

1038MO

Single-dose carboplatin and involved-node radiotherapy for seminoma stage IIA/B: Long-term follow-up from the international multicenter phase II trial SAKK 01/10

A. Papachristofilou¹, J. Bedke², S. Hayoz³, U. Schratzenstaller⁴, M. Pless⁵, M. Hentrich⁶, S. Krege⁷, A. Lorch⁸, D. Aebersold⁹, P-M. Putora¹⁰, D.R. Berthold¹¹, D. Zihler¹², F. Zengerling¹³, A. Dieing¹⁴, A-C. Mueller¹⁵, C. Schaer³, C. Biaggi³, S. Gillesen¹⁶, R. Cathomas¹⁷

¹ Department of Radiation Oncology, Universitätsspital Basel, Basel, Switzerland, ² Department of Urology, University of Tuebingen, Tuebingen, Germany, ³ Competence Center of SAKK, Swiss Group for Clinical Cancer Research, Bern, Switzerland, ⁴ Department of Radiation Oncology, University Hospital Basel, Basel, Switzerland, ⁵ Medical Oncology, Kantonsspital Winterthur, Winterthur, Switzerland, ⁶ Department of Hematology and Oncology, Red Cross Hospital Munich, Munich, Germany, ⁷ Department of Urology, Pediatric Urology and Urologic Oncology, Kliniken Essen-Mitte, Essen, Germany, ⁸ Department of Medical Oncology and Hematology, University Hospital Zürich, Zurich, Switzerland, ⁹ Department of Radiation Oncology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland, ¹⁰ Department of Radiation Oncology, HOCH, Cantonal Hospital St.Gallen, St. Gallen, Switzerland, ¹¹ Department of Medical Oncology, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland, ¹² Department of Oncology, Kantonsspital Aarau, Aarau, Switzerland, ¹³ Department of Urology, University Hospital of Ulm, Ulm, Germany, ¹⁴ Department of Internal Medicine, Hematology and Oncology, Vivantes Klinikum am Urban, Berlin, Germany, ¹⁵ Department of Radiation Oncology, University of Tuebingen, Tuebingen, Germany, ¹⁶ Medical Oncology Department, Istituto Oncologico della Svizzera Italiana, Bellinzona, Switzerland ¹⁷ Division of Oncology/Hematology, Kantonsspital Graubünden, Chur, Switzerland

Background

The SAKK 01/10 trial (NCT01593241) tested de-escalated treatment with single-dose carboplatin followed by involve-node radiotherapy (RT) for seminoma stage IIA or IIB. The primary analysis of the trial in 2021 showed favorable progression-free survival (PFS) and minimal toxicity (Lancet Oncol. 2022;23:1441-1450). The current National Cancer Center Network (NCCN) guidelines endorse this regimen as a treatment alternative to standard of care. We report extended follow-up, addressing efficacy and safety.

Methods

SAKK 01/10 is a multicenter, single arm, phase II trial of the Swiss Group for Clinical Cancer Research (SAKK) and the German Testicular Cancer Study Group (GTCSG) in patients with seminoma stage IIA/B (de novo or relapse on active surveillance). Treatment consisted of one cycle carboplatin AUC7 followed by involved-node RT (IIA: 30 Gy; IIB: 36 Gy). The primary endpoint was 3-year progression-free survival (PFS). Key secondary endpoints included late renal, thromboembolic and gastrointestinal events as well as secondary malignancies (SM) at least possibly related to treatment.

Results

A total of 120 pts were included and 116 pts were eligible. 46 pts had stage IIA and 70 pts IIB seminoma. Current median follow-up is 8 years (minimal 5.9, maximal 12) for 85 patients still on follow-up. PFS at 10 years is 92.8% (IIA: 95.2%; IIB: 91.3%) and no further events have been recorded since the primary analysis in 2021. OS at 10 years is 99.1% (1 death due to SM). One late thromboembolic event was reported, possibly related to treatment. A total of 9 cases of SM, including 4 contralateral germ cell tumors, were recorded, none of which were deemed related to treatment.

Conclusions

Extended follow-up of SAKK 01/10 confirms the favorable efficacy with no further events in the past 5 years and a 10-year PFS of 92.8%. Furthermore, this novel treatment causes minimal toxicity also in the long-term. Our findings oppose concerns about higher incidence of SM or late toxicities due to the combined treatment. Single-dose carboplatin and involved-node radiotherapy for seminoma stage IIA/B should be considered as a new standard of care given its efficacy, minimal acute toxicity, and long-term safety.

Clinical trial identification

NCT01593241.

Legal entity responsible for the study

Swiss Group for Clinical Cancer Research (SAKK).

Funding

Swiss State Secretariat for Education, Research and Innovation Rising Tide Foundation for Clinical Cancer Research.

Disclosure

A. Papachristofilou: Non-Financial Interests, Personal, Member: SAKK, GTCSSG. J. Bedke: Financial Interests, Personal, Advisory Board: AstraZeneca, Astellas, Eisai; Financial Interests, Personal, Advisory Board, Advisory Board and Speaker's Bureau: BMS, Ipsen, MSD, Merck Sorono, Pfizer, Roche, Janssen; Financial Interests, Institutional, Advisory Board: Pfizer; Financial Interests, Institutional, Local PI: AstraZeneca, Eisai, Novartis, Nektar; Financial Interests, Institutional, Coordinating PI: Astellas, BMS, MSD, Ipsen, Pfizer, Roche, Seagen; Financial Interests, Institutional, Steering Committee Member: BMS, MSD, Pfizer, Seagen; Other, Other, Member of the Renal Cell Carcinoma Guidelines Panel: European Association of Urology. A. Lorch: Financial Interests, Personal, Advisory Board: BMS, Merck, Pfizer, MSD, Astellas, Janssen, Roche, Ipsen, Bayer; Non-Financial Interests, Principal Investigator: PI in several phase II and III trials in the field of urooncology; Non-Financial Interests, , Member: ASCO, DGHO, DKG, AIO, EAU, MAGIC, Swiss Ethics Committee, SAKK, SAKK Scientific Committee, EAU Guideline Bladder Cancer, Onkopedia Guideline Testis Cancer, Bladder cancer, German S3 Guidelines Testis Cancer, Wilsede School of Oncology; Non-Financial Interests, , Other, Invited advanced training talks: SAMO Switzerland; Other, , Other, Traveling expenses: Bayer; Other, , Other, Traveling expanses: Janssen, Ipsen. S. Gillesen: Financial Interests, Institutional, Invited Speaker, 02/2023: ASCO GU; Financial Interests, Institutional, Invited Speaker, 09/2023: AdMeTech Foundation; Financial Interests, Institutional, Advisory Board, 02/2025: Amgen, Merck; Financial Interests, Institutional, Advisory Board, 06/2024: Astellas; Financial Interests, Institutional, Advisory Board, 2024: Avalere Health; Financial Interests, Institutional, Advisory Board, I-One Prostate Cancer ESMO 09/2024: Avalere Health; Financial Interests, Institutional, Advisory Board, 02/2023: BMS, Daiichi Sankyo; Financial Interests, Institutional, Other, Consultant service 01.2025-12.2026: BMS; Financial Interests, Institutional, Advisory Board, 02/2023, 11/2023, 06/2024, 09/2024, 11/2024: Bayer; Financial Interests, Personal, Other, Travel support 06/2023, 06/2024: Bayer; Financial Interests, Institutional, Advisory Board, 06/2023: Boehringer Ingelheim Ingelheim; Financial Interests, Institutional, Invited Speaker, 11/2023, 09/2024, 02/2025: EPG Health; Financial Interests, Personal, Invited Speaker, ESMO Preceptorship prostate cancer 12/2023: ESMO; Financial Interests, Institutional, Invited Speaker, ESMO Preceptorship prostate cancer 12/2024: ESMO; Financial Interests, Personal, Other, Travel support 01/2024: Gilead; Financial Interests, Institutional, Advisory Board, 07/2023: Innomedica; Financial Interests, Institutional, Invited Speaker, 01/2024: Intellisphere LLC; Financial Interests, Personal, Other, Travel Support 01/2024: Intellisphere LLC; Financial Interests, Institutional, Advisory Board, 09/2023, 02/2024: Ipsen; Financial Interests, Institutional, Other, Scientific Advisory Committee, 07/2024: LinkinVax; Financial Interests, Institutional, Advisory Board, 03/2024: MacroGenics; Financial Interests, Institutional, Invited Speaker, Speaker Oncosummit 02/2024: Meister ConCept GmbH; Financial Interests, Personal, Invited Speaker, Speaker OncoSummit 2023: Meister ConCept GmbH; Financial Interests, Institutional, Advisory Board, 07/2024, 11/2024: Novartis; Financial Interests, Institutional, Invited Speaker, Speaker Pro.State of the art 01.2025: Orikata; Financial Interests, Institutional, Other, Interview 09/2024: PeerVoice; Financial Interests, Institutional, Other, Scientific Committee Pfizer Forschungspreis 11/2023: Pfizer; Financial Interests, Institutional, Invited Speaker, 02/2023, 09/2023: SAKK; Financial Interests, Institutional, Invited Speaker, 09/2023, 09/2024: Silvio Grasso Consulting; Financial Interests, Personal, Other, Travel support 02/2025: Johnson & Johnson; Financial Interests, Institutional, Invited Speaker, 01/2025: Medtoday Switzerland; Financial Interests, Personal, Other, Advisory commission 11/2024: University of Applied Sciences and Arts of Southern Switzerland (SUPSI); Financial Interests, Institutional, Invited Speaker, GU Event Apr 2nd, Sao Paulo - Brazil: UroPratica Group in Sao Paulo; Financial Interests, Personal, Other, Part of a patent for a biomarker, but (for the moment) no income, but I could not write none in the dropdown menu: Proteomedix/Onconetix; Financial Interests, Institutional, Funding, 2021, Unrestricted grant for a Covid related study as co-investigator: Astellas; Non-Financial Interests, , Advisory Role, Continuing: ProteoMediX; Non-Financial Interests, , Other, Guest engagement agreement 03/2023: ASCO; Non-Financial Interests, , Advisory Role, Steering Committee Charter PEACE6-Vulnerable 04/2023: Unicancer; Non-Financial Interests, , Other, Senior Executives meeting 05/2024: AstraZeneca; Non-Financial Interests, , Advisory Role, Consultat service 01/2025: Pfizer. R. Cathomas: Financial Interests, Institutional, Advisory Board: AstraZeneca, BMS, Bayer, MSD, Roche, Astellas, Ipsen, Merck, Pfizer, Sandoz, Accord, Debiopharm; Financial Interests, Personal, Advisory Board: Janssen; Financial Interests, Personal, Invited Speaker: Janssen, Merck; Financial Interests, Institutional, Invited Speaker: Astellas; Non-Financial Interests, , Member of Board of Directors: SAKK Swiss Working Group for Clinical Cancer Research. All other authors have declared no conflicts of interest.