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Corresponding author:
Boštjan Šeruga

bseruga@onko-i.si

Author Affiliation:
Onkološki Inštitut Ljubljana.

Maintenance of a complete response after cessation of a novel systemic therapy in patients with advanced solid cancers: a systematic review

Stefanovski, D¹; Pavlin, T²; Ilc, S³; Matos, E⁴; Šeruga, B⁵.

ADMINISTRATIVE INFORMATION

Support - Slovenian Research and Innovation Agency, ARIS (P3-0321).

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 February 2024 and was last updated on 15 February 2024.

INTRODUCTION

Review question / Objective 1. Do patients with advanced solid cancers remain in a long-term complete response after cessation/discontinuation of novel systemic anticancer therapy which resulted in a complete response?

P: Adult patients with advanced solid cancers
I: Cessation of novel systemic anticancer therapy after achievement of complete response
C: Continuation of systemic anticancer therapy after achieved complete response (if available)
O: Proportion of patients who remain in complete response 3- and 5- years after the cessation of a systemic therapy
S: Observational studies.

Rationale In principle, most patients with advanced solid cancers are incurable. Systemic anticancer treatment has tremendously changed in the last two decades. Patients with different advanced solid cancer can nowadays be treated with targeted agents, which include small molecule

targeted agents and biological agents, including immune checkpoint inhibitors. In some patients complete disappearance of disease (i.e. complete response) can occur after introduction of the novel systemic therapy. Available evidence suggests that some patients with advanced cancer who achieved a complete response may enjoy a long-lasting remission of their cancer despite the cessation/discontinuation of systemic therapy.

Condition being studied Patients with advanced solid cancers.

METHODS

Search strategy The following databases will be searched:

- 1. PubMed
- 2. Scopus
- 3. Web of Science:
TS=(((("treatment*" OR "treated" OR "therapy") AND ("discontinuation*" OR "cessation*" OR "stop*")) AND ("Complete response" OR "complete responders" OR "complete responses" OR "complete clinical

response" OR "Complete remission" OR "Complete regression" OR "No evidence of disease") AND ("Neoplasm*" OR "Cancer*" OR "Malignanc*" OR "Malignant" OR "Tumor*" OR "sarcoma*" OR "carcinom*" OR "melanom*")) AND DOP=2000-01-01/2023-08-31.

Participant or population Patients with advanced solid cancers who achieved a complete response with a novel systemic therapy AND then discontinued treatment with a novel systemic therapy.

Intervention Cessation/discontinuation of novel a systemic therapy once a complete response of cancer is achieved.

Comparator Continuation of a novel systemic therapy once a complete response is achieved.

Study designs to be included Observational studies, case series and case reports (the latter for rare cancers only).

Eligibility criteria Patients with haemathological malignancies and lymphoma and those who patients with solid cancers who do not achieve complete response not eligible.

Information sources

1. PubMed
2. Scopus
3. Web of Science

When relevant information will not be available, a corresponding author will be contacted.

Main outcome(s) 1. To determine a proportion of patients who remain in complete response 3-years and 5-years (i.e. long-term) after cessation/discontinuation of a novel systemic anticancer therapy for each cancer type.

Additional outcome(s) None.

Data management Study selection:

1. Three reviewers will independently screen the records, another one will check the decisions.
2. Disagreements will be resolved by the consensus.
3. Decisions will be recorded in an Excel spreadsheet.

Data extraction:

1. The following data will be collected: type of study, type of cancer, sample size, control group (y/n), type of systemic therapy, biomarker-based treatment (y/n), median time of treatment to achieve complete response (CR), median follow-up time after cessation of treatment, proportion of

patients with CR 3- and 5-years after cessation of systemic therapy

2. Two reviewers will independently collect the data and another two reviewers will independently check the collected data.

3. Disagreements will be resolved by consensus.

4. Study investigators will be contacted for unreported/missing data.

5. Data will be recorded in an Excel spreadsheet.

Quality assessment / Risk of bias analysis A Newcastle-Ottawa assessment scale will be used for the assessment of bias in cohort studies.

Assessment will be done at study level.

Risk of bias will be assessed by two reviewers.

Disagreements will be resolved by the consensus.

Strategy of data synthesis We do expect very few, if any, studies with a comparator arm as defined above in this systematic review. Therefore, we plan only to pool proportions of patients who will remain in a complete response 3- and 5-years after omission/discontinuation of therapy for each cancer type. The overall pooled estimate will be calculated for each cancer type by the inverse-variance weights obtained from random-effect meta-analysis models.

Subgroup analysis None.

Sensitivity analysis None.

Country(ies) involved Slovenia.

Keywords Cessation; Discontinuation; systemic therapy; complete response.

Dissemination plans Cancer meeting conference; Cancer journal.

Contributions of each author

Author 1 - Boštjan Šeruga.

Email: bseruga@onko-i.si

Author 2 - Dimitar Stefanovski.

Email: dstefanovski@onko-i.si

Author 3 - Tina Pavlin.

Email: tpavlin@onko-i.si

Author 4 - Erika Matos.

Email: ematos@onko-i.si

Author 5 - Sara Ilc.

Email: silc@onko-i.si