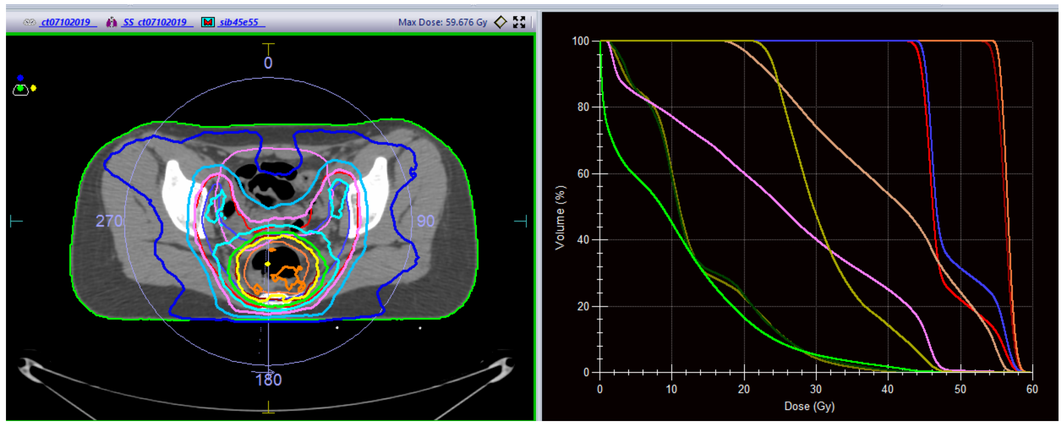
Table 1. GU Toxicity

GU TOXICITY Bladder (non infective cystitis)						
	Start of RT	I week	II week	III week	IV week	End of RT
G1	4 (44%)	1 (11%)	3 (33%)	3 (33%)	2 (22%)	4 (44%)
G2	0	0	0	0	0	0
G3	0	0	0	0	0	0
G4	0	0	0	0	0	0

Table 2. GI Toxicity

GI TOXICITY						
	Start of RT	I week	II week	III week.	IV week	End of RT
G1	5 (55%)	0	1 (11%)	2 (22%)	4 (44%)	3 (33%)
G2	2 (22%)	0	0	0	0	0
G3	0	0	0	0	0	0
G4	0	0	0	0	0	0

Fig. 1 An example of RT planning of a treatment on a patient with rectal cancer



Conclusions

These results appear to suggest that supplement dietary with Cis 400 is of a clinical benefit in terms of GI and GU acute toxicity, to delay arise of acute toxicity, decrease G2 or G3 acute toxicity during RT treatment, even in those patients with initial GI or GU disorders. We will increase the number of patients of this trial and follow them due to evaluate the efficacy of CIS 400 in preventing of GI and GU acute and late toxicity in patients receiving WPRT.

Conflicts of interest

We are grateful to **Leonardo Medical srl** who provided free medical samples of Cis 400 to patients enrolled in this study.

Poster No: P0135 ***XXX Congresso Nazionale AIRO 9-13 dicembre 2020***
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