King's Thrombosis Centre

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Thromboprophylaxis in Multiple Myeloma (TiMM) Study: The Patient Perspective

Dr. Zara Sayar

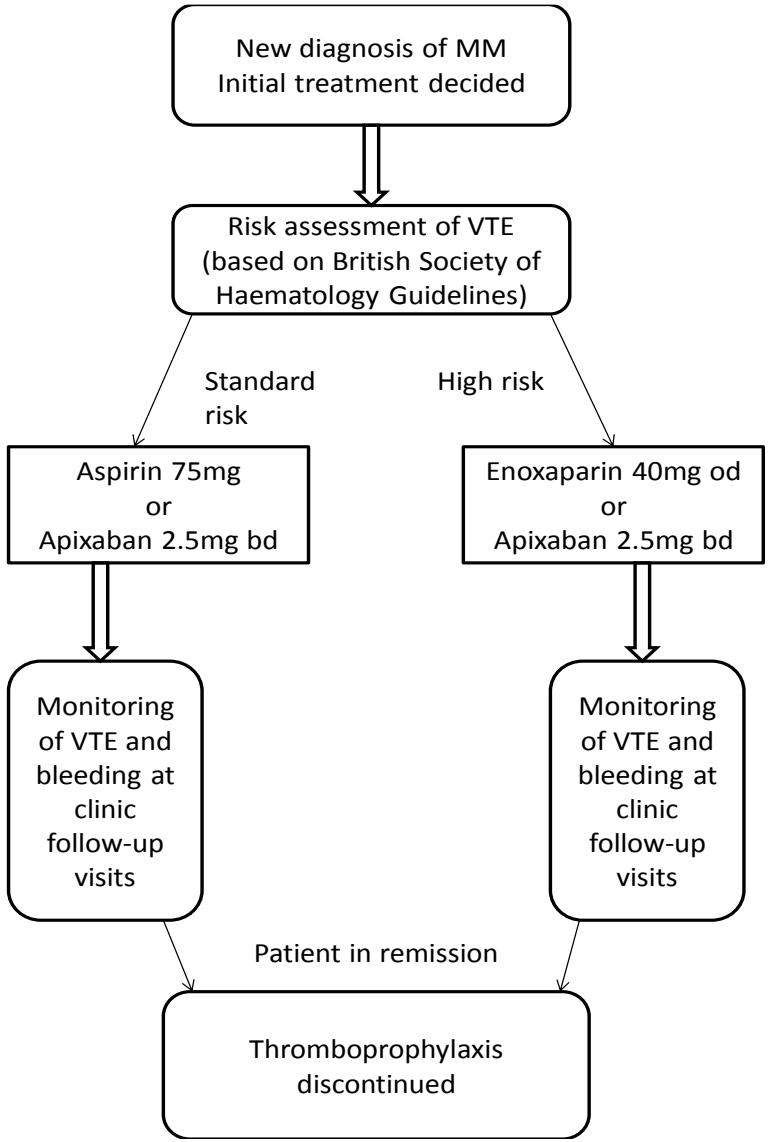
MBChB, MRCP, FRCPath

Overview

- TiMM Study
- Background
- Focus group 1 – how we could improve the study design, views on thromboprophylaxis
- Focus group 2 – review of experience of TiMM and views on thromboprophylaxis
- Conclusions

TiMM Study

- Open label, phase IV feasibility clinical trial
- National institute for Health Research (NIHR) funded
- Open from 12th April 2016 until 21st April 2017



Background

- Myeloma patients are the only ambulatory patients with cancer receiving thromboprophylaxis[1]
- VTE risk in cancer not as well known about as neutropenic sepsis[2] despite second cause of mortality[3]
- Minimal work on preferred route of administration[2]
- No work on thoughts around co-recruitment

1.Lyman GH, Khorana AA, Kuderer NM, Lee AY, Arcelus JI, Balaban EP, et al. Venous thromboembolism prophylaxis and treatment in patients with cancer: American Society of Clinical Oncology clinical practice guideline update. Journal of Clinical Oncology. 2013;31(17):2189-204.2.Noble S, Prout H, Nelson A. Patients' Experiences of LIving with CANcer-associated thrombosis: the PELICAN study. Patient Prefer Adherence. 2015 Feb 24;9:337-45 3. Khorana AA. Venous thromboembolism and prognosis in cancer. Thromb Res. 2010;125(6):490-3.

Aims

- Establish the awareness of thrombotic risk
- Attitudes to co-recruitment to studies
- Explore views and experience of thromboprophylaxis

Methods

- Two separate focus groups for patients and carers
- Focus group guides
- Each lasting an hour
- Recorded, transcribed and analysed using Nvivo 11

Focus Group 1 Discussion Questionnaire Guide

Introductions

Aims: We want to know what your thoughts are on the study we are organising. We would like to know what would encourage you to take part in the study and what would make you less likely to get involved. We are interested in hearing your views on the risk of blood clots in patients with cancer

Information on the Trial:

The study we are planning is looking at patients newly diagnosed with cancer who are starting chemotherapy. As these patients are at higher risk of blood clots they may get some medication to prevent blood clots. If they are at low risk they get aspirin and if they are at high risk they get an injection. We aim to give everyone a relatively new medication called apixaban. If you are low risk you will get either aspirin (once/day) or the study drug (twice/day). If high risk you will get either an injection or the study drug (twice/day tablet)

Questions to cover:

1. What issues do you see with this trial? (15 mins)
   - Would being in 2 trials put you off?
   - Would taking 2 tab twice a day rather than once per day put you off?
   - Thoughts on tablet vs. Injection
   - How can we make it easier for you to participate
2. Views on TP (15mins)
   - Do you view yourself at risk of having blood clots because you have cancer?
   - What do you understand by the term blood clot
   - Do you think blood clots are worrying

Conclusion

Focus Group 2 Discussion Questionnaire Guide

Introduction:

The TiMM trial was a study looking into trying to prevent blood clots in patients with newly diagnosed myeloma. You would have been risk assessed as part of the trial and then randomly allocated to a medication. If you were low risk the options would have been between aspirin and apixaban. Both oral medications but the apixaban was twice per day rather than once per day like aspirin. If you were high risk, you would have been randomly allocated to LMWH or apixaban. Some of you may have been in 2 trials at the same time for example, the CARDAMON study for chemotherapy, and we would be interested to hear how you felt being in 2 trials went for you.

Aims:

We are interested in hearing your views on the TiMM trial that you were part. We want to know what you thought went well and what areas could be improved

Questions/Issues to be discussed:

1. Understand what went well during the clinical trial you participated in
2. Understand what could be improved if we went forward into a larger multicentre trial
3. For those on more than just the TiMM trial: how did you feel about taking part in more than one clinical study at the same time?
4. Understand patients and their carers views of the larger clinical trial plans of the research team

Conclusion

Participants

- Focus Group 1
  - 3 patients (2 females, 1 male)
  - 1 carer (female)
  - Cancer diagnoses: colorectal, breast, leukaemia
- Focus Group 2
  - 2 patients (1 male, 1 female)
  - 1 carer (female)
  - 1 high risk, 1 standard risk

Awareness of thrombotic risk

Knowledge acquired predominantly from non-medical sources

No one remembered a discussion with their physician in FG1

- *'I looked it up afterwards and I couldn't find that……So I don't think it's greatly publicised'* [FG0101]

Overwhelmed at first meeting

- *'Well, if it was, it certainly didn't register anywhere in my brain and then I would have forgotten what was said'* [FG0104]

Those in TiMM had good awareness of risk

Attitudes to co-recruitment: Positive

- *'It makes you feel good about yourself'* [FG0102]
- *'Twice as good'* [FG0102]
- *'…..would prefer to be treated with the newer drug - because they want to be protected'* [FG0103]

Attitudes to co-recruitment: Other comments

Communication between teams

- *'….all I want is a simple word just to explain what's going on and then I can understand. That's all I want'* [FG0201]

Chemotherapy trial more important

- *'….dealing with your cancer, so I suppose just by that nature, you would feel that that was more important to you'* [FG0203]

Views and experience of thromboprophylaxis

Efficacy rather than route

Easier to forget a tablet

- *'I'm youngish but I have problems remembering to take my tablets sometimes'* [FG0104]

Main issue expressed with LMWH: accessing an injectable

If injecting for other reasons - may want to avoid another injection

- *'….dreaded any, you know, extra injections'* [FG0201]

Conclusions

- Those receiving thromboprophylaxis were more aware of thrombotic risks
- Enrolment into TiMM increased awareness of risk of VTE
- Co-recruitment – largely positively viewed
- Oral route of thromboprophylaxis preferred, provided efficacy is the same

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- TiMM investigators

Questions?

Results: Baseline Characteristics

Code	Age (years)	Sex (M/F)	Carer/Patient?	Underlying malignancy	VTE	TP	Participated in the TiMM trial?
Focus Group 1 (FG1)							
FG0101	69	F	Patient	Breast Cancer	Incidental PE during chemotherapy -treated with LMWH		N
FG0102	71	M	Patient	Leukaemia	N/A	N/A	N
FG0103	72	F	Carer	Husband with prostate cancer	N/A	N/A	N
FG0104	66	F	Patient	Colorectal cancer	N/A	Now has AF on warfarin	N
Focus group 2 (FG2)							
FG0201	63	M	Patient	Myeloma	No	Apixaban (high VTE risk)	Y
FG0202	60	F	Carer (Wife) of FG0201	N/A	N/A	N/A	N/A
FG0203	54	F	Patient	Myeloma	Yes – cannula associated thrombus on trial	Aspirin (low VTE risk)	Y