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ANTI SARS-CoV-2 MONOCLONAL ANTIBODIES: FROM CLINICAL TRIAL TO REAL WORLD EVIDENCE

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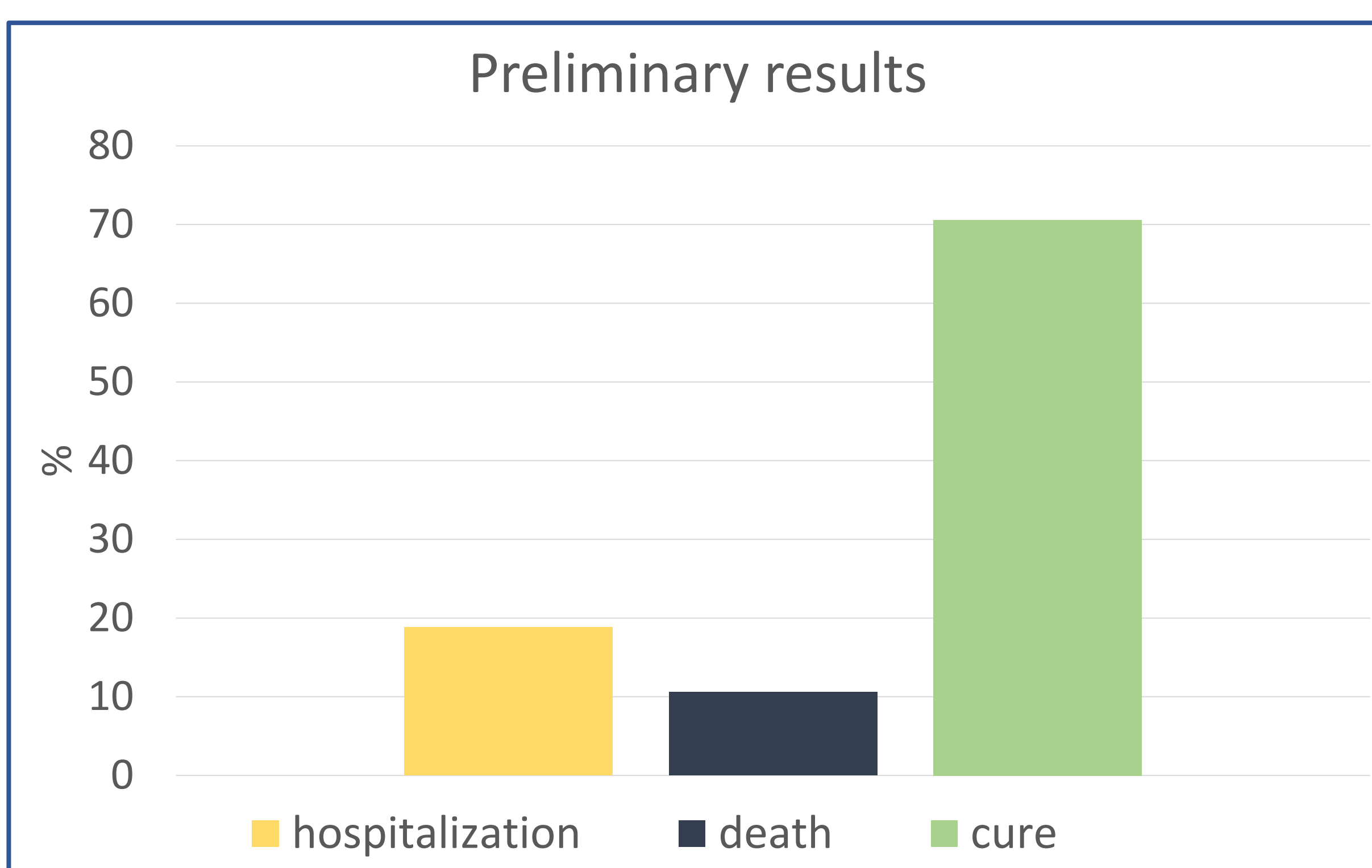
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Background and importance

Monoclonal antibodies (mAbs) against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were recently showed to be promising in preventing hospitalization and death among patients with mild to moderate COVID-19 symptoms in randomized controlled trials. These medicines are subject to additional monitoring and, in our country, this occurs through the Italian Medicine Agency (AIFA). They has been authorized in subjects> 12 years, positive for SARS-CoV-2, not hospitalized for COVID-19, not on oxygen therapy, with mild to moderate symptoms of recent onset at high risk of progression into severe disease. In the absence of solid safety and efficacy data, regulatory bodies recommend infusion in a hospital/protected setting. To our knowledge, limited data are available from real life use of mAbs.

Aim and objective

The aim of the work was to evaluate the risk of a hospitalization or death in patients using these medications and the occurrence of side effects.

Materials and methods

Clinical data of SARS-Cov-2 patients that initiated mAb infusions supplied by our SC Pharmacy, Eastern Piedmont Storage Hub Centres (serving over 1 million inhabitants), were retrospective collected during March-August 2021 period. The primary endpoint was a composite of COVID-19-related hospitalization or death at day 28.

Preliminary results

ID	sex	age	comorbidities	SAE
1				

first swab date	administration mAb	endpoint at 28 day	negative swab date

Table 1. CRF example

Results

The population included 85 patients; median age was 68 years (80% male); 18 positive due to nosocomial infection; main comorbidities were cardiovascular and onco-haematological diseases (33-16%). The proportion of patients with COVID-19-related hospitalization at 28 days was 16% (14 events). There were total of 9 deaths. The mean time between mAb therapy and RT-PCR negative nasopharyngeal swab test was 19 days. For only 3 patients were observed AEs (hypotension, dyspnoea, chills, fever).

Conclusion and relevance

Our results were consistent with recent results showing a reduced risk of hospitalizations or death in outpatients with mild-to-moderate COVID-19. Multidisciplinary dialogue between pharmacist, virologist and general practitioner showed the need to define homogenous methodologies of collection clinical data in real world context (i.e. nasopharyngeal swab test execution's data). Further real-world studies are needed to validate these findings.

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