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RE-START: A study on behalf of AIRO

Re-SBRT after previous definitive or salvage radiotherapy

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Biochemical recurrence
1/3rd of patients after
definitive radiotherapy or
adj RT after radical
prostatectomy

Treatment options

Androgen deprivation
therapy (ADT)
+/-androgen receptor targeted
agents
and salvage local approaches
surgery / focal therapies
re-irradiation

Problem of persistant side effects of systemic treatment

Hence salvage local approaches appealing

- With all salvage techniques: 5 years relapse free survival is comparable
- Reirradiation may lead to lower toxicity
- This study aimed to assess safety and efficacy of reirradiation

RE-START is a multicentric international registry.

Patients included in the current analysis were retrospectively enrolled.

Primary endpoint was rate of acute and late gastrointestinal (GI) and genitourinary (GU) toxicity

reported according to Common Terminology Criteria for Adverse Events (CTCAE). Biochemical relapse after a previous course of radical or postoperative radiotherapy (European Urology Association criteria)

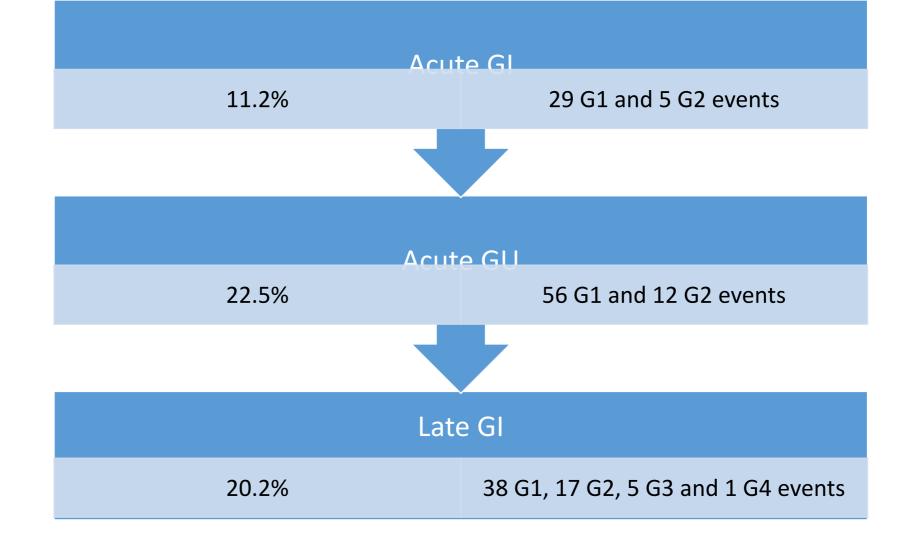
Intra prostatic or prostate bed macroscopic recurrence detected by PET CT / MRI

All treatment schedules allowed But at least 5 Gy per fraction dose Patients with metastatic disease, regional nodal disease

Residual severe toxicities from previous treatments

Less than 6 months of follow-up for the analysis.

- 302 patients
- 177 patients received concomitant ADT
- Median follow up 42 months (95% CI 37-48 months)
- SBRT median total dose of 30 Gy (2-5 fractions)





Data Available for Biochemical relapse-free

287 Patients

171 Events



291 Patients

77 Events



296 Patients

65 Events

Median Riochemical relanse-free survival

30 months

(95% CI 24-34 months)



Median Metastasis-free survival

Not Reached

Not reached



Median Overall survival

98 months

(95% CI 81-142 months)

At univariate analysis,

- baseline high-risk disease (p=0.01),
- time between end of first radiotherapy course and relapse ≤36 months (p<0.001),
- concomitant ADT (p<0.001)
- PSA at relapse ≤1 ng/ml (p=0.001)

were all significantly associated with BRFS, and persisted as independent prognostic factors at multivariate analysis

- None of the above mentioned factors was significantly associated with MFS.
- Only time between end of first radiotherapy course and relapse ≤36 months was significantly associated with OS (p=0.02).

Conclusion

After more than 3 years of median follow up,toxicity rate after reirradiation was mild

Clinical outcomes in terms of BRFS, MFS and OS were promising.

RE-START is a multicentric international registry including long term follow-up data about patients undergoing reirradiation for macroscopic relapse within prostate or prostate bed,

that could provide reliable information about implementation of this approach in current clinical practice.