COVID-19 and venous thromboembolism

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Disclosure

Speaker’s name: Stefano Barco

I have the following potential conflicts of interest to report:

☒ Consulting: Boston Scientific, Bayer Healthcare
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Other(s): Daiichi Sankyo, Bayer (travel costs); Sanofi (institutional grant)

☐
COVID-19

- Wide clinical spectrum of severity
- Systemic inflammatory response
- Endothelial damage, coagulation activation
- High risk of venous thromboembolism

COVID-19 and VTE

- non-ICU patients 8%
- ICU patients 23%

- 1 of 3 angio-CT positive for PE → underdiagnosis
- Often subsegmental PEs

- 0.5-3% VTE risk after discharge

- 50% of VTE events diagnosed upon hospital admission

Nopp S, RPTH 2020
Gaps of knowledge

- VTE diagnosis in COVID-19
  - High- vs. standard-dose thromboprophylaxis in hospital
  - Extended thromboprophylaxis (after discharge)
  - Primary outpatient thromboprophylaxis
High- vs. standard-dose thromboprophylaxis (ICU)

- Multiple-platform, randomized controlled REMAP-CAP, ACTIV-4, ATTACC prematurely stopped for futility/safety

- “Therapeutic anticoagulation drugs did not improve outcomes”
- No evidence supporting deviations from standard regimens

Home therapies

Deaths per 100,000 people per week, selected regions

Region's normal death rate  Confirmed covid-19 deaths
Excess deaths not attributed to covid-19

Bergamo, Italy
Pop. 1,115,000  Mar 1st-Mar 31st

Castile & León, Spain
Pop. 2,419,000  Mar 17th-Mar 24th

Castile-La Mancha, Spain
Pop. 2,033,000  Mar 15th-Mar 24th

Haut-Rhin, France
Pop. 761,000  Mar 1st-Mar 20th

Madrid, Spain
Pop. 6,425,000  Mar 10th-Mar 16th

→ The increases in total mortality in these areas were more than twice the number of deaths officially attributed to covid-19

Source: BAG site and The Economist
Lodigiani C. et al., Thromb Res 2020
OVID phase III RCT

The OVID study will show whether a 14-day enoxaparin prophylaxis improves survival and reduces hospitalizations.

- >50 years and SARS-CoV2+ <5 days
- Eligible for ambulatory treatment
- Respiratory symptoms or Tc >37.5° C
- No contraindications to anticoagulation
- No other indications for an anticoagulant treatment

NCT02996305
Barco S, Trials 2020
OVID phase III RCT

- Patients aged 50 years or older with a positive test for SARS-CoV2 in the past 5 days and eligible for ambulatory treatment.
- Presence of respiratory symptoms (i.e., cough, sore throat, or shortness of breath) or body temperature >37.5°C

Enoxaparin 40 mg sc qD

Recruitment procedure (see 7.2)

No treatment

3 days 7 days 14 days 30 days 90 days

Secondary outcome analysis
Primary outcome analysis
- Unplanned rehospitalizations
- All-cause death

Secondary outcome analysis
End of follow-up

In-hospital visit

Telephone Follow-up

NCT02996305
Barco S, Trials 2020
OVID phase III RCT: status

- 6 active sites in Switzerland
- Approval in Germany and Italy pending
- Interim analysis (n=500) in ca. 3 months

Need for multinational cooperation and high-quality RCTs
Many thanks for your attention