

Deep Vein Thrombosis: resolution, recurrence and post-thrombotic syndrome

UH Bristol Research Day
4th December 2015

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NIHR/CSO Healthcare Science Research Fellowships

Doctoral Research Fellowship

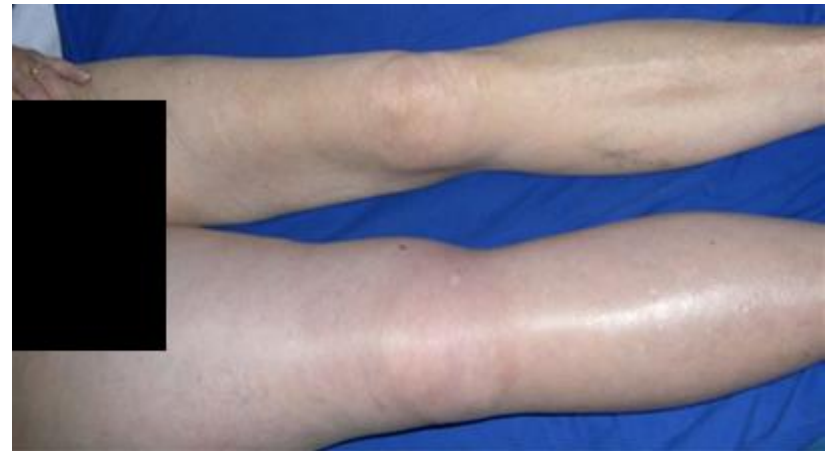
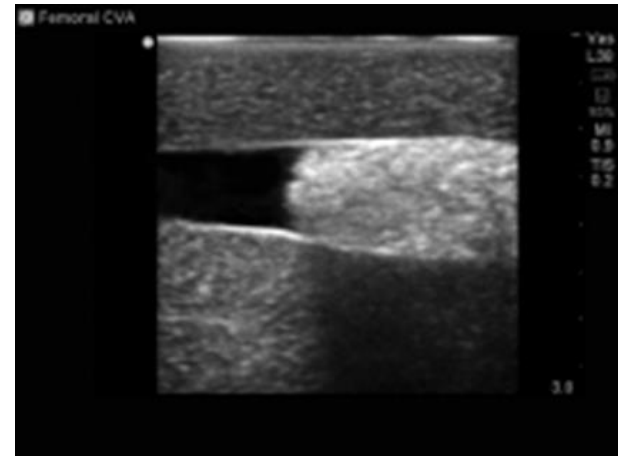
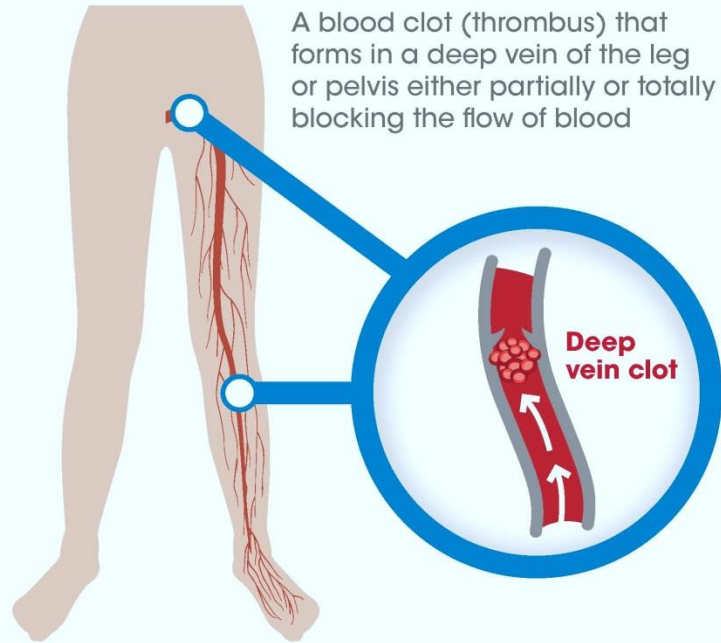
- 3 years FT (4 or 5 years PT)
- Must be employed by NHS & supported by academic partner
- Must have completed professional training (HCPC)
- Need to register PhD at HEI
- Research experience and/or training (e.g. MSc, BSc, publications)

Award covers: salary, direct research costs; training & development costs and tuition fees (doctoral)

Deep Vein Thrombosis (DVT)

What is Deep Vein Thrombosis (DVT)?

A blood clot (thrombus) that forms in a deep vein of the leg or pelvis either partially or totally blocking the flow of blood



Post thrombotic syndrome

Symptoms:

- Pain
- Heaviness
- Itching
- Oedema
- Ulceration



- Chronic condition
- Difficult to treat
- Can become established as soon as 2 years after DVT
- 20 - 50% patients with DVT develop PTS within 2 years

Rationale for Research

The three questions most commonly asked by patients with a DVT are:

1. When will it go away?
2. Will I get it again?
3. Will it do any permanent damage?



Not every patient that has a DVT will develop a recurrent DVT or PTS but there is a lack of research evidence to indicate which patients will, making these difficult questions to answer.

Project Overview

To identify the key factors that predict recurrent deep vein thrombosis and the development of post thrombotic syndrome to inform future intervention research.

PHASE 1

Systematic literature review – identify evidence base for risk factors for DVT recurrence and the development of PTS.

PHASE 2

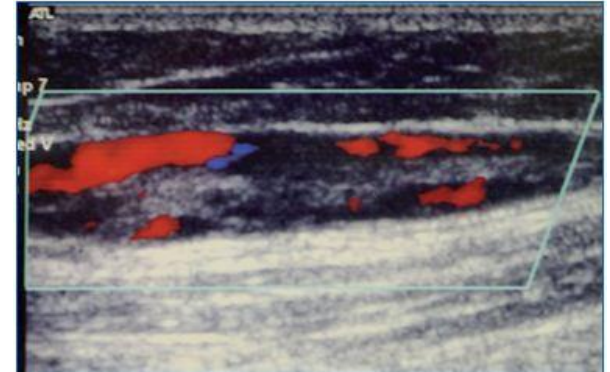
Consensus study – identify potential risk factors not revealed by literature review & explore which factors experts believe are most influential.

PHASE 3

Prospective observational study – variation in DVT resolution, patient outcomes & examination of predictive risk factors for the development of recurrent DVT and PTS.

Phase 3: Observational Study

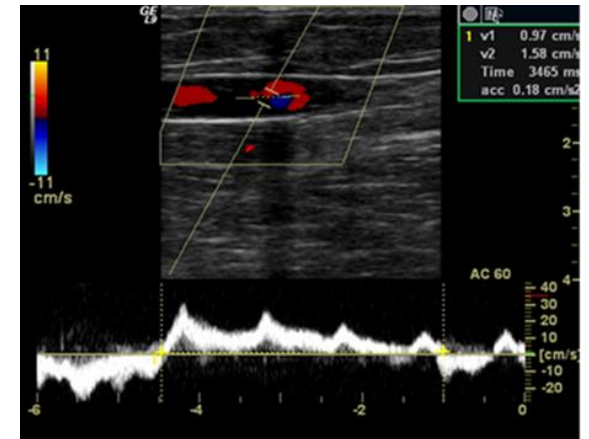
- Using ultrasound imaging to examine :
 - Changes in thrombus characterisation over time
 - How quickly the DVT resolves
 - Resolution extent by end of treatment
 - Any damage caused to the vein valves
 - Any extension to original DVT
 - Any recurrence during follow up period



- 2 groups:

Patients with first episode of DVT

Patients with previous ipsilateral DVT



- 6 visits over 2 years: 1 week, 1 month, 3 months, 6 months, 1 year, 2 years

Data Analysis



- **Primary endpoints:**
 - DVT resolution
 - Recurrence
 - Development of PTS

- **Logistic regression - identify variables to best predict DVT recurrence &/or PTS**
- **Probability of recurrence & PTS estimated using survival analytical methods (Kaplan and Meier & Cox regression) to investigate coefficients of predictor variables**



Recruitment



83 declined:

4305 patients scanned for DVT

1023 +ve DVT

276 patients met inclusion criteria

193 patients recruited to study:

- **169 First episode of DVT**
- **24 Previous ipsilateral DVT**

= 70% Recruitment Rate

Carer for dependent	8
Did not want to give reason for decline	21
Does not want to come back to hospital for follow up	12
Geographical	11
Does not feel well enough to attend for follow up	8
No time for follow-up	22
Found scan too painful	1

Participants



118 Male and 75 female

Age range 21-85 years (mean 56 years, median 57 years)

36 current smokers, 67 ex-smokers, 90 never smoked

10 NIDDM, 4 IDDM, 179 no diabetes

52 hypertension, 141 no hypertension

2 heart failure, 191 no heart failure

Treatment: 29 Clexane then warfarin, 160 NOACS, 2 aspirin only, 2 NOACS then warfarin (drug reaction)



DEMOGRAPHICS

Retention

5 patients have missed one appointment

8 patients are off study:



3 deceased:

- 1 Heart Failure
- 1 MI and PE
- 1 Cancer

5 withdrew:

- 1 too unwell
- 1 caring for husband
- 1 unable to find time
- 2 did not give reason



75/81 patients with first episode of DVT have completed 1 complete year of follow up (no gaps).

Of the 6 that have not: 3 deceased, 1 withdrew, 2 missed 1 year F/U appointment).

19/19 patients with previous ipsilateral DVT have completed 6 complete months of follow up (no gaps).

The road ahead

- Half way through – time flies!
- December 2015 stop recruiting new patients
- February 2016 first patients recruited to study complete 2 years follow up



- January 2017 - 1 year data analysis for all participants
- December 2017 all patients to complete follow up.
- December 2017-April 2018 Final data analysis & complete write up