Mediterranean Journal of Hematology and Infectious Diseases

Original Article

Nationwide Survey on the Use of Thrombopoietin Receptor Agonists (TPO-RA) for the Management of Immune Thrombocytopenia in Current Clinical Practice in Italy

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Appendix:

APPENDIX 1

to "Nationwide survey on the use of thrombopoietin receptor agonists (TPO-RA) for the management of immune thrombocytopenia in current clinical practice in Italy"

SURVEY (ENGLISH TRANSLATION)

1)Based on the available scientific literature, do you think that TPO-RA may be adopted even at an earlier stage than allowed by the currently approved indications?

- o Yes
- o No
- o I don't know

2)Where would you position TPO-RA treatment?

- o As first line treatment, in association with steroids
- o As first line treatment, as an alternative to steroids
- o As first line treatment in selected cases (e.g. in diabetic or elderly or septic patients)
- o Immediately after steroids failure, administered for the time indicated by guidelines
- o After steroids failure and second line treatment failure (anti CD20 or splenectomy or other immunosuppressive drugs)

3)Which characteristics/factors may favour the administration of TPO-RA? (multiple answers allowed)

- ☐ Costs
- ☐ Home administration/delivery, drug availability
- ☐ Age
- ☐ Need of frequent contacts with the patient
- ☐ Time needed to reach a safe platelet count
- ☐ Easy dose definition
- ☐ Intolerance
- ☐ Platelet count fluctuations
- ☐ Comorbidities/concomitant medications/patient compliance
- ☐ Other

If answer to question 3 is "Other", **please specify which other characteristics/factors may favour TPO-RA administration**.

4)Which characteristics/factors may disadvantage the administration of TPO-RA? (multiple answers allowed)

- ☐ Costs
- ☐ Home administration/delivery, drug availability
- ☐ Age
- ☐ Need of frequent contacts with the patient
- ☐ Time needed to reach a safe platelet count
- ☐ Easy dose definition
- ☐ Intolerance
- ☐ Platelet count fluctuations
- ☐ Comorbidities/concomitant medications/patient compliance
- ☐ Other

If answer to question 4 is "Other", **please specify which other characteristics may disadvantage TPO-RA administration**.

5)Do you administer TPO-RA more frequently:

- o In young patients
- o In elderly patients

- o Indifferently

6)If you adopt different approaches in young and elderly patients, please specify the main reasons that lead you to this choice: (multiple answers allowed)

- ☐ Different thrombotic risk
- ☐ Different bleeding risk
- ☐ Toxicity
- ☐ Lifestyle (e.g. frequent travels)
- ☐ Nutrition
- ☐ Different patient expectations
- ☐ Higher frequency of concomitant disorders in the elderly patient
- ☐ Higher burden for the elderly patient in accessing the hospital for frequent visits
- ☐ I do not adopt different approaches in young and elderly patients

7)Do you think that TPO-RA may be administered at different time points to patients older than 65 years of age, compared to younger subjects?

- o No
- o Yes, I adopt them as a second line therapy after cortisone, regardless of the presence or not of cardiovascular risk factors or comorbidities
- o Yes, I adopt them as second line therapy, only in the absence of comorbidities impacting the cardiovascular risk

8)What is your aim in prescribing TPO-RA to young patients?

- o To reach a safe platelet count (above 30-50 x 10^9/L)
- o To reach a complete response (in order to evaluate tapering/discontinuation at a later time)
- o Other

If answer to question 8 is "Other", **please specify for what purpose you administer TPO-RA in young patients**.

9)What is your aim in prescribing TPO-RA to elderly patients?

- o To reach a safe platelet count (above 30-50 x 10^9/L)
- o To reach a complete response (in order to evaluate tapering/discontinuation at a later time)
- o Other

If answer to question 9 is "Other", **please specify for what purpose you administer TPO-RA in elderly patients**.

10)When do you switch from one TPO-RA to another? (multiple answers allowed)

- ☐ When PLT count is less than 20-30 x 10^9/L or less than double the basal value, after the administration of the maximum allowed dose for four consecutive weeks
- ☐ When PLT count is less than 20-30 x 10^9/L or less than double the basal value, even without waiting to have reached the maximum allowed dose if the patient has bleeding diathesis
- ☐ When a stable PLT count cannot be obtained, due to wide fluctuations in PLT count
- ☐ In case of grade 3 toxicity
- ☐ When the patient loses the response to the first TPO-RA
- ☐ Patient preferences
- ☐ Other

If answer to question 10 is "Other", **please specify when to switch from one TPO-RA to another**.

11)According to your experience, in what percentage of cases is it possible to maintain a haematological response, even after treatment discontinuation (Treatment Free Response, TFR)?

- o In no case

- In 5-10% of patients
- In 10-20% of patients
- In 20-30% of patients
- In 30-40% of patients
- In 40-50% of patients

12)When do you take into account the possibility to discontinue TPO-RA treatment, aiming to achieve TFR?

- When PLT≥100 x 10^9/L for at least 3 months
- When PLT≥100 x 10^9/L for at least 6 months
- When PLT≥100 x 10^9/L for at least 9 months
- When PLT≥100 x 10^9/L for at least 12 months
- When PLT≥50 x 10^9/L for at least 3 months
- When PLT≥50 x 10^9/L for at least 6 months
- When PLT≥50 x 10^9/L for at least 9 months
- When PLT≥50 x 10^9/L for at least 12 months

13)How do you manage TPO-RA discontinuation (tapering schedule)?

- I adopt a pre-defined tapering method that I apply regularly for both TPO-RA in all patients in which I try tapering
- I do not adopt a pre-defined tapering method that I apply regularly for both TPO-RA and I define the tapering schedule for each patient based on the patient's response

13A)How do you taper TPO-RA?

- I only reduce the TPO-RA dosage, keeping standard intervals between doses, as suggested by the drug technical sheet
- I only prolong the interval between TPO-RA doses, keeping the effective dose unchanged, up to complete treatment discontinuation
- I modify both the TPO-RA dosage and the intervals between administrations

13B) What is the tapering duration?

- Slow, progressive tapering, for a stable PLT count, until discontinuation within 4-6 months
- Slow, progressive tapering, for a stable PLT count, until discontinuation within 2-4 months
- Slow, progressive tapering, for a stable PLT count, until discontinuation within 1-2 months
- Other

If answer to question 13B is "Other", **please specify the timing of the tapering**.

14)During TPO-RA tapering, if platelet count decrease < 50 x 10^9/L without bleeding diathesis:

- The effective dosage before tapering attempt is restored, and no further tapering is attempted
- The dosage immediately preceding the last one is restored, even if lower than the one before the start of tapering, and tapering is then continued with prolonged time intervals
- Low doses of steroids are temporarily associated to TPO-RA and tapering is continued

15)Are TPO-RA associated with a higher risk of thrombotic complications? (multiple answers allowed)

- ☐ Yes, compared to patients not receiving TPO-RA
- ☐ Yes, but only in elderly patients compared to the younger ones
- ☐ Yes, in women under hormonal treatment
- ☐ Yes, but only in the presence of other concomitant risk factors for thrombosis
- ☐ No

16)Do you take into account the administration of TPO-RA in patients with previous thrombotic events?

- o Yes
- o Yes, based on thrombophilia screening
- o No, never

17)Do you administer TPO-RA in elderly patients with other concomitant risk factors for thrombosis in addition to advanced age?

- o No, I avoid TPO-RA in these subjects
- o Yes, I adopt it anyway
- o Yes, I adopt TPO-RA in these subjects, aiming to reach a PLT count between 50-100 x 10^9/L, and adding an antiplatelet or anticoagulant agent when PLT count is above 50 x 10^9/L

18)What is the mean incidence of thrombotic events you observe in patients treated with TPO-RA?

- o <1%
- o 1-5%
- o 6-10%
- o 11-15%
- o 16-20%
- o >20%

19)Thrombotic events mainly involve

- o Arteries
- o Veins
- o Indifferently

20)Do you discontinue treatment with TPO-RA in patients experiencing a thrombotic event during treatment?

- o Yes
- o No, never
- o Only in case of venous thrombosis
- o Only in case of arterial thrombosis
- o Only in the acute phase of the event
- o Only if it is clinically significant (requiring hospital admission or interventional procedures), regardless the anatomical site

21)If you continue treatment with TPO-RA after a thrombotic event, do you change treatment schedule? (multiple answers allowed)

- ☐ Yes, I change TPO-RA
- ☐ No, I do not change TPO-RA
- ☐ I continue with the same TPO-RA but I reduce it to the minimum dosage able to maintain PLT count between 50-100 x 10^9/L
- ☐ I combine TPO-RA with an antithrombotic therapy in the acute phase
- ☐ I combine TPO-RA with an antiplatelet agent in the acute phase
- ☐ After the acute phase (3-6 months), I continue the TPO-RA and I combine it with an antithrombotic prophylaxis
- ☐ After the acute phase, I continue TPO-RA but I do not associate it with an antithrombotic prophylaxis

If answer to question 21 is "I combine TPO-RA with an antithrombotic therapy in the acute phase", **which antithrombotic treatment do you administer in the acute phase?**

If answer to question 21 is "I combine TPO-RA with an antiplatelet agent in the acute phase", **which antiplatelet agent do you administer in the acute phase?**

If answer to question 21 is "After the acute phase (3-6 months), I continue the TPO-RA and I combine it with an antithrombotic prophylaxis", **which antithrombotic prophylaxis do you administer after the acute phase? How long?**

22)During COVID-19 pandemic, do you administer TPO-RA in a different way?

- o No, I have not changed my practice
- o Yes, already as first line treatment
- o Yes, as second line treatment
- o I prefer TPO-RA over further more immunosuppressive treatments

23)According to your personal experience (direct clinical experience or knowledge from the scientific literature), what is the incidence of thrombosis, within one year of treatment with TPO-RA, in patients with ITP older than 60?

- o <1%
- o 1-5%
- o 6-10%
- o 11-15%
- o 16-20%
- o >20%

24)According to your personal experience (direct clinical experience or knowledge from the scientific literature), what is the incidence of thrombosis, after the first year of treatment with TPO-RA, in patients with ITP older than 60?

- o <1%
- o 1-5%
- o 6-10%
- o 11-15%
- o 16-20%
- o >20%

25)Do you think that TPO-RA may induce thrombotic events with the same incidence?

- o Yes
- o No

If answer to 25 is "No", **which TPO-RA do you consider is more dangerous?**

- o Eltrombopag
- o Romiplostim

26)In what percentage of cases do you associate another therapy to the TPO-RA?

- o <20%
- o 20-30%
- o 31-40%
- o 41-50%
- o >50%

27)Which drug do you administer in association with TPO-RA? (multiple answers allowed)

- ☐ Steroid
- ☐ High Dose Immunoglobulins (HDIg)
- ☐ Rituximab
- ☐ Mycophenolate mofetil

- ☐ Cyclosporine
- ☐ Azathioprine
- ☐ Danazol
- ☐ Other

If answer to question 27 is "Other", **specify the drug(s) you combine with TPO-RA.**

28)Have you ever administered both TPO-RA at the same time?

- o Yes
- o No

If answer to question 28 is "Yes", **specify the reason**.
If answer to question 28 is "Yes", **specify the response rate**.

29)Did you have patients that, after years of treatment with TPO-RA, even with a good response, asked to change treatment to avoid the chronic intake of the drug?

- o Yes
- o No

If answer to question 29 is "Yes", **which treatment did you choose?**

- o Rituximab
- o Splenectomy

30)Have you ever administered TPO-RA in pregnant women?

- o Yes
- o No

If answer to question 30 is "Yes", **during the first, second or third trimester? (multiple answers allowed)**

- ☐ First trimester
- ☐ Second trimester
- ☐ Third trimester

If answer to question 30 is "Yes", **in how many patients?**

31)Do you consider the concomitant detection of antiphospholipid antibodies (APL) an absolute contraindication to TPO-RA administration?

- o Yes
- o No

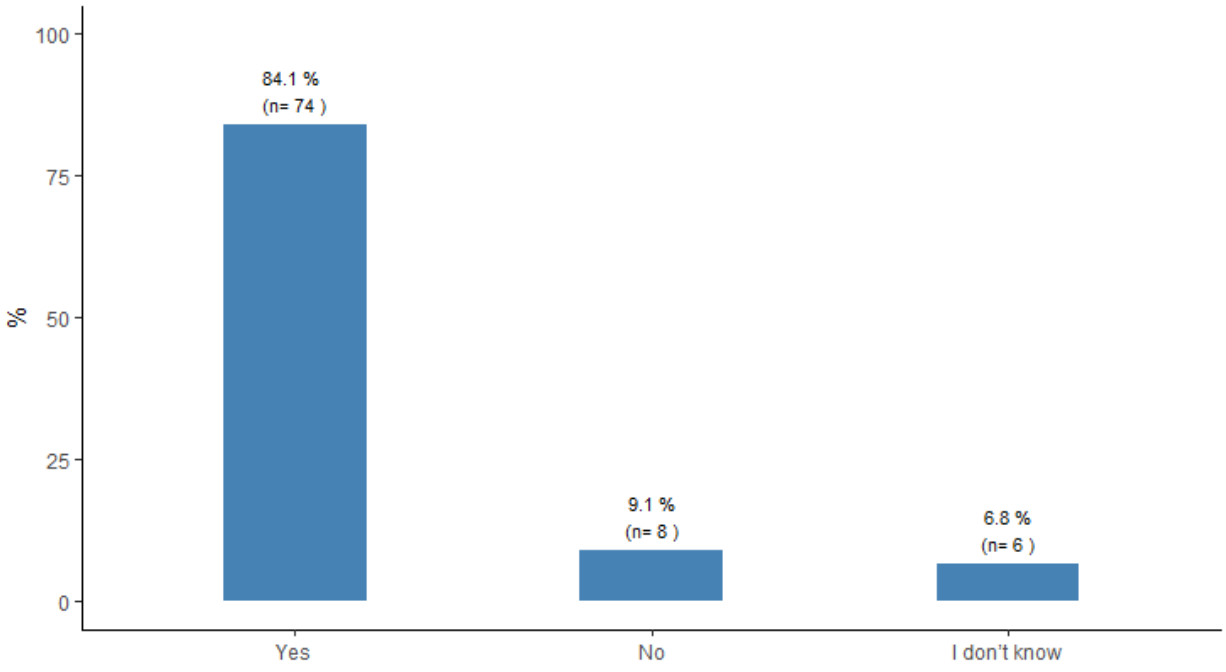
If answer to question 31 is "No", **how many patients have you treated?**

Comments

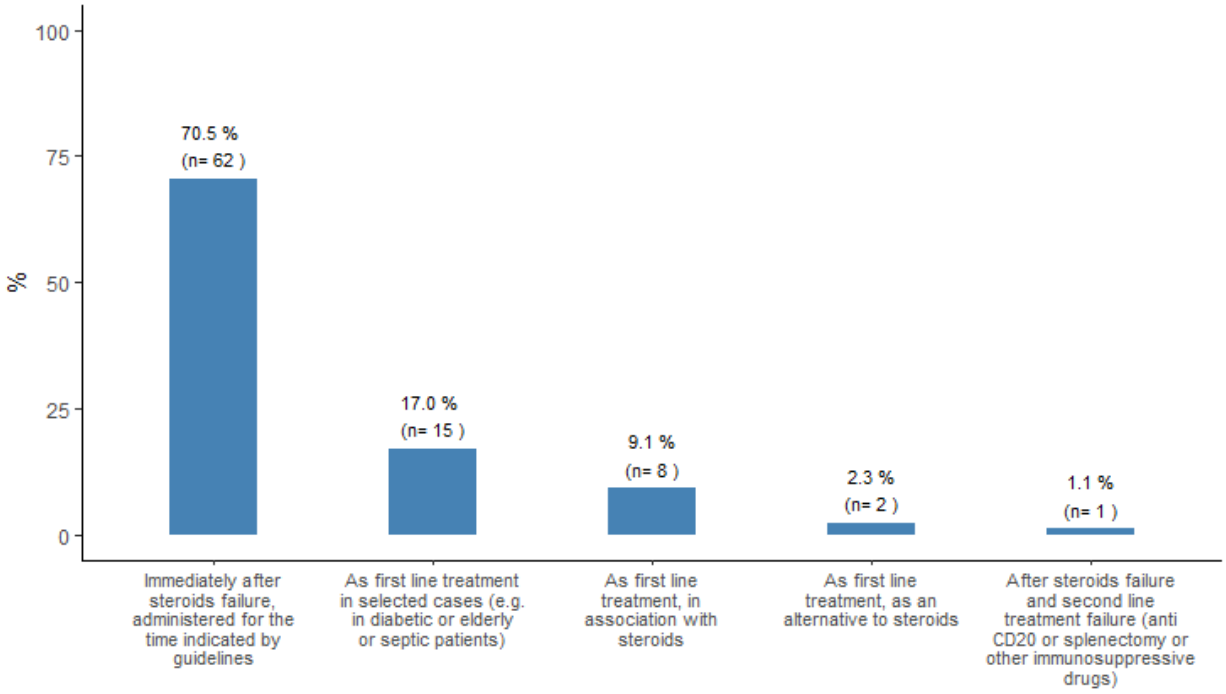
SUMMARY OF THE ANSWERS TO THE ITEMS DIVIDED IN THE 9 ADDRESSED DOMAINS

Timing of administration of TPO-RA and preferred agent

Question 1: Based on the available scientific literature, do you think that TPO-RA may be adopted even at an earlier stage than allowed by the currently approved indications?

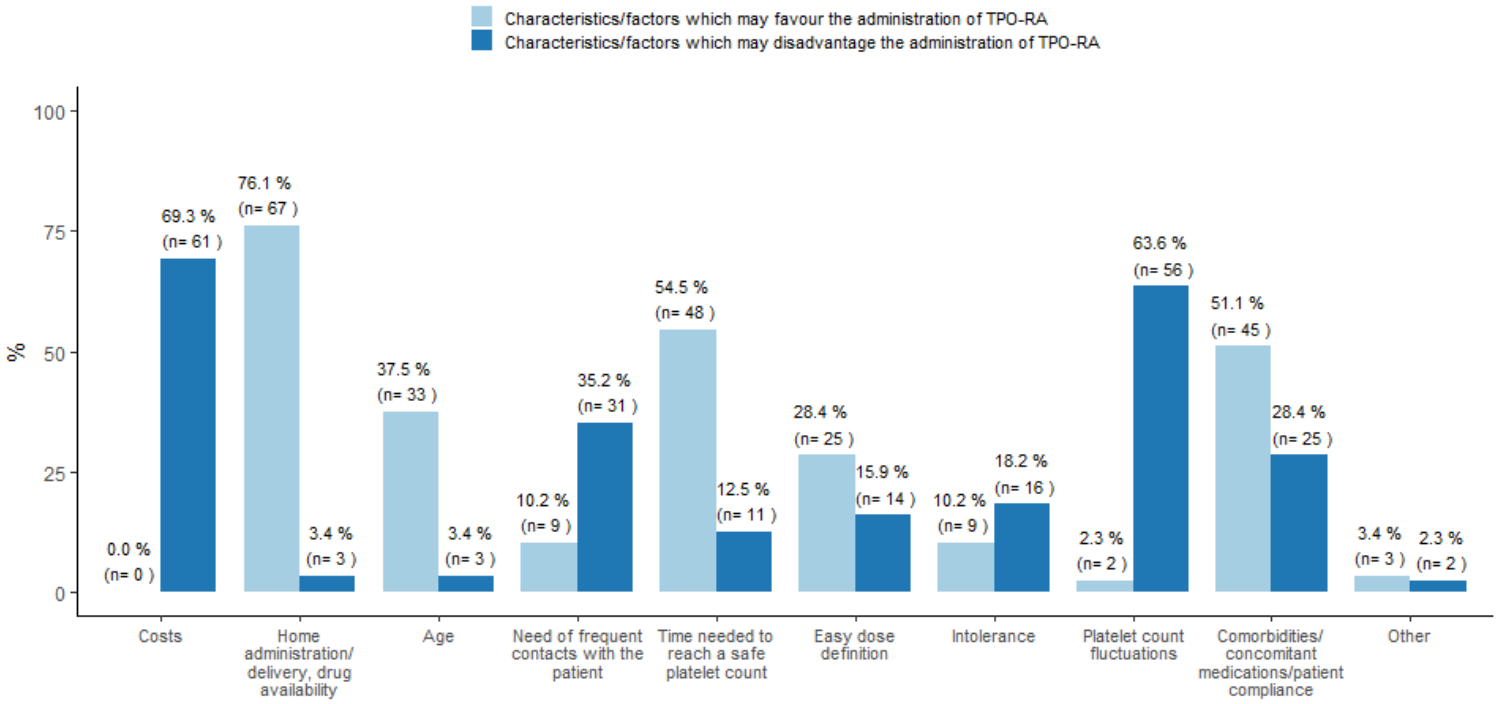


Question 2: Where would you position TPO-RA treatment?

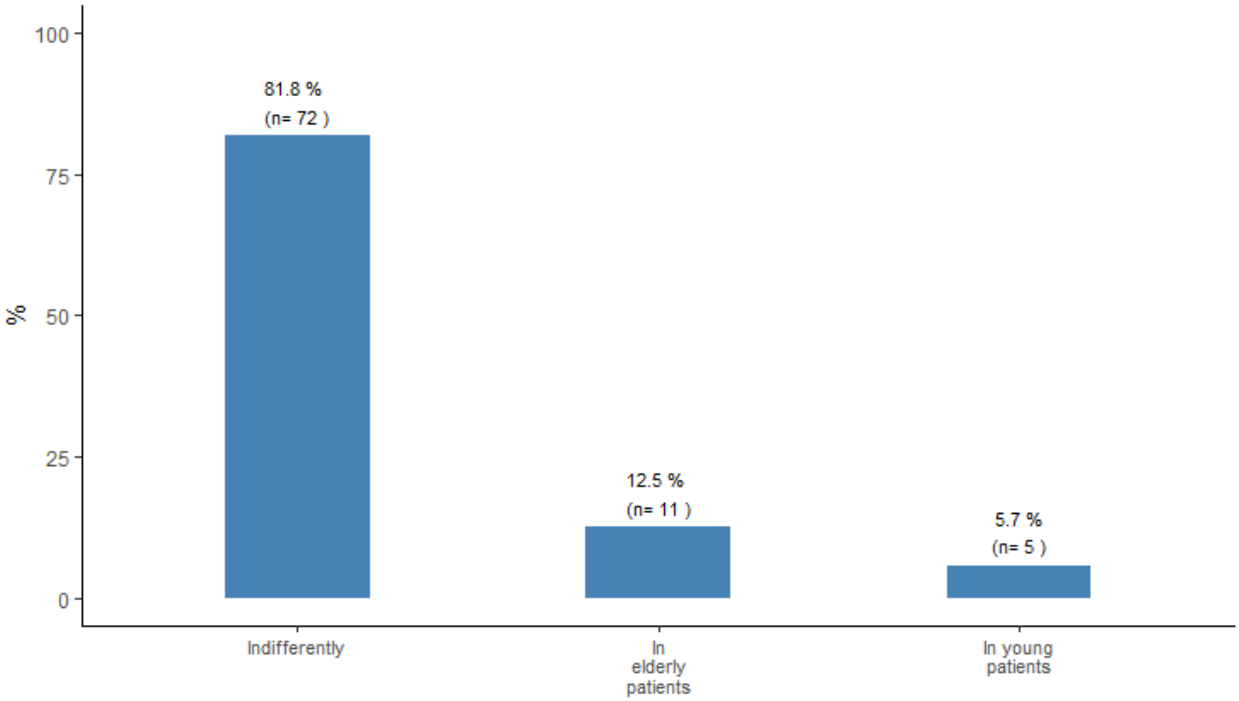


Modality and purpose of treatment in young and elderly patients

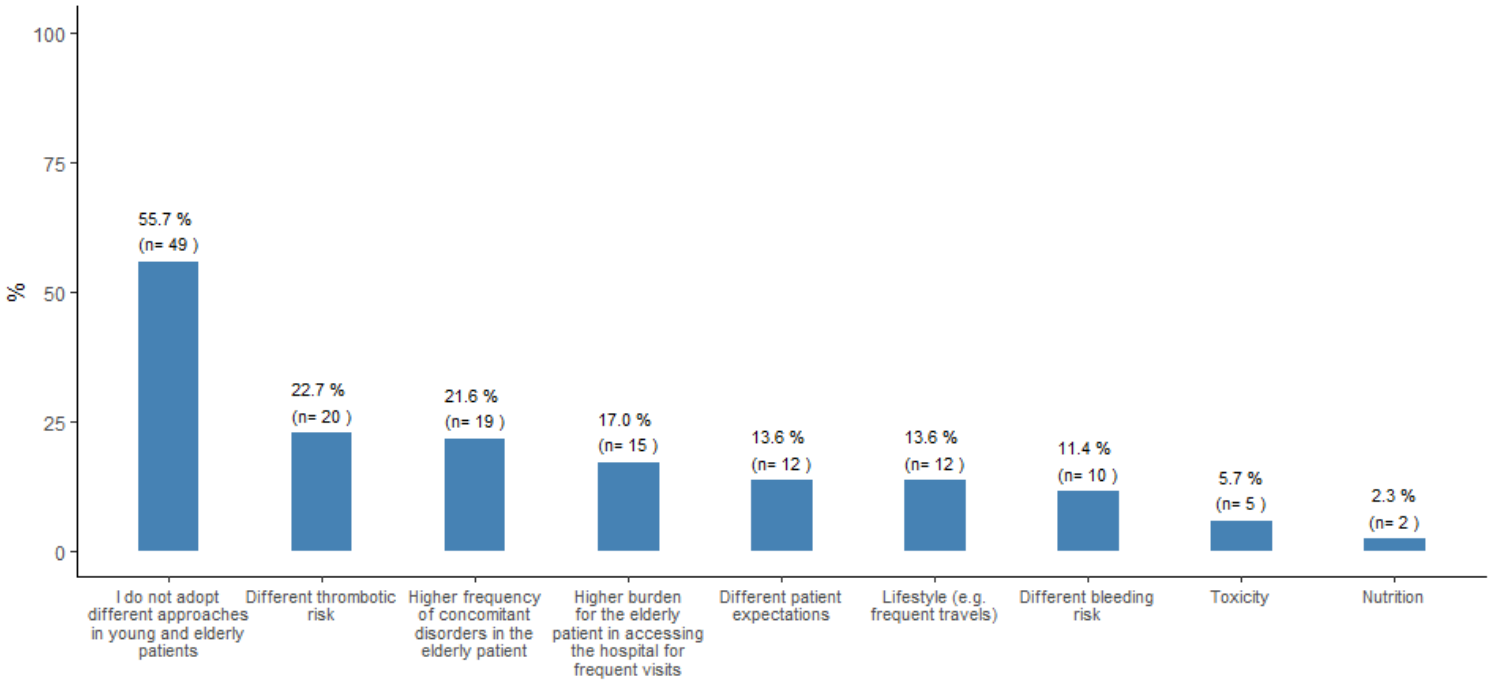
Questions 3-4: Which characteristics/factors may favour/disadvantage the administration of TPO-RA? (multiple answers allowed)



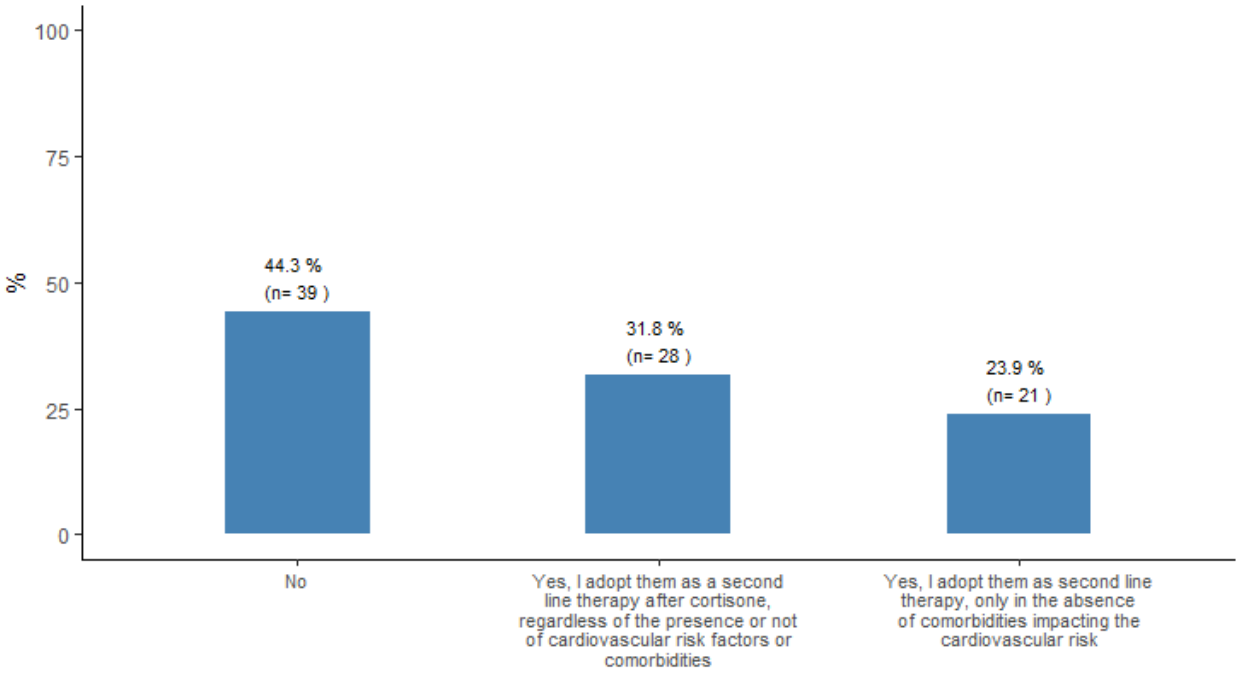
Question 5: Do you administer TPO-RA more frequently



Question 6: If you adopt different approaches in young and elderly patients, please specify the main reasons that lead you to this choice (multiple answers allowed)

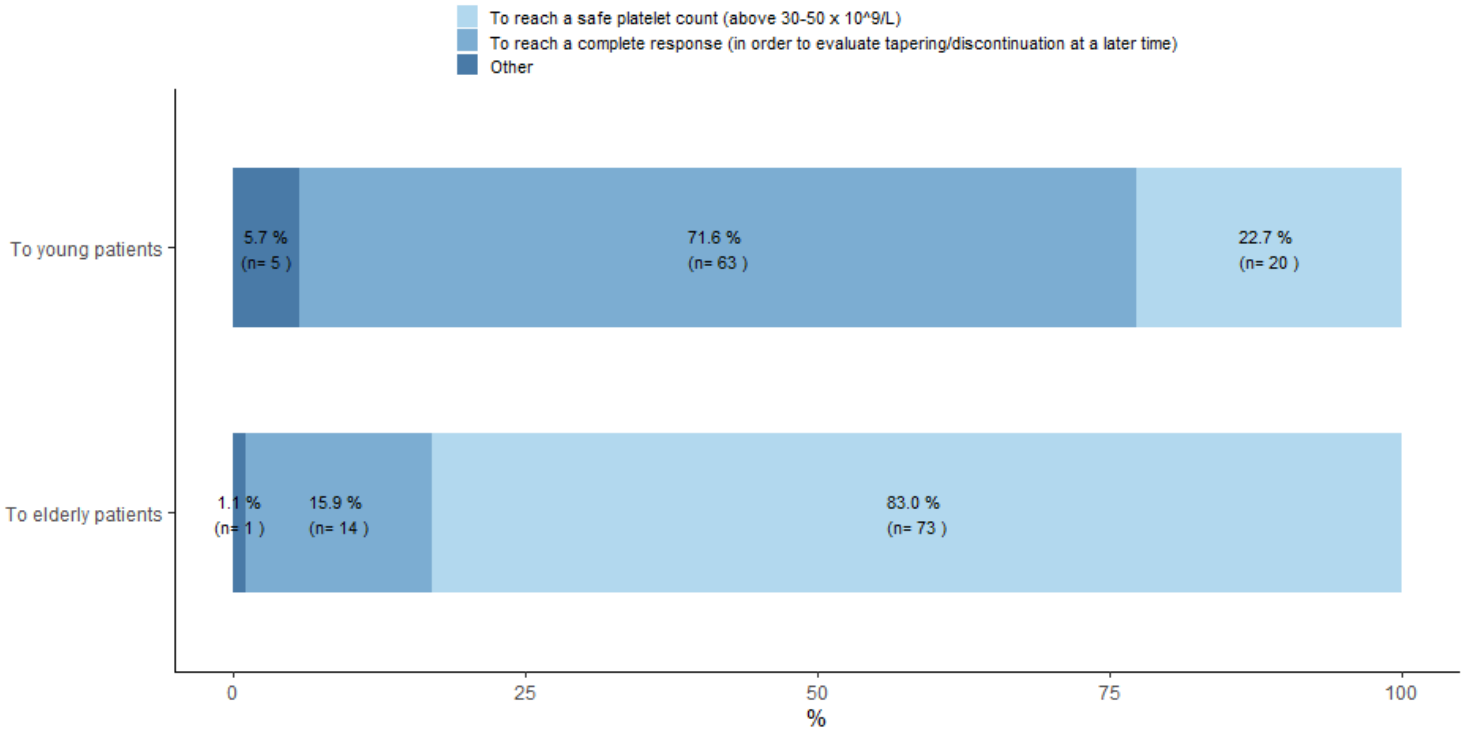


Question 7: Do you think that TPO-RA may be administered at different time points to patients older than 65 years of age, compared to younger subjects?

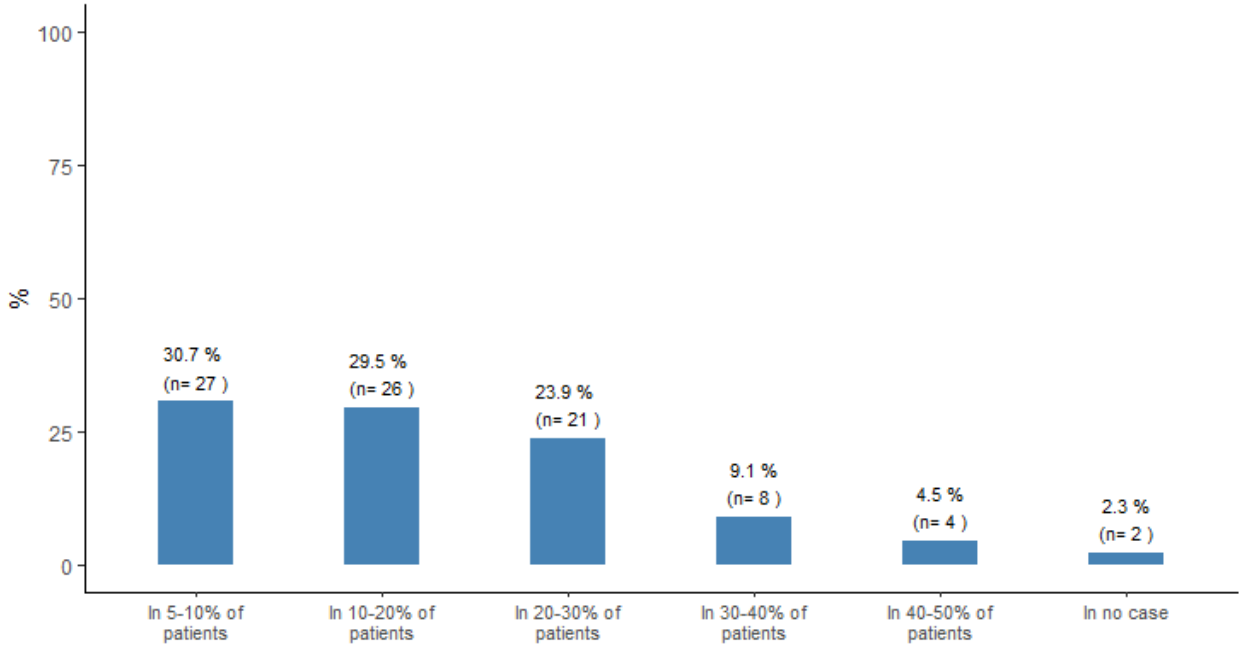


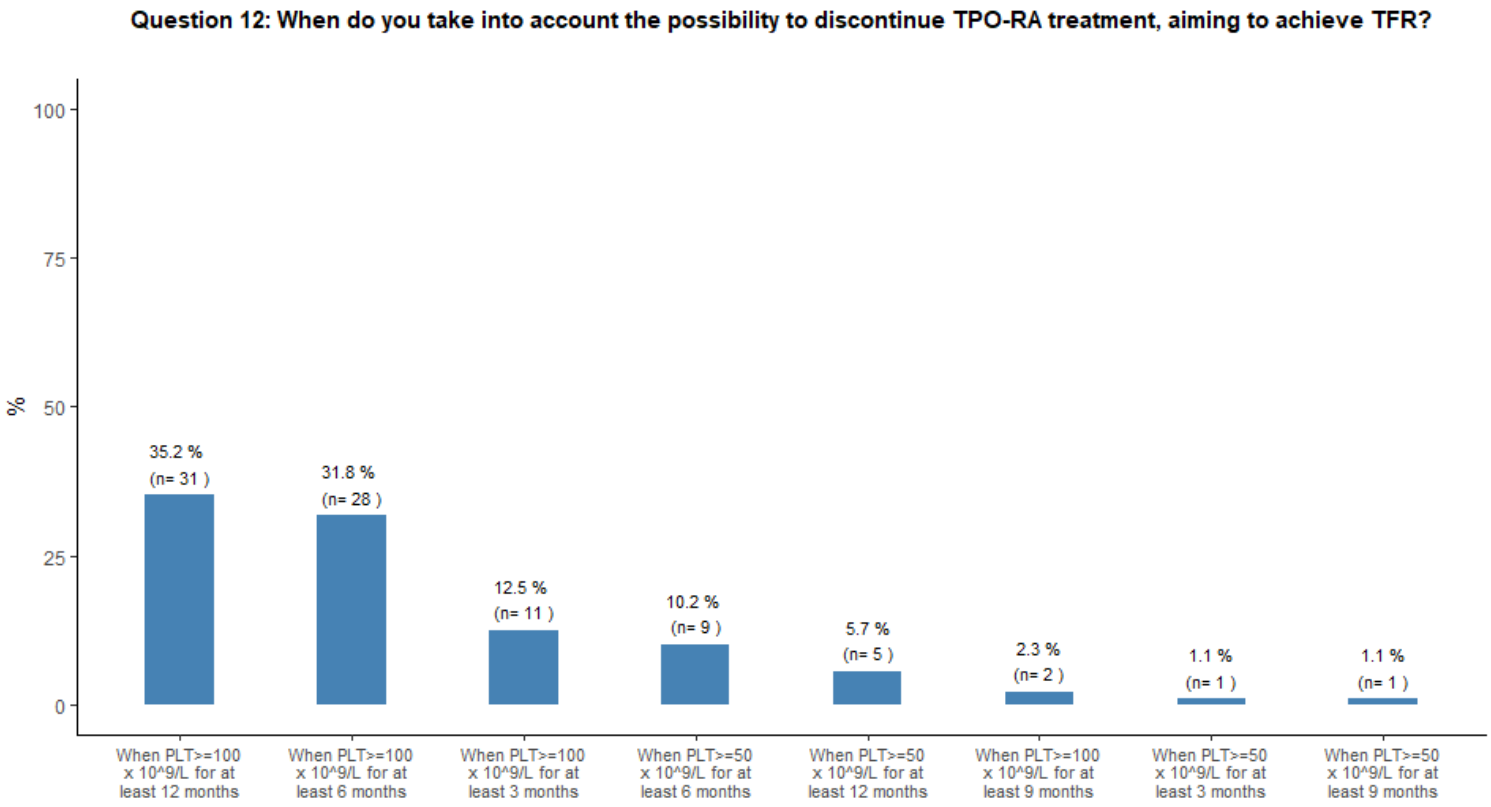
Parameters evaluated to discontinue treatment in young and elderly patients

Questions 8-9: What is your aim in prescribing TPO-RA to young vs. elderly patients?

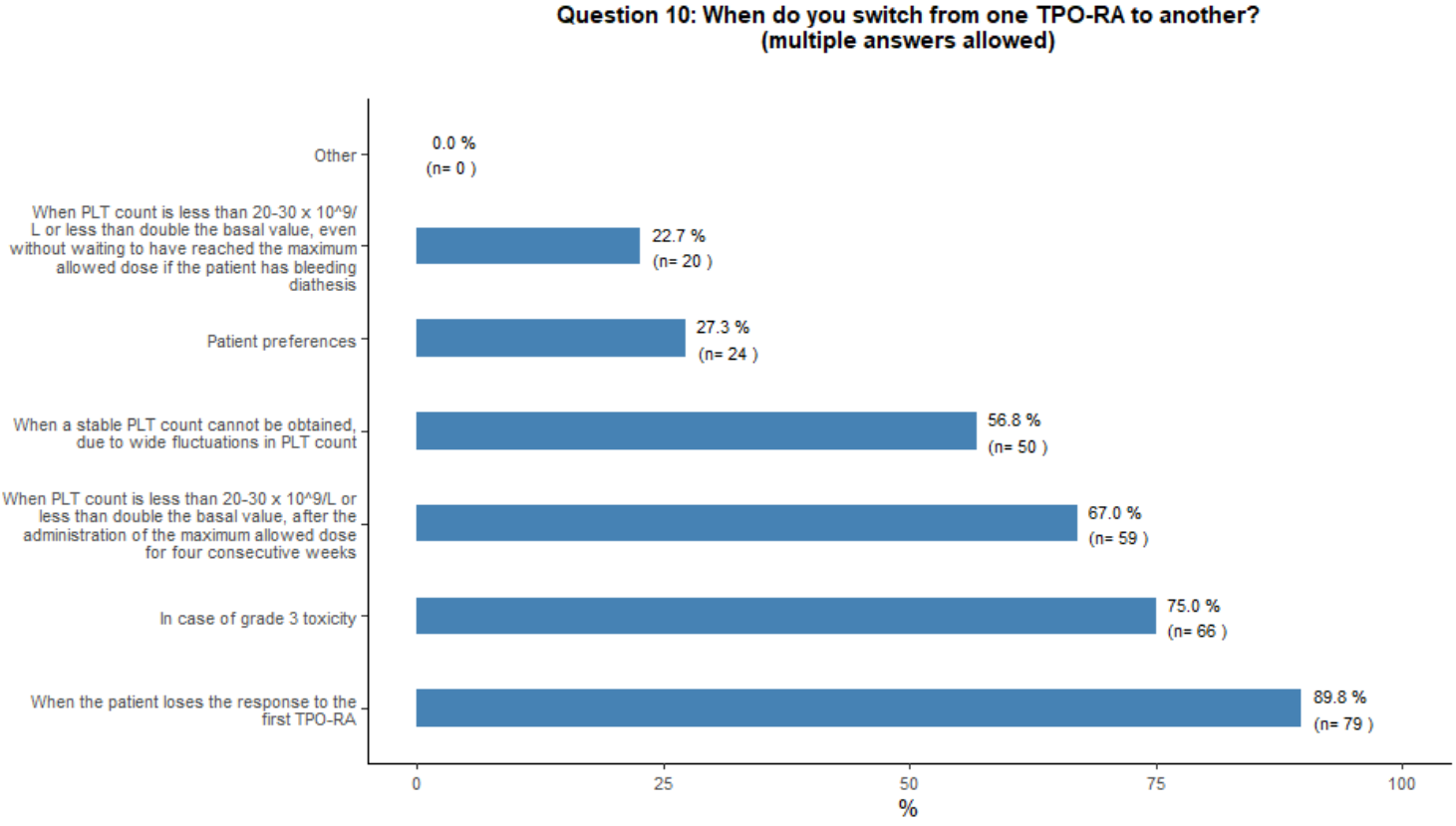


Question 11: According to your experience, in what percentage of cases is it possible to maintain a haematological response, even after treatment discontinuation (Treatment Free Response, TFR)?

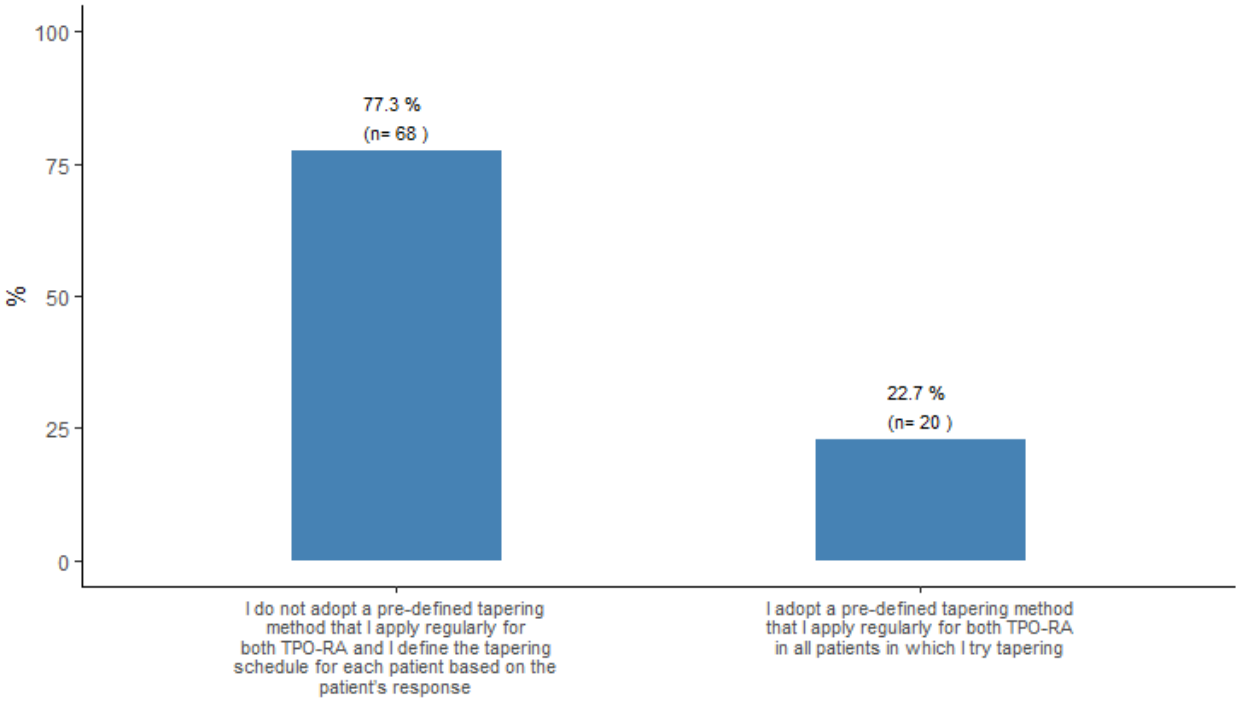




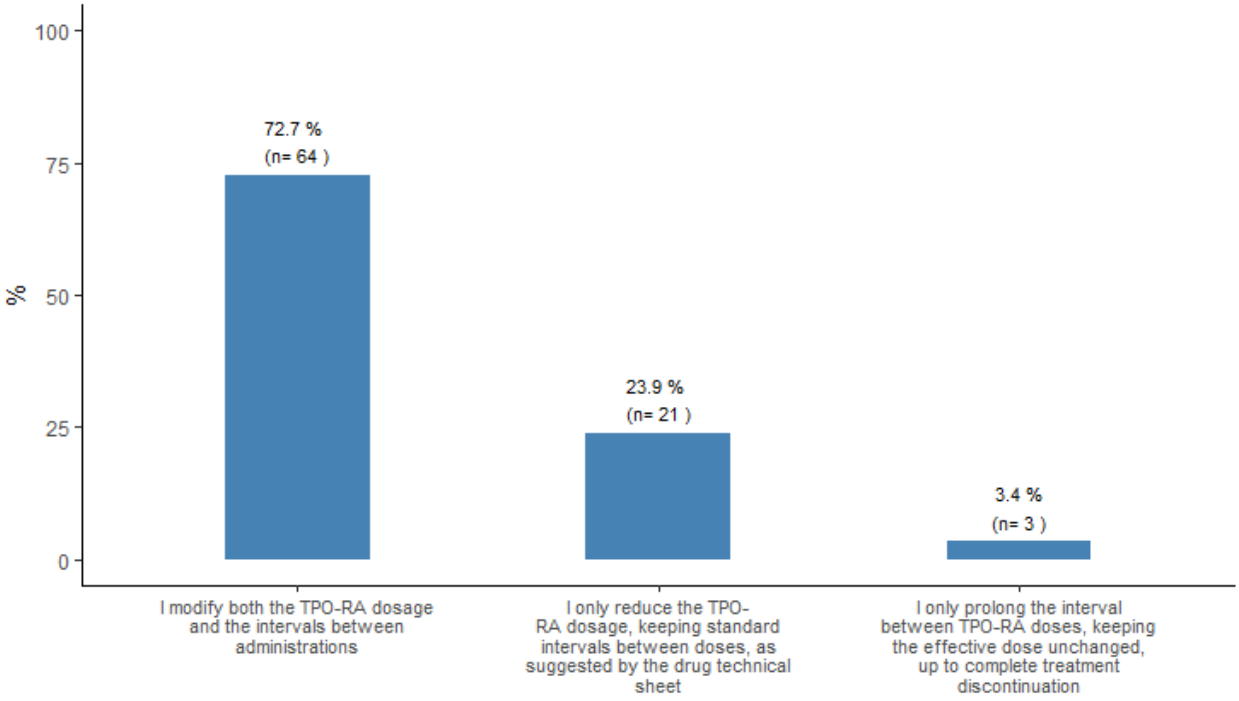
Switching and tapering of TPO-RA



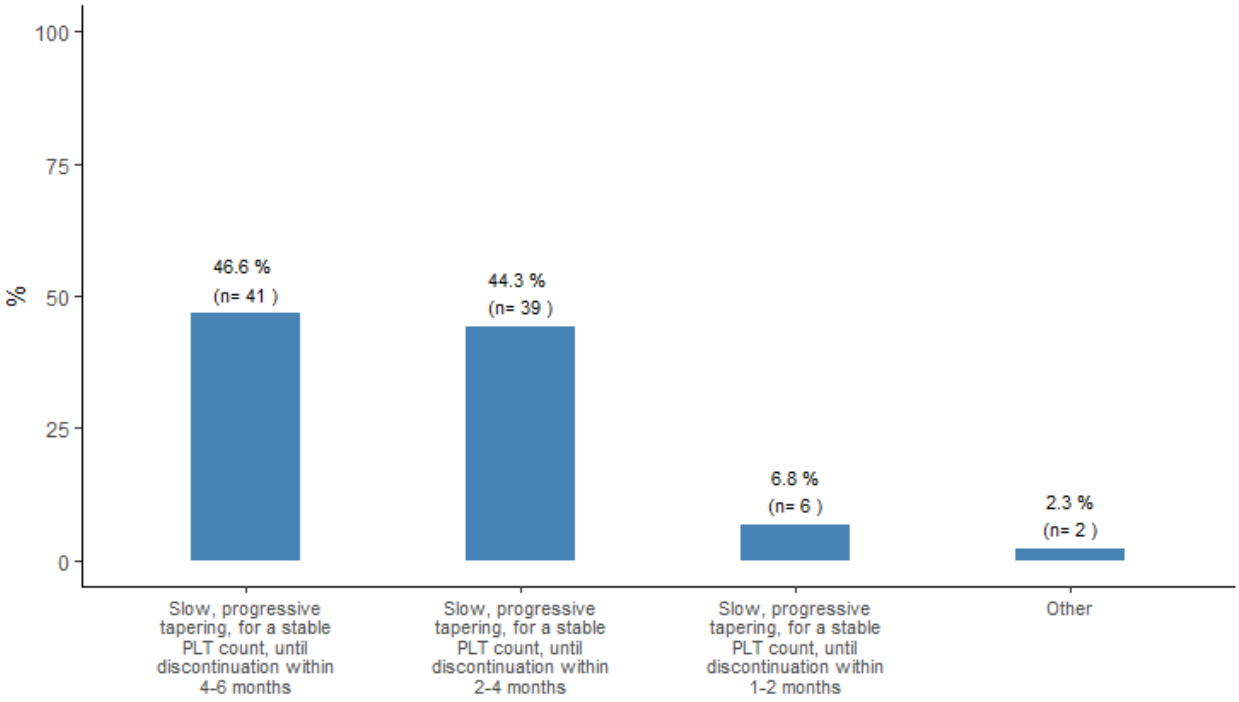
Question 13: How do you manage TPO-RA discontinuation (tapering schedule)?



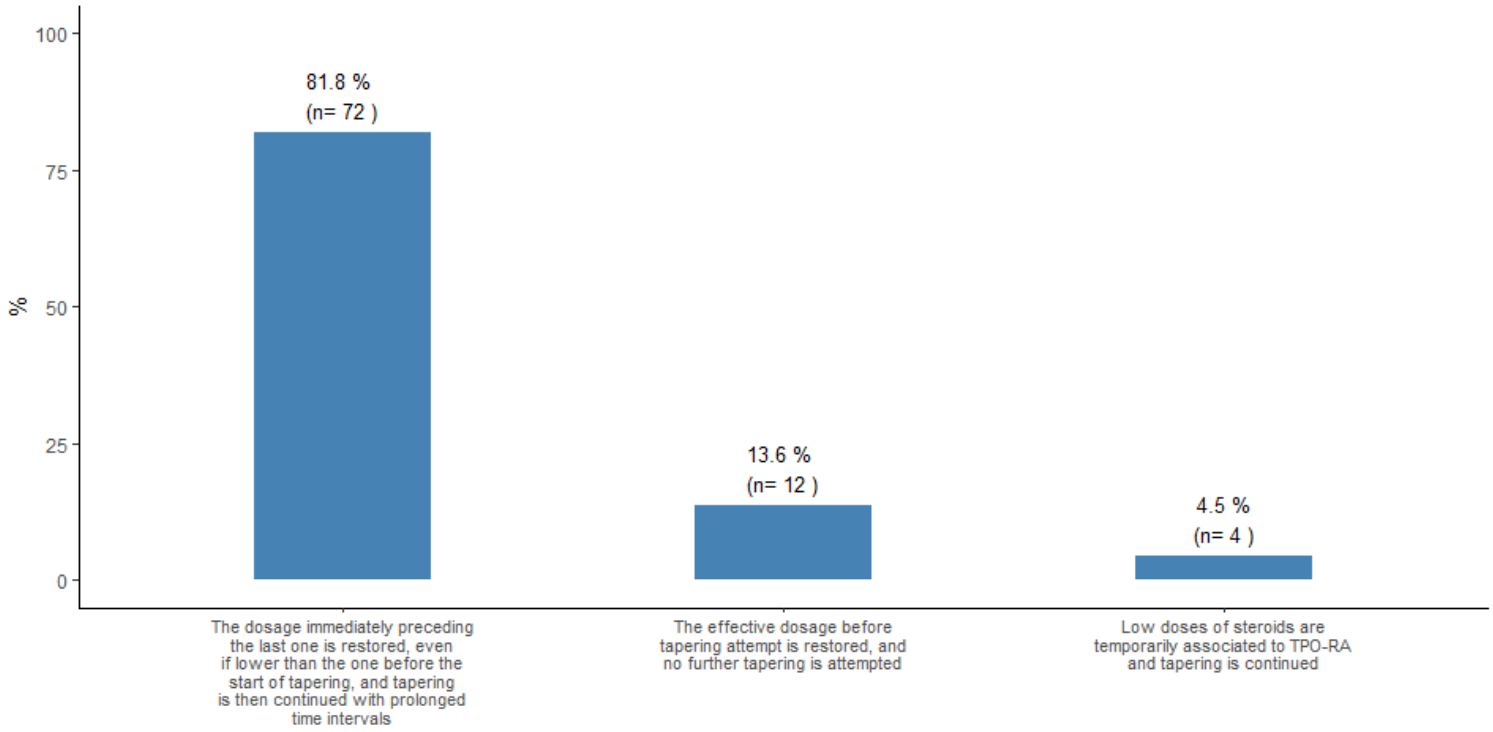
Question 13A: How do you taper TPO-RA?



Question 13B: What is the tapering duration?

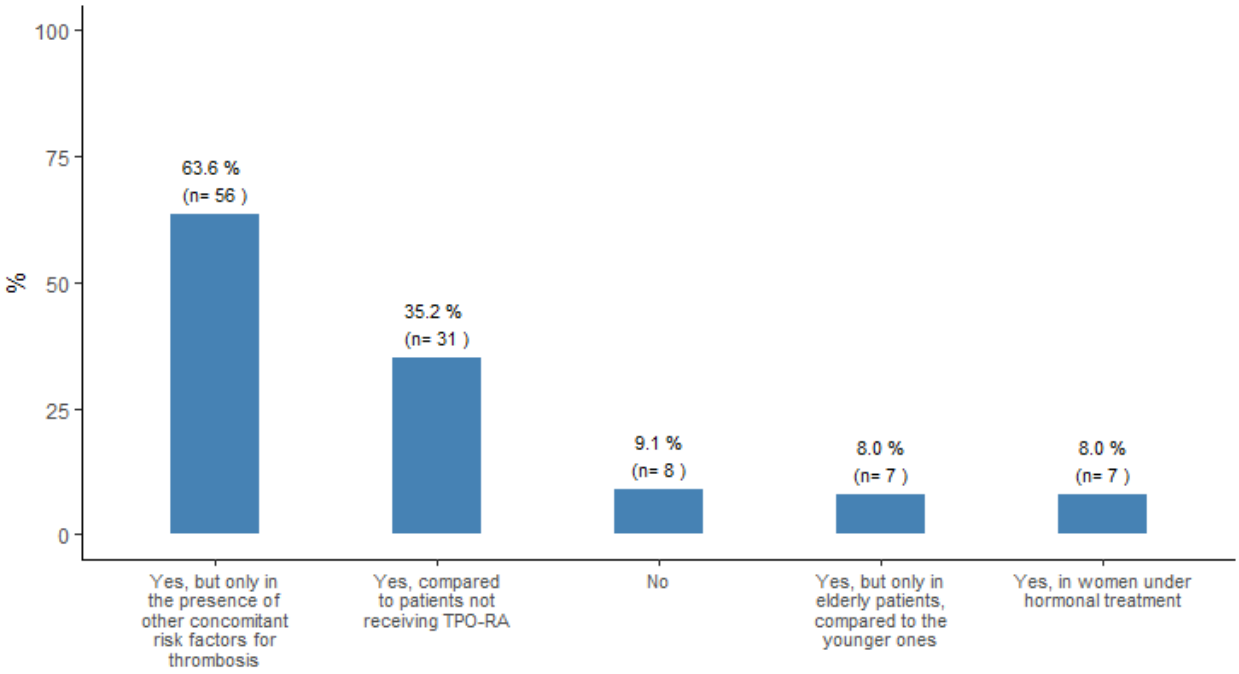


Question 14: During TPO-RA tapering, if platelet count decrease < 50x10^9/L without bleeding diathesis

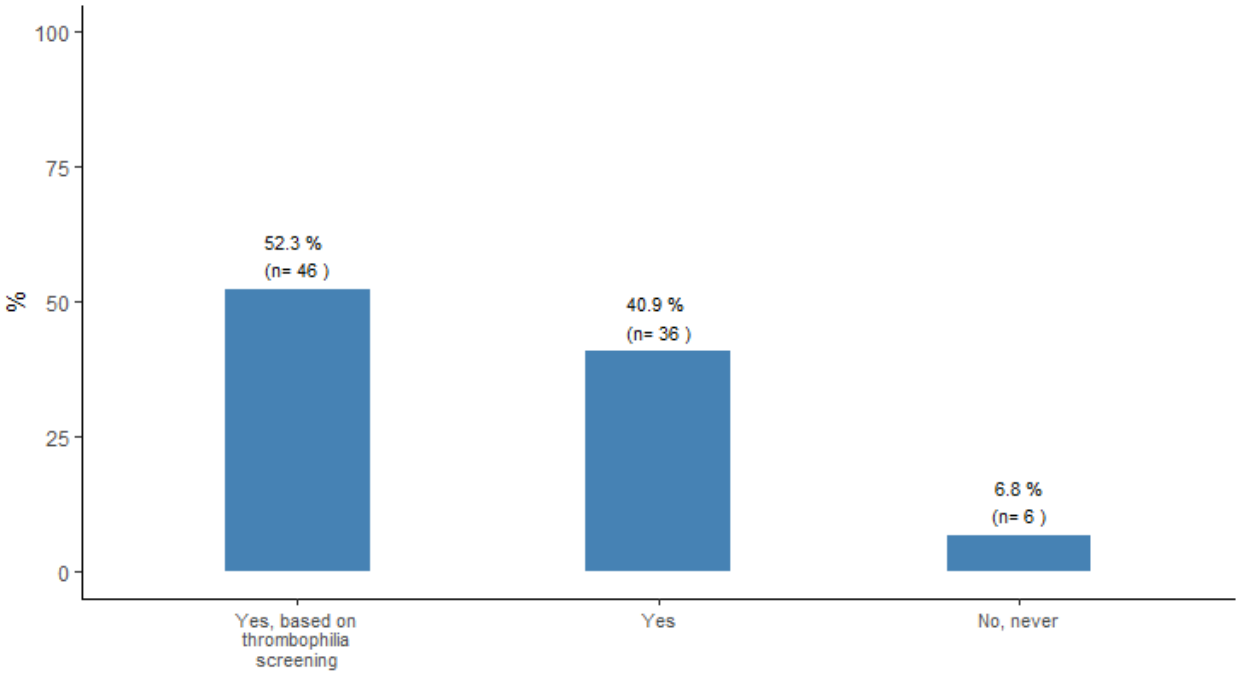


Perceived thrombotic risk associated with TPO-RA

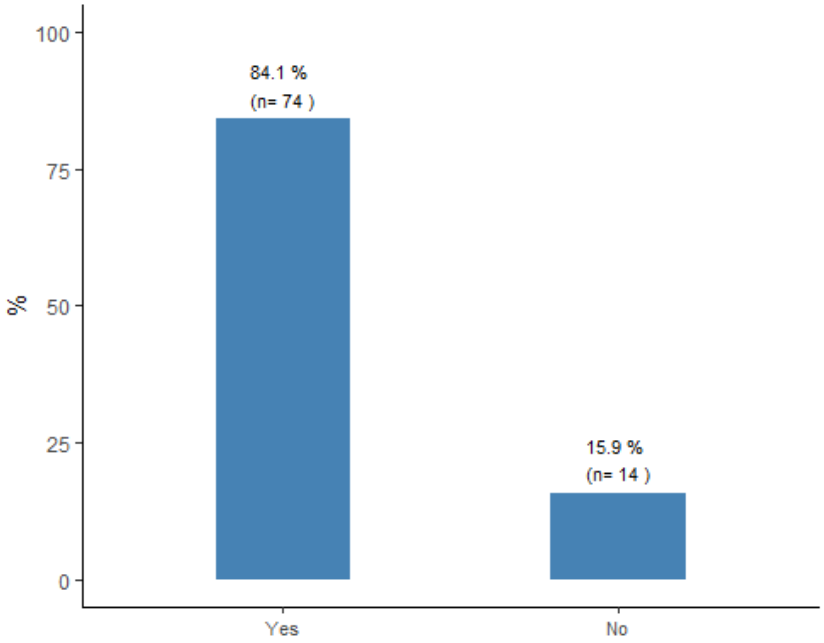
Question 15: Are TPO-RA associated with a higher risk of thrombotic complications? (multiple answers allowed)



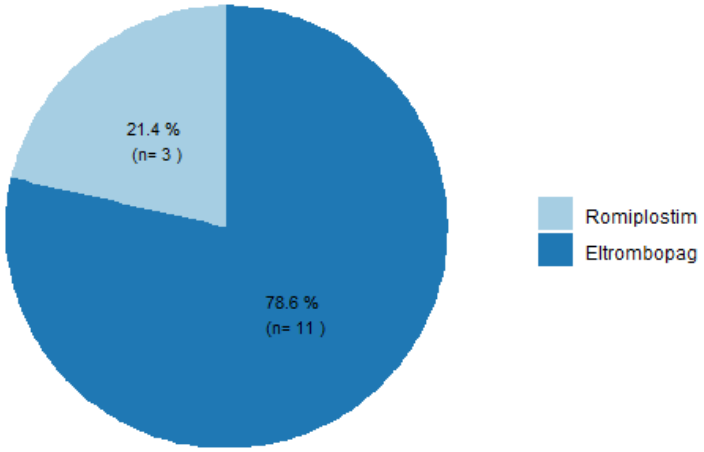
Question 16: Do you take into account the administration of TPO-RA in patients with previous thrombotic events?



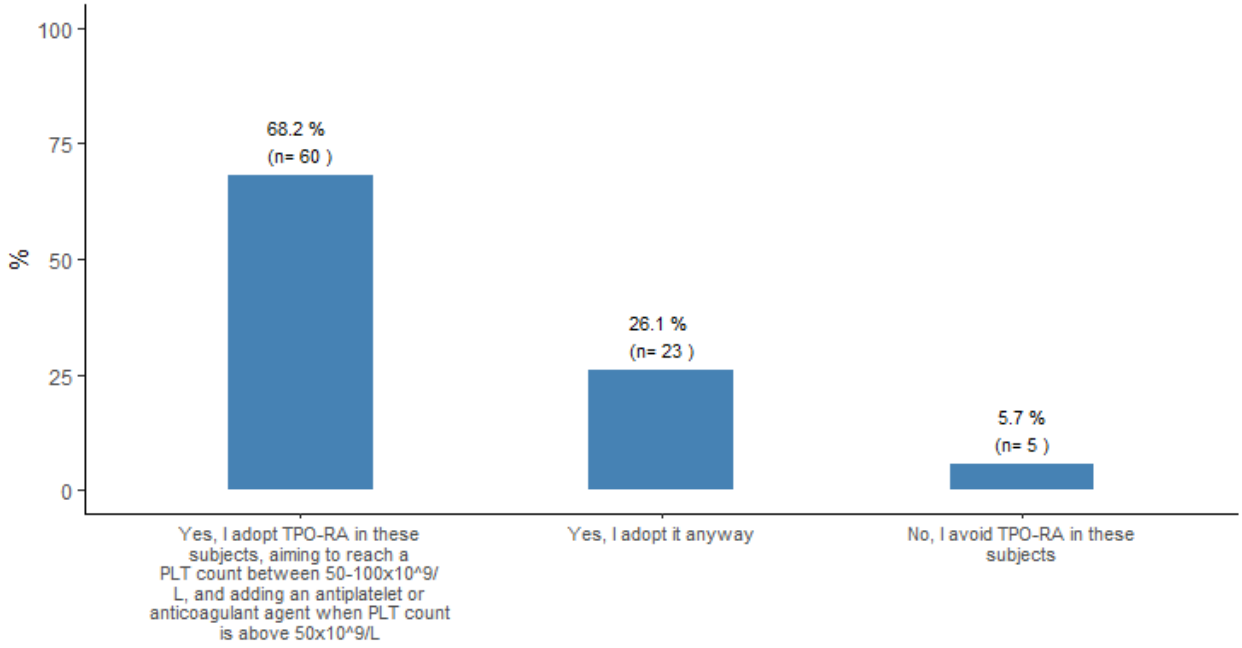
Question 25: Do you think that TPO-RA may induce thrombotic events with the same incidence?



If answer to question 25 is "No", which TPO-RA do you consider is more dangerous?

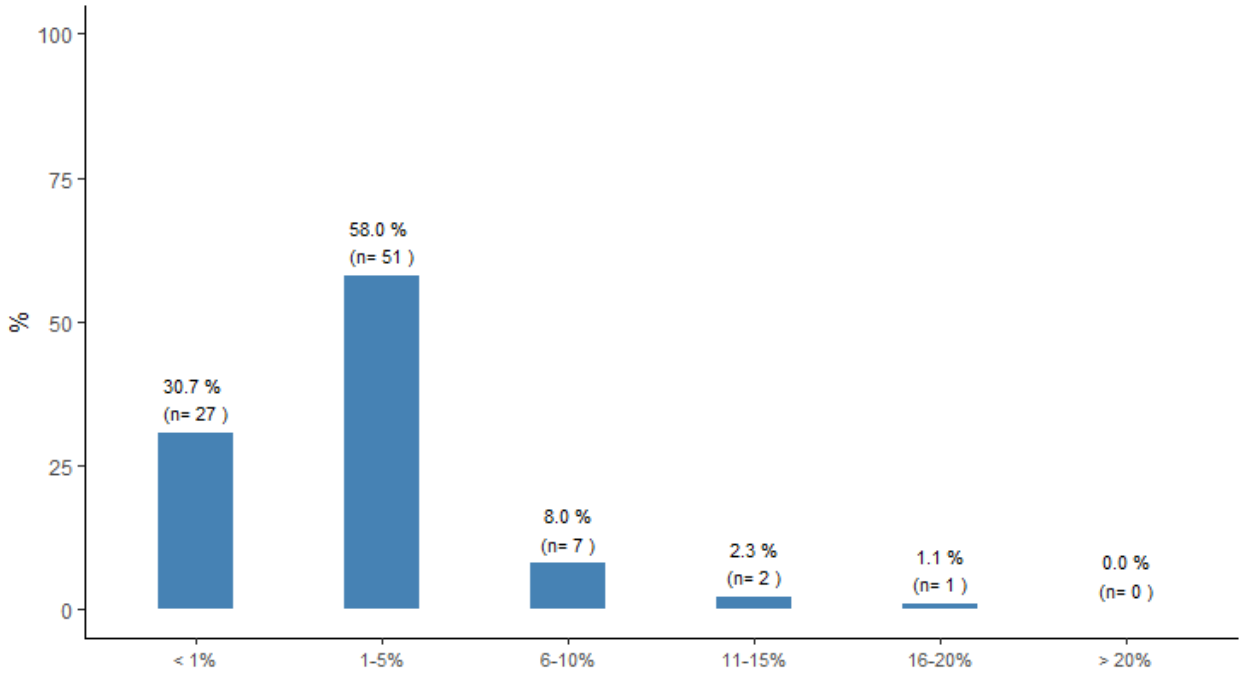


Question 17: Do you administer TPO-RA in elderly patients with other concomitant risk factors for thrombosis, in addition to advanced age?

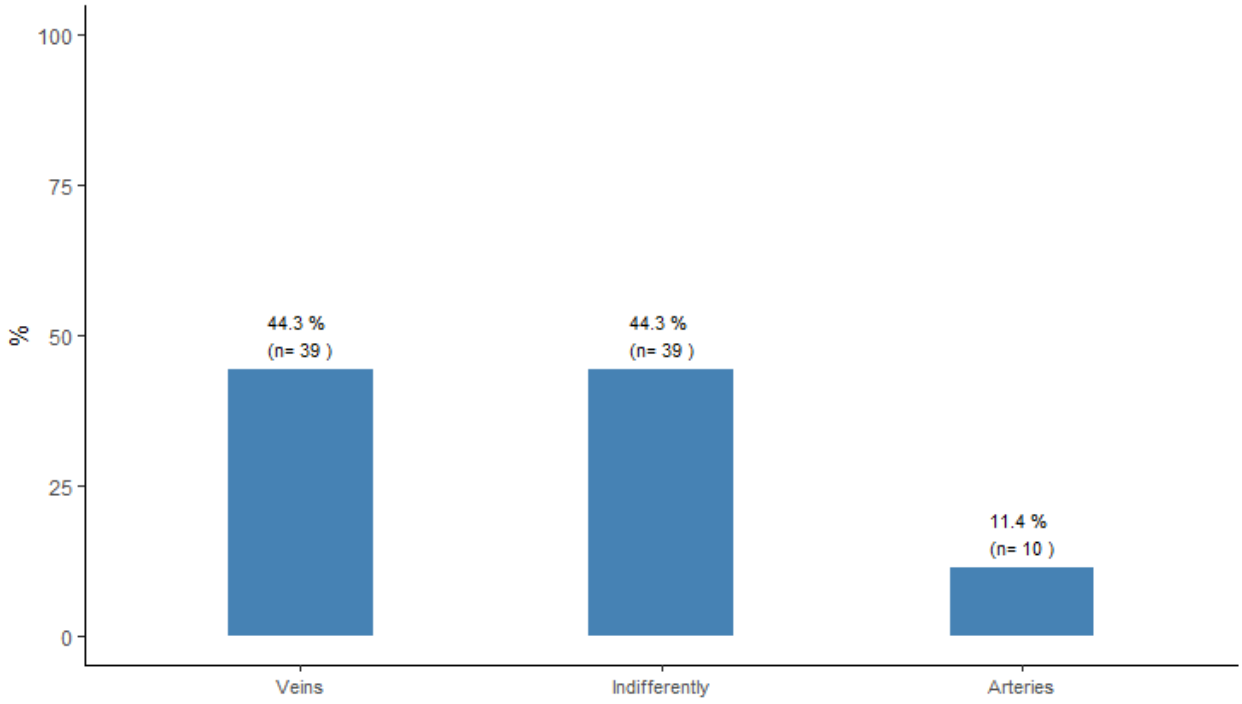


Perceived incidence of thrombosis during TPO-RA treatment and its management

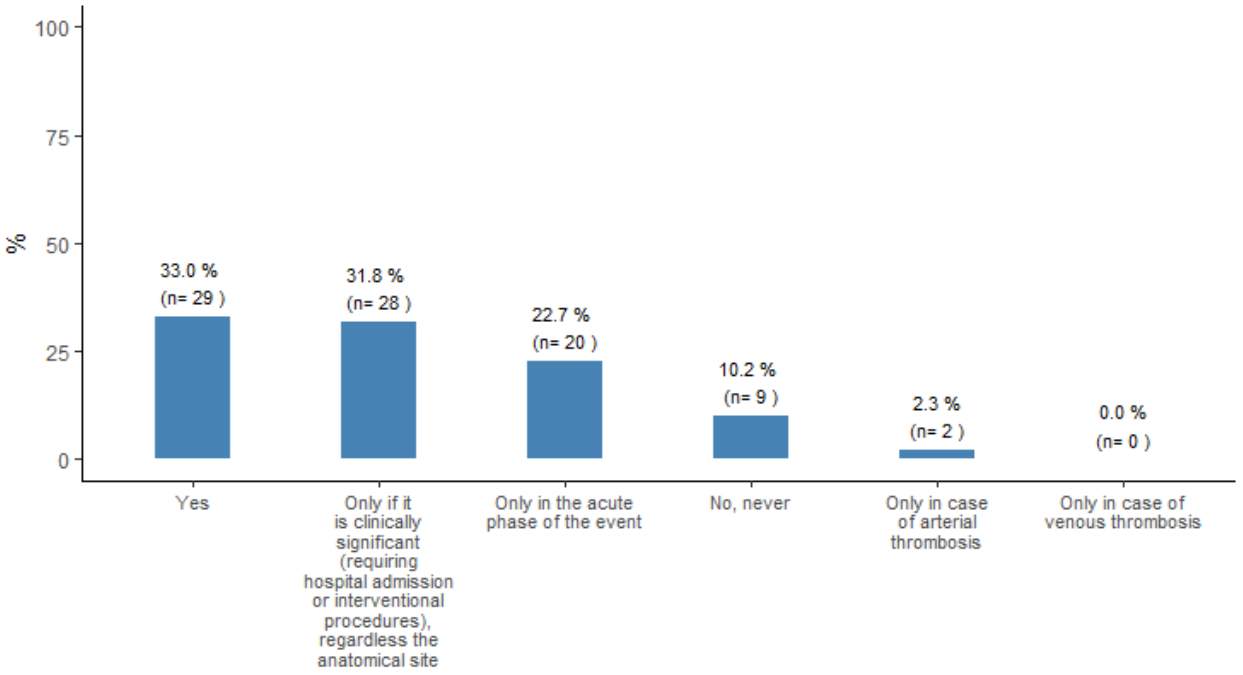
Question 18: What is the mean incidence of thrombotic events you observe in patients treated with TPO-RA?



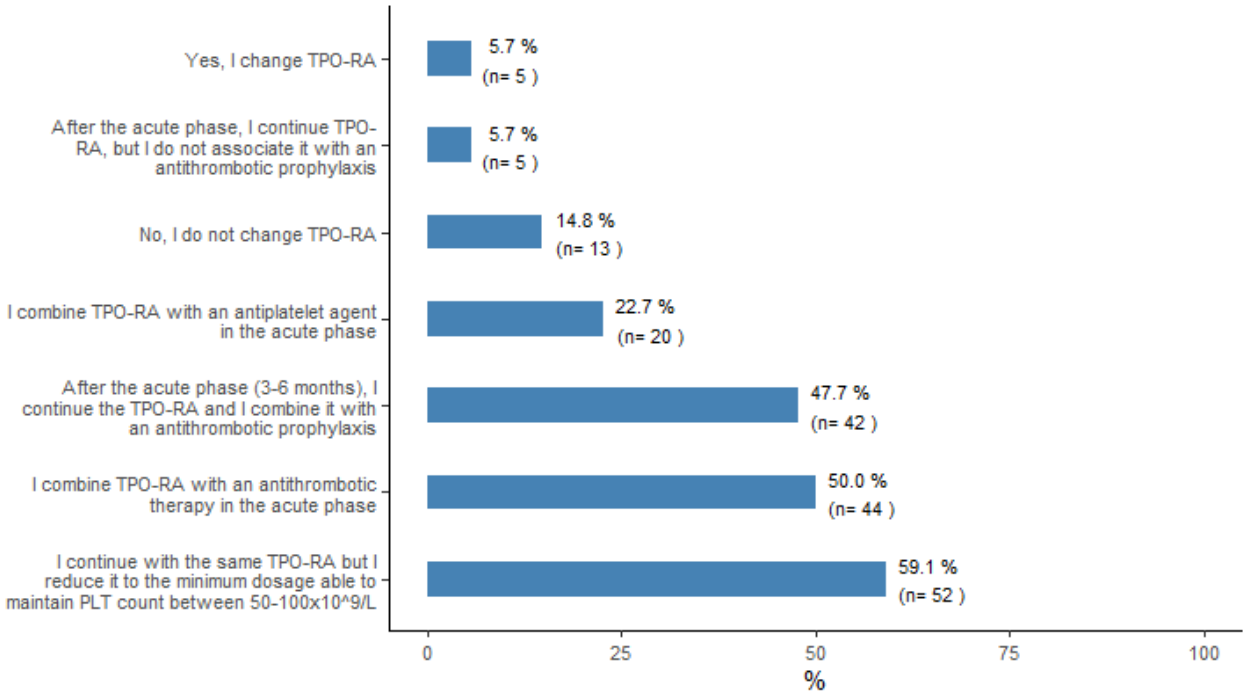
Question 19: Thrombotic events mainly involve



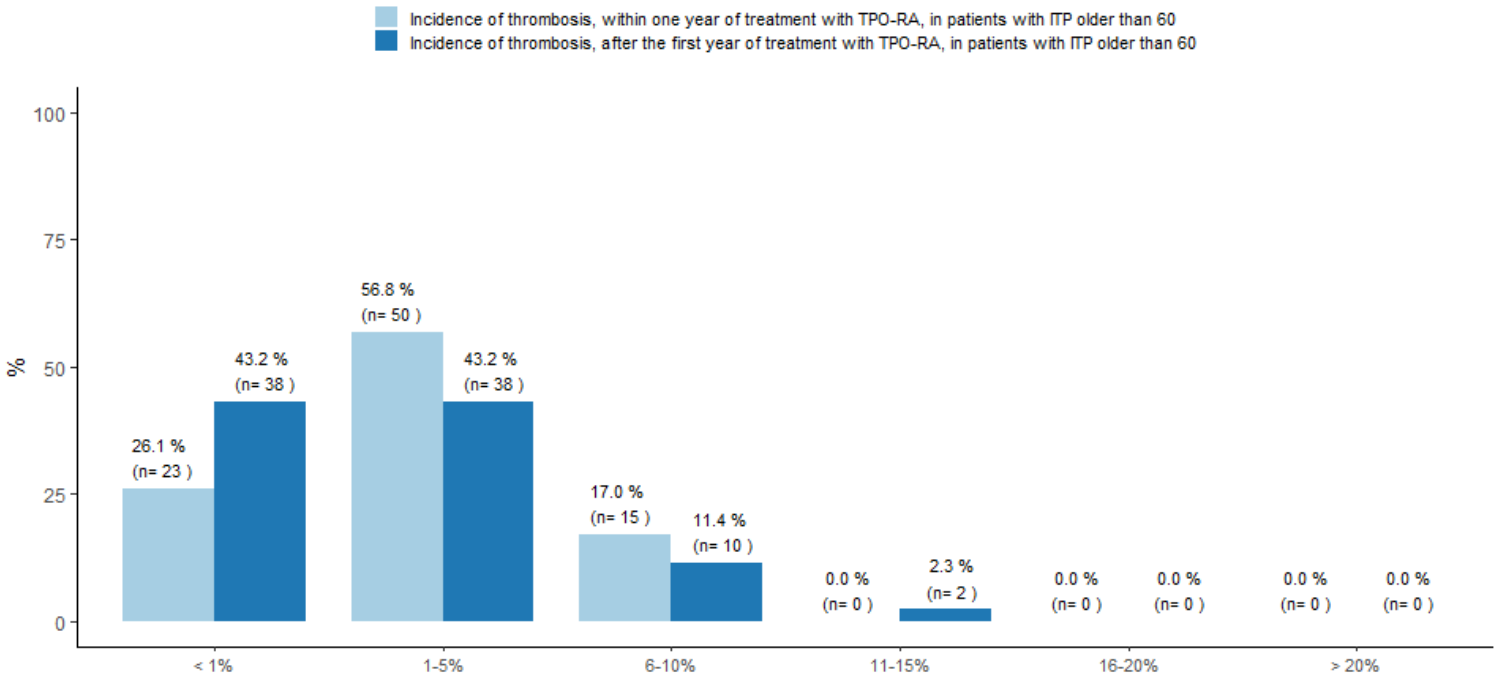
Question 20: Do you discontinue treatment with TPO-RA in patients experiencing a thrombotic event during treatment?



Question 21: If you continue treatment with TPO-RA after a thrombotic event, do you change treatment schedule? (multiple answers allowed)

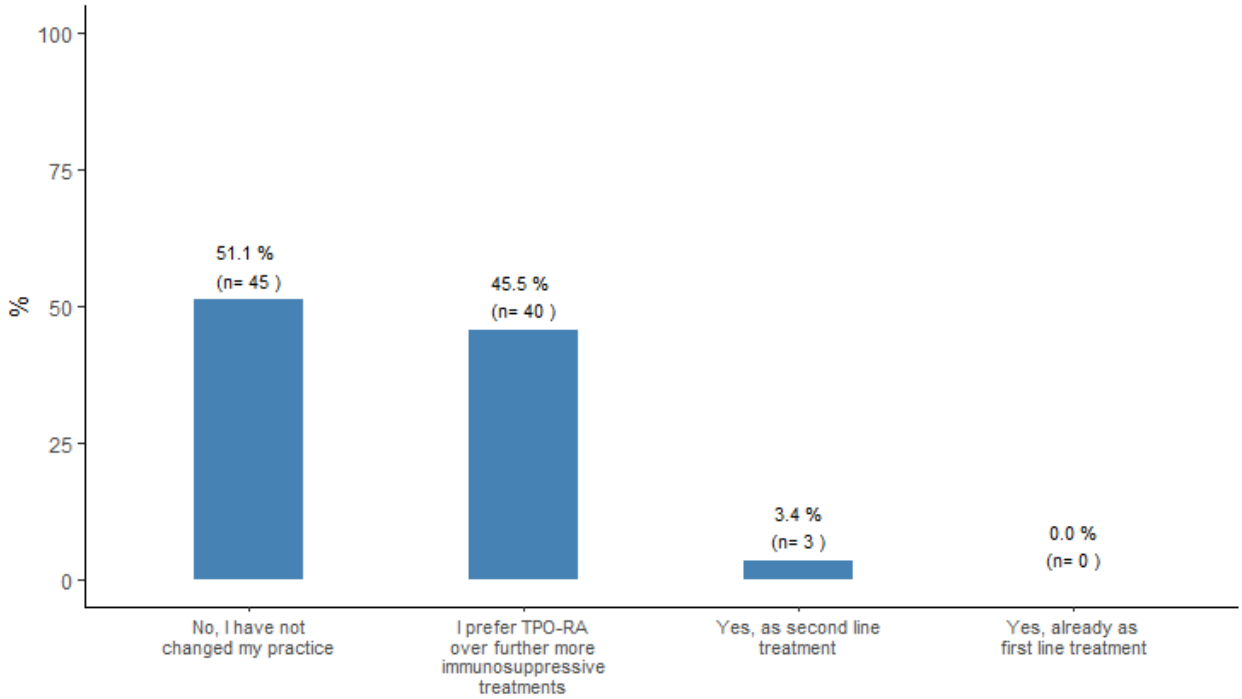


Questions 23-24: According to your personal experience (direct clinical experience or knowledge from the scientific literature), what is the incidence of thrombosis, within one year of treatment with TPO-RA and after the first year of treatment with TPO-RA, in patients with ITP older than 60?



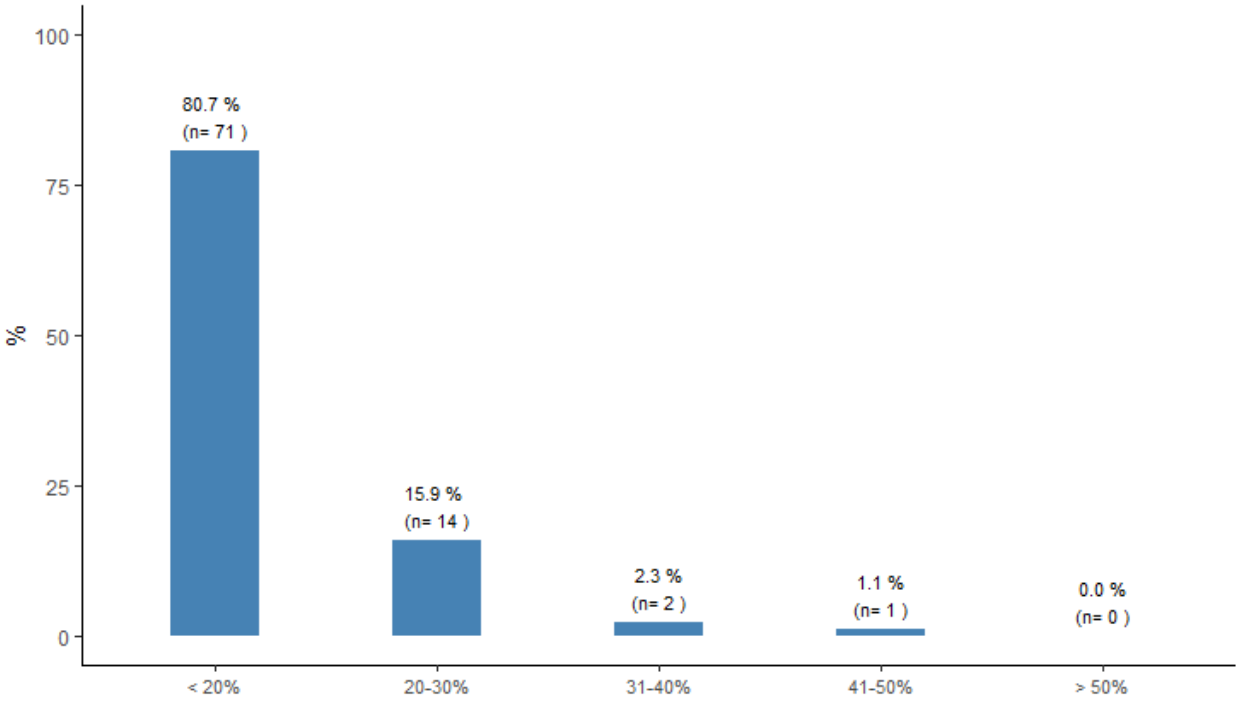
TPO-RA during COVID-19 pandemic

Question 22: During COVID-19 pandemic, do you administer TPO-RA in a different way?

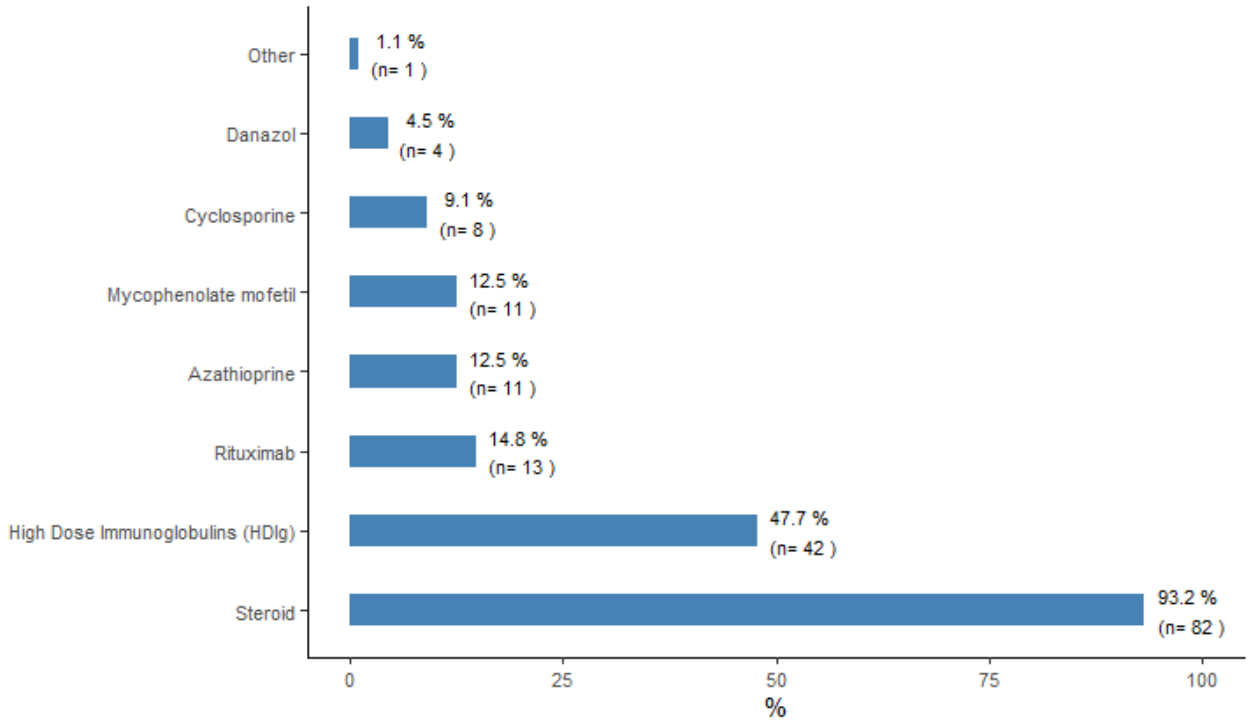


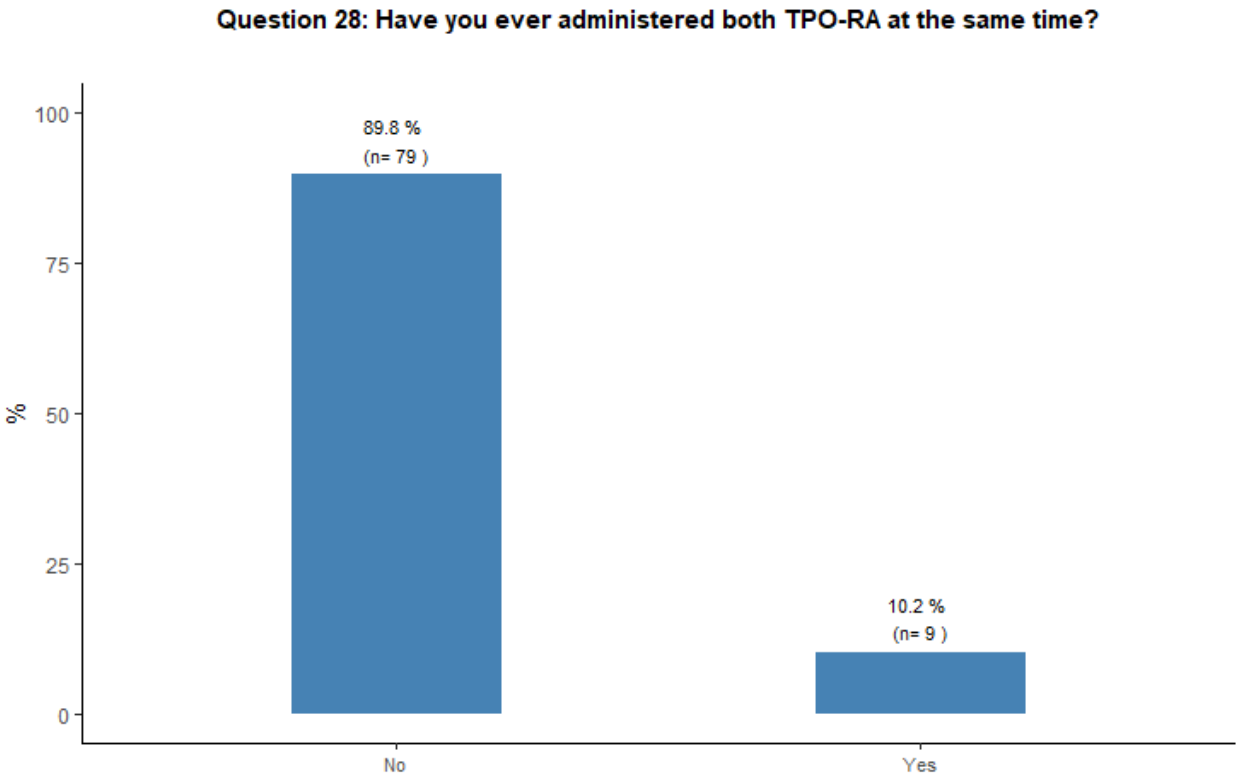
Administration of TPO-RA in combination or associated with other agents

Question 26: In what percentage of cases do you associate another therapy to the TPO-RA?

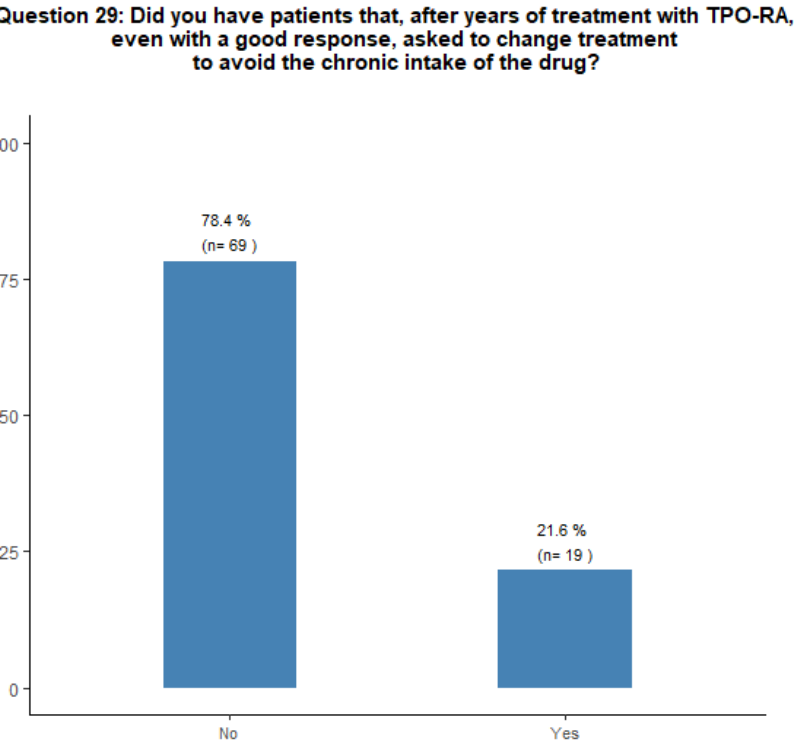


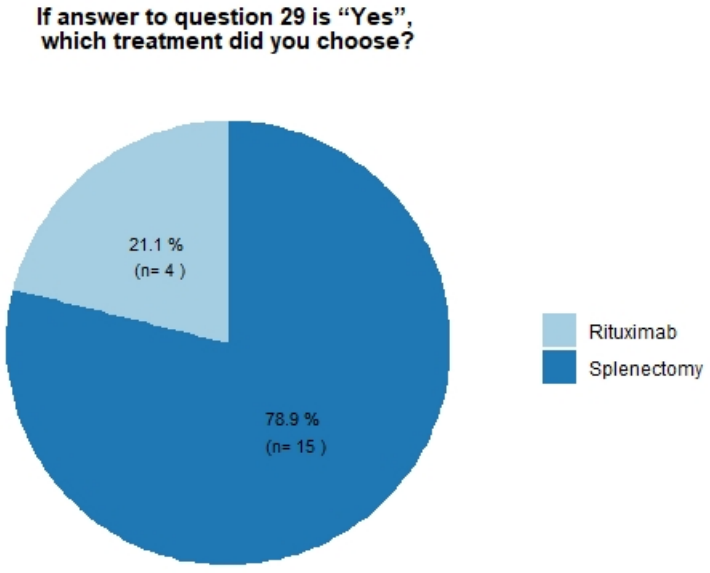
Question 27: Which drug do you administer in association with TPO-RA? (multiple answers allowed)



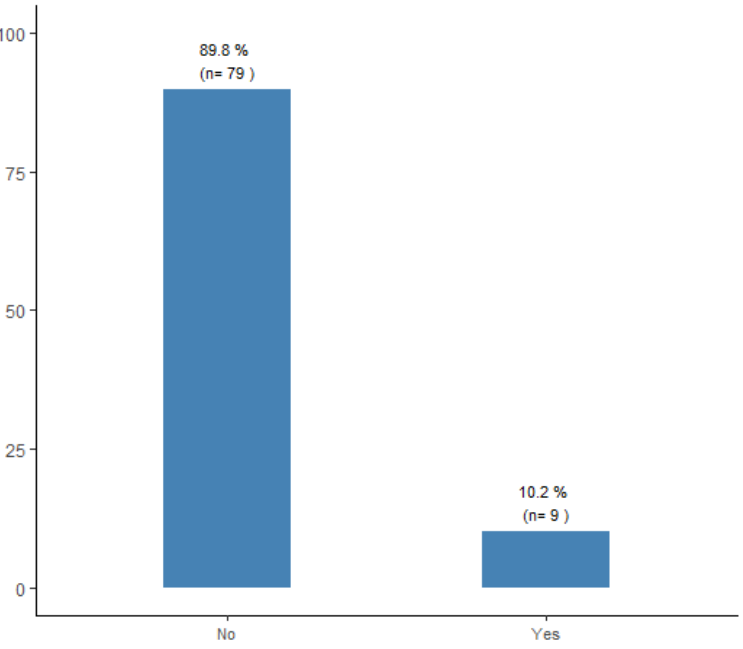


Selected challenging scenarios

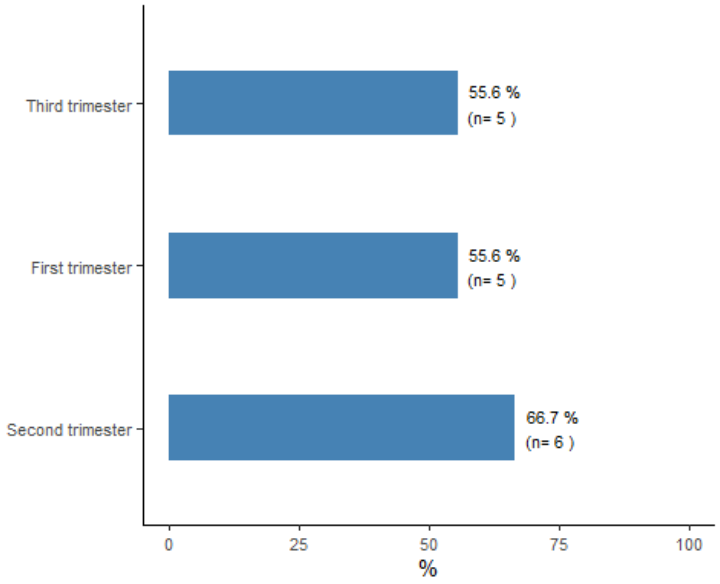




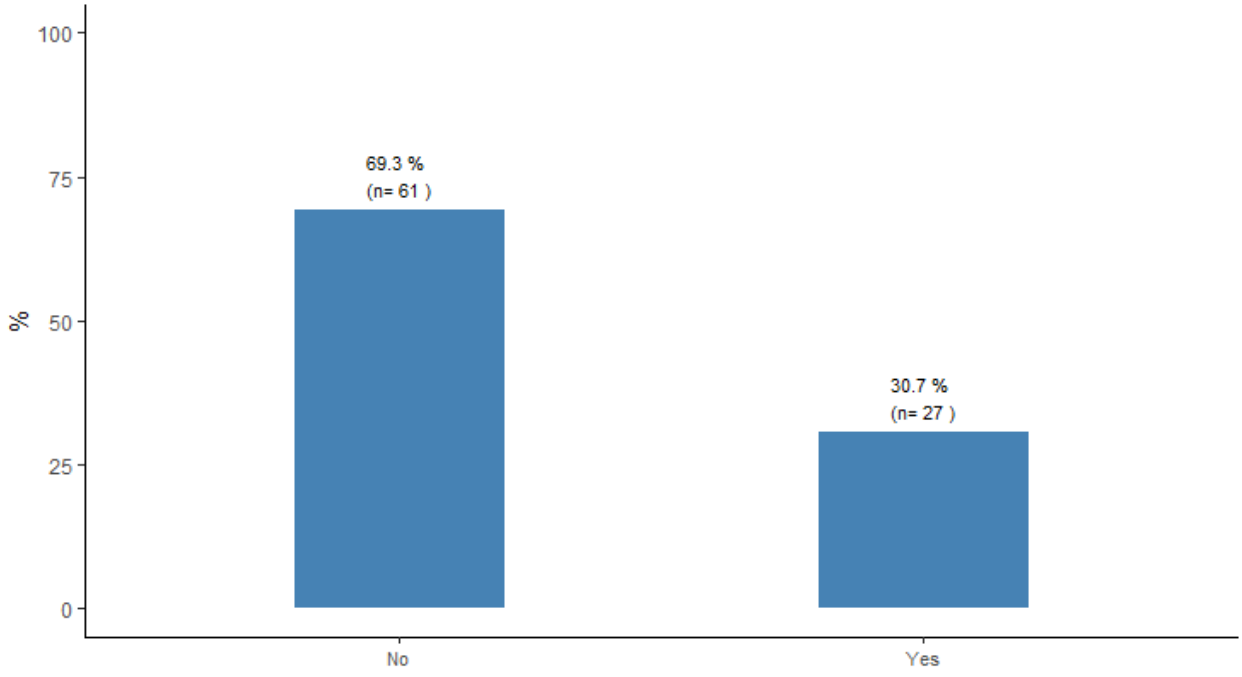
Question 30: Have you ever administered TPO-RA in pregnant women?



If answer to question 30 is "Yes", during the first, second or third trimester? (multiple answers allowed)



Question 31: Do you consider the concomitant detection of antiphospholipid antibodies (APL) an absolute contraindication to TPO-RA administration?



APPENDIX 2

to "Nationwide survey on the use of thrombopoietin receptor agonists (TPO-RA) for the management of immune thrombocytopenia in current clinical practice in Italy"

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*Affiliations refer to the time of completing the survey.