





Maysa Silveira Vilbert ^{1,2,} Ian Hirsch ^{1,2}, Erica Koch ^{1,2}, Thiago P. Muniz ^{1,2}, Débora Pinheiro Xavier³, Mauricio Ribeiro ^{1,2}, Luke Mantle ^{1,2}, Marcus O. Butler ^{1,2,4}, Anna Spreafico ^{1,2,4}, Samuel D. Saibil ^{1,2,4}, and David Hogg ^{1,2}

1 Department of Medical Oncology and Hematology, Princess Margaret Cancer Centre, University Health Network, Toronto, Canada. 2 Department of Medicine, Division of Medical Oncology, University of Toronto, Toronto, Canada. 3 Health Science Institute, Federal University of Pará. 4 Tumor Immunotherapy Program, Princess Margaret Cancer Centre, University Health Network, Toronto, Canada.

* Kaposi sarcoma (KS) is a rare cutaneous tumor of endothelial origin, caused by human herpesvirus type 8. Chemotherapy is the standard treatment for KS patients with extensive cutaneous or visceral disease. However, long-term remission is rare. Early phase studies of immune checkpoint inhibitors (ICI) in KS patients have demonstrated acceptable safety and efficacy profiles. We conducted a systematic review and meta-analysis of efficacy and safety of ICI in patients with KS.

METHODS

- We searched for clinical trials and observational cohort studies assessing KS patients treated with ICI on PubMed, Scopus, the Cochrane Library, ASCO publications, ESMO and AACR databases.
- Efficacy was measured as best overall response rate (BORR), which is defined as the proportion of patients who have a partial (PR) or complete response (CR) to therapy.
- Heterogeneity was examined with the Cochran Q test and I(2) statistics; p values < 0.05 and I(2) > 25% were considered significant for heterogeneity. We used a DerSimonian and Laird random effects model.

RESULTS

- We included five studies: four phase I/II clinical trials and one observational retrospective cohort, for a total of 65 patients. Fifty-three (81.5%) had previously received at least one treatment for KS.
- Forty-seven (72%) received single agent anti-PD1 and 18 (28%) the combination of nivolumab 240 mg d1, d15, d28 and ipilimumab 1mg/kg d1 q.42 days.
- In a pooled analysis, BORR was 58% (95% CI 39, 77). Five patients achieved complete response (CR), 32 had partial response (PR) and 2 had sustained stable disease (SD) for ≥ 24 months.
- Patients with classic and endemic KS had a BORR of 74% (95%) CI 60, 89) with a follow-up of >20 months. HIV-related KS patients had a BORR of 44% (95% CI 22, 66) with a follow-up range of 3.7 to 5 months.
- Grade 3 or 4 toxicity were reported in 6/44 patients (13.6%). One patient died of KS herpesvirus associated polyclonal B-cell proliferation.

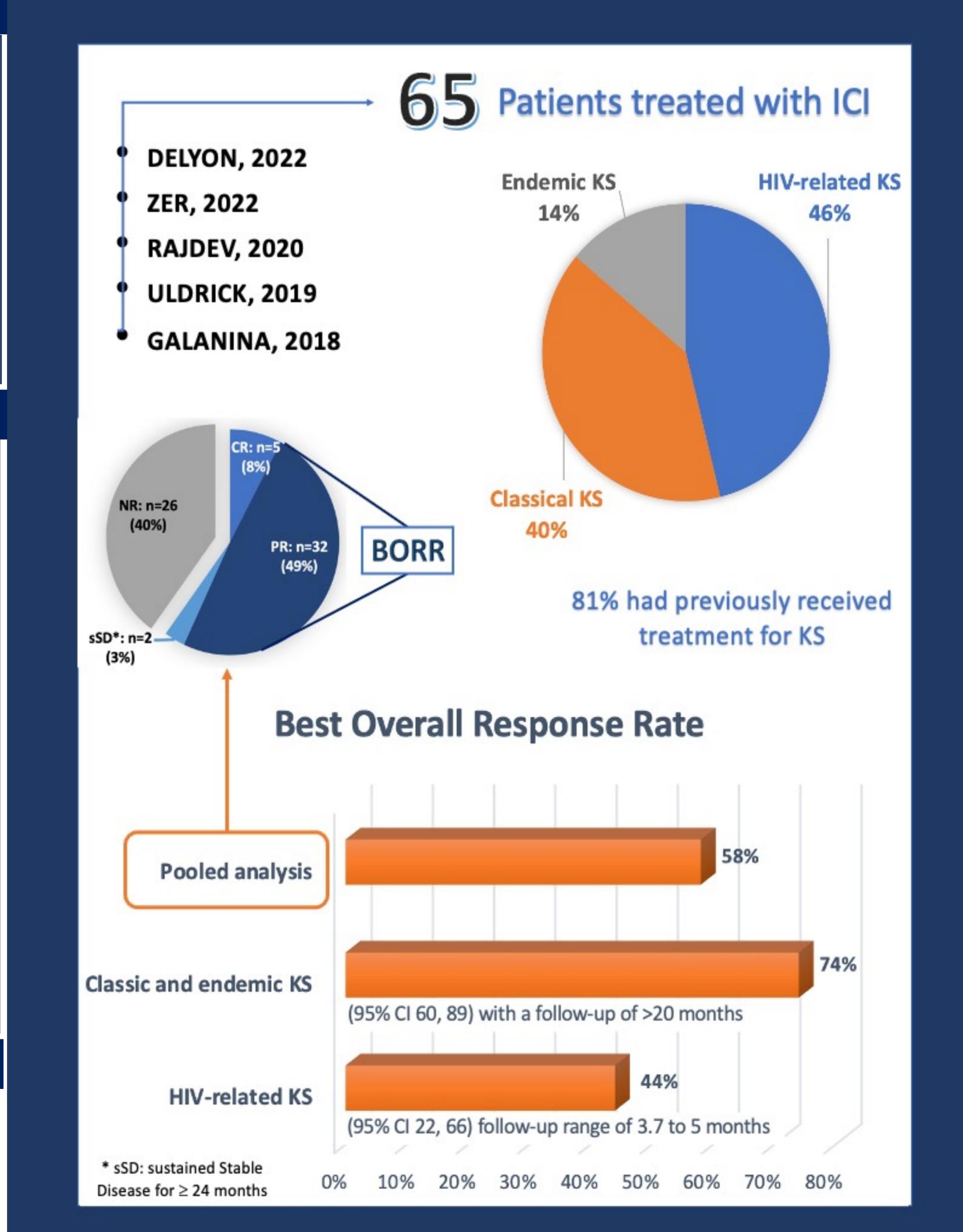
CONCLUSIONS

This single-arm meta-analysis confirms that ICI has anti-tumor activity in patients with KS. Other studies are ongoing and may shed more light on the activity of ICI in KS. Larger phase 3 studies with longer follow up are warranted.

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BACKGROUND



| Table 1. Characteristics of studies included in the meta-analyses. | | | | | |
|--|--|----------------------------------|--------------------|------------------------|---|
| Study | Design | Intervention | No. of Patients | Type of KS | Previous treatments |
| Delyon 2022 | Phase II | Pembro | 17 | 8 C, 9 E | 12 pts: 5 RT, 3 IFN, 11 CT |
| Zer 2022 | Phase II | Nivo + Ipi | 18 | 18 C | 18 pts: 12 RT, 4 IFN, 16 CT, 1 pazopanib |
| Rajdev 2020 | Phase I | Nivo | 15 | 15 HIV | 15 pts: NA |
| Uldrick 2019 | Phase I | Pembro | 6 | 6 HIV | >2 pts: NA |
| Galanina 2018 | Retrospective cohort | Nivo or Pembro | 9 | 9 HIV | 6 pts: 5 CT, 3 Lenalidomide |
| Footnote: Pembro: pembrolizumab; Nivo: Nivolumab; Ipi: Ipilimumab; NA: not available; KS: Kaposi sarcoma C: classic; E: endemic; pts: patients; RT: radiation therapy; IFN: intereron; CT: chemotherapy. | | | | | |
| Pooled analysis of Kaposi Sarcoma patients treated with ICI | | | | | |
| Studies Estimated BORR (95% C.I.) Responders/Total | | | | | |
| Delyon 2022 0.706 (0.489, 0.922) 12/17 Galanina 2018 0.667 (0.359, 0.975) 6/9 Rajdev 2020 0.333 (0.095, 0.572) 5/15 Uldrick 2019 0.333 (0.000, 0.711) 2/6 Zer 2022 0.778 (0.586, 0.970) 14/18 Overall: I ² = 63.77 %, P = 0.026 0.584 (0.395, 0.773) 39/65 | | | | | |
| Classic and Endemic Kaposi Sarcoma patients treated with ICI | | | | | |
| Studies Classic and Endem Delyon (eKS) 2022 Delyon (cKS) 2022 Zer (cKS) 2022 Overall: I ² = 0 %, P = 0.835 | nic KS Estimated BORR (1 0.667 (0.35) 0.750 (0.45) 0.778 (0.58) 0.747 (0.60) | 0, 1.000) 6/B 6, 0.970) 14/18 | | I.4 Best Overall F | 0.6 0.8 1 |
| HIV-related Kaposi Sarcoma patients treated with ICI | | | | | |
| Studies with HIV-related KS Estimate BORR (95% C.I.) Responders/Total | | | | | |
| Galanina 2018 Rajdev 2020 Uldrick 2019 Overall: I ² = 36.51 %, P = 0.20 | 0.667 (0.359, 0.333 (0.095, 0.333 (0.000, 0.441 (0.223, | 0.572) 5/15 0.711) 2/6 | | | |
| | 0.111 (0.113, | 13/30 | 0 0.2 | 0.4 Best Overall Re | 0.6 0.8 1 esponse Rate |

