

## **Supplemental materials for:**

**Mumoli N, Vitale J, Giorgi-Pierfranceschi M, et al. General practitioner-performed compression ultrasonography for diagnosis of deep vein thrombosis of the leg: a multicenter, prospective cohort study. *Ann Fam Med.* 2017;15(6):536-539.**

# Supplementary Appendix:

**(PRACTICUS) study, (ClinicalTrial.gov NCT02114983)**

**PRACTI**tioner-performed

**C**ompression

**U**ltra

**S**onography in the diagnosis of proximal symptomatic deep vein thrombosis of the lower limbs

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## Steering Committee

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- Josè Vitale, M.D., Department of Internal Medicine, Ospedale Beata Vergine di Mendrisio, Ticino, Switzerland
- Renato Tulino, M.D., Primary Care; Porto Santo Stefano, Grosseto, Italy
- Silvia Sabatini, M.D., Primary Care; Livorno, Italy
- Matteo Giorgi-Pierfranceschi, M.D., Emergency Medicine Department, Ospedale della Val d'Arda, Piacenza, Italy
- Marco Cei, M.D., Department of Internal Medicine, Ospedale di Cecina; Livorno, Italy
- Daniela Mastroiacovo, M.D., Angiology Unit, ASL 1 Avezzano Sulmona L'Aquila, Avezzano (AQ), Italy
- Francesco Dentali, M.D.; Department of Internal Medicine, Ospedale di Circolo, Varese; Insubria University, Italy

## **Vascular centers, Investigators and Ultrasound equipment**

### **- Livorno, Italy:**

**Expert Physicians in vascular ultrasound:** Nicola Mumoli, M.D.; Stefano Giuntoli, M.D.; Giovanni Carmignani, M.D.; Lorenzo Bocci, M.D.;

**General practitioner investigators:** Silvia Sabatini, M.D.; Laura Trinci, M.D.; Carolina Manni, M.D.; Sara Bolognese, M.D.; Daniela Talarico, M.D.; Giulio Rosellini, M.D.; Lorenzo Luschi, M.D.; Fabrizio Cosci, M.D.; Rosanna D'Apice, M.D.; Luca Puccetti, M.D.; Renato Tulino, M.D.;

**Ultrasound machines:** GE, Logiq E9, 5-10 Mhz probe; Esaote MyLab Seven, 3-11 Mhz probe; GE, Vivid S5, 7 Mhz probe.

### **-Cosenza, Italy:**

**Expert Physician in vascular ultrasound:** Carlo Bova, M.D.;

**General practitioner investigator:** Antonio Arcuri, M.D.;

**Ultrasound machine:** GE, Logiq E9, 5-10 Mhz probe

### **-Piacenza, Italy:**

**Expert Physician in vascular ultrasound:** Matteo Giorgi-Pierfranceschi, M.D.;

**General practitioner investigators:** Sara Bottazzi, M.D.; Greta Gregori, M.D.;

**Ultrasound machine:** Esaote MyLab 30 gold, 7 Mhz probe;

### **-Avezzano (Aquila), Italy:**

**Expert Physician in vascular ultrasound:** Daniela Mastroiacovo, M.D.;

**General practitioner investigators:** Antonio Camerota, M.D.;  
Nicoletta Dell'Elce, M.D.;  
**Ultrasound machine:** Acuson Sequoia 512, 7 Mhz probe

**-Ravenna, Italy:**

**Expert Physician in vascular ultrasound:** Eugenio Bucherini, M.D.;  
**General practitioner investigators:** Juliana Mourao Pires, M.D.;  
Fabrizia Farolfi, M.D.;  
**Ultrasound machines:** Acuson X300, 7 Mhz probe; Philips, EnVisor,  
5-7 Mhz probe

## Inclusion Criteria

- Men or women, 18 years of age or older
- First episode of DVT
- Clinically suspected DVT freely assessed by every single physician on the basis of medical history and clinical picture of the patient
- Medical history suggestive of DVT: active cancer, bedridden for more than 3 days, recent (< 4 weeks) major surgery or hospitalization, family DVT history, paralysis of the lower limbs, estroprogestinic therapy or other hormonal therapy, thrombophilia, long travel, obesity, older age, chemotherapy, nephrotic syndrome, polycythemia, severe autoimmune diseases.
- Clinical picture suggestive of DVT: pain or local tenderness in lower limb, entire leg swelling, calf swelling, asymmetric pitting edema, collateral superficial veins distention, asymmetric signs or symptoms, Bauer and Homans signs, unilateral cyanosis of entire leg, unilateral circumferential increasing, local warmth, redness or discoloration.
- Signed informed consent

## Exclusion Criteria

- Age less than 18 years
- A previous objectively documented episode of venous thromboembolism
- Predominant symptoms of pulmonary embolism
- Pregnancy
- Life expectancy less than 3 months
- Ongoing mandatory anticoagulant treatment
- Symptoms lasting for more than 2 weeks
- Geographic inaccessibility for follow-up
- Anticipated low-compliance
- Refusal of written informed consent





Section & Topic	No	Item	Reported on page #
<b>STARD (Standards for Reporting of Diagnostic Accuracy Studies)</b>			
<b>TITLE OR ABSTRACT</b>			
	<b>1</b>	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	1
<b>ABSTRACT</b>			
	<b>2</b>	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	2
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	<b>7</b>	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	5
	<b>8</b>	Where and when potentially eligible participants were identified (setting, location and dates)	5
	<b>9</b>	Whether participants formed a consecutive, random or convenience series	5
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	<b>10b</b>	Reference standard, in sufficient detail to allow replication	6
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	<b>13a</b>	Whether clinical information and reference standard results were available to the performers/readers of the index test	5
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## Training Protocol

The ultrasonographic course, provided by our study for the training of general practitioners in the diagnosis of DVT of the lower limb, had a total period of two months.

- Physicians attended the first 12 hours of lectures (6 hours per month) addressing: the venous anatomy of the lower limbs, the principles and the ultrasound technique, deep vein thrombosis, the normal and the pathological sonographic appearance of femoral and popliteal vein.

The learning material (books, manuals and slides) was available from the individual vascular centers.

- During the second session dedicated to the acquisition of practical skills, the trainees were kept under control by their tutors (experienced sonographers with various types of professional experience).

In order to give the trainee sufficient time to learn and run independently the ultrasound compression, each practitioner had to complete at least 15 hours per month.

In the first month, every GP performed the CUS in at least 30 patients (in particular, in 15 selected patients with proximal DVT and in 15 healthy controls) previously tested by his tutor.

In the second month of training, at least 30 CUS were performed first by the GPs. Subsequently, the result of each test was confirmed and validated by their tutors.

- Finally, eight hours of training were devoted to interactive lessons designed to discuss a number of clinical cases, improve the competence related to other differential diagnoses and to review vascular ultrasound images and video clips.

## Board-certification

Experts in vascular ultrasound have all earned at least an ultrasound vascular certification through national and international companies of ultrasonography (SIEC, SIUMB, EFSUMB, WINFOCUS, SIMEU). Their recognition provides for the execution of at least 500 tests to get a diploma and a minimum of 300 examinations a year to maintain the excellence and be able to continuously update.

In particular our Expert in vascular ultrasound group are:

-Livorno: Nicola Mumoli, MD has more than 15 years of experience in vascular ultrasonography (more than 1000 exams per year); Stefano Giuntoli, MD has more than 10 years of experience in vascular ultrasonography (more than 500 exams per year); Giovanni Carmignani, MD has more than 10 years of experience in vascular ultrasonography (more than 500 exams per year); Lorenzo Bocci, MD has more than 15 years of experience in vascular ultrasonography (more than 700 exams per year).

-Cosenza: Carlo Bova, MD has more than 15 years of experience in vascular ultrasonography (more than 500 exams per year).

-Piacenza: Matteo Giorgi-Pierfranceschi, MD has more than 10 years of experience in vascular ultrasonography (more than 600 exams per year).

-Avezzano (Aquila): Daniela Mastroiacovo, MD has more than 7 years of experience in vascular ultrasonography (more than 1500 exams per year).

-Ravenna: Eugenio Bucherini, MD has more than 15 years of experience in vascular ultrasonography (more than 1200 exams per year).

**Table S1: CUS Agreement**

CUS		Expert in Vascular Ultrasound		total
		positive	negative	
General Practitioners	positive	180	26	206
	negative	20	881	901
total		200	907	1107

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