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1 Clinical Appropriateness in the Suspicion of Venous Thrombosis 2 of the Lower Limbs in the Emergency Department

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6 **Abstract**

7 Methods: The purpose of this study is to report and analyze the experience gained over ten
8 years on patients sent to the emergency department of reference for the area with the
9 presumed diagnosis of deep or superficial vein thrombosis of the lower limbs. From March
10 2001 to December 2011, 30350 patients were examined as an emergency; all underwent an
11 accurate medical history, for the evaluation of the Wells score, and venous Doppler ultrasound
12 examination of the lower limbs, with detailed CUS technique, only on the affected lower limb.

13

14 **Index terms—**

15 **1 INTRODUCTION**

16 The significant and rapid development of non-invasive diagnostic equipment led to the design of the ecocolor-doppler, a tool that has now taken a key role both in the diagnosis and follow-up of the venous "vascular patient".
17 The validity of the ultrasonography (US) approach is well established in the diagnosis of thrombotic diseases,
18 either deep or superficial, by several worldwide clinical trials. Indeed, only a few cases are left to contrast-based
19 tests. Thus, the US test is the diagnostic method recognised by worldwide Guidelines as the gold-standard
20 in venous diseases (Grade A), while venography should be considered only in a small number of patients with
21 anatomical anomalies, malformations or when there is an indication for surgery on the deep venous system (Grade
22 B) 1.

23 Deep vein thrombosis (DVT), and the thromboembolic complications that may ensue (pulmonary embolism,
24 PE), is a potentially fatal disease, which often complicates the clinical London Journal of Medical and Health
25 Research course of patients already suffering from other diseases, but is also able to affect apparently healthy
26 individuals.

27 Healthcare providers and institutions must therefore be made aware of the need for citizens who develop
28 symptoms consistent with DVT to be urgently referred to an appropriate diagnostic workup in order to ascertain
29 the presence or absence of the disease. This is a prerequisite to make it possible to establish a timely and effective
30 anticoagulant therapy capable of reducing the morbidity and mortality associated with acute thrombotic event,
31 the incidence of relapses and remote sequelae.

32 For this reason the "Diagnosis of venous vascular urgency," service has been active for about ten years, with a
33 specialist physician available every day from 8 am to 8 pm, at the Centre for Phlebology of the University
34 of Siena, whose task is to visit patients sent from the ER with a diagnosis of ongoing acute phlebopathy.

35 The purpose of this study is to report and analyze the experience gained over ten years with patients sent to
36 the emergency room of the Santa Maria alle Scotte Hospital (Siena) with the presumed diagnosis of deep vein
37 (DVT) or superficial (TVS) thrombosis of the lower limbs. The considered patient pool had a mean age of 65
38 years, ranging between 3 and 98 years, and if the seventh decade was the most representative for the female
39 population, for the male it was the sixth. The requests sent to a trusted phlebology specialist turned out by
40 75,2% to be suspected DVT, 17.8% VBS and 7% other related diseases, with a slightly higher percentage in the
41 right lower limb (52% right vs. 48% left). The ECD test was performed with the patient in the supine position
42 for the investigation of the proximal femoral artery, and then in the prone position (with one leg above the other,
43 alternately) for the popliteal portion and finally in a sitting position on the edge of the bed to examine the distal
44 deep veins (stretching the veins promotes the display of anatomical detail). The posterior tibial compartment is
45

5 III. RESULTS

46 visualised in the medial retromalleolar region, mostly in cross section, and the veins are displayed by squeezing
47 the sole of the foot, while the anterior tibial veins are identified on the neck of the foot. You can directly and
48 comprehensively examine the common femoral vein, deep femoral artery to the confluence with the common
49 femoral vein, the superficial femoral artery, the popliteal artery, the sub-popliteal arteries at the convergence
50 with the popliteal artery and, finally, the venous plexus of the calf. The exploration of the veins in the calf is
51 quite time consuming, as it requires the examiner to have a special skill and to use suitable latest-generation
52 equipment 2 .

53 2 II. MATERIALS AND METHODS

54 The presence or absence of DVT has been evaluated mainly with the compression test (compression ultrasonography = CUS), run by exercising adequate pressure with the probe on the venous tract to be examined. This allows
55 you to determine if the walls of the vein fall into place or not, in fact, a fully compressible vein certainly does not
56 contain any thrombi. It should be noted, however, that for various reasons some venous portions are difficult to
57 compress (superficial femoral by Hunter's canal and deep femoral) and this can occur due to anatomical location,
58 depth, overlap of bone and tendon structures, or, finally, for the presence of surrounding sclerotic tissue.

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61 Clinical Appropriateness in the Suspicion of Venous Thrombosis of the Lower Limbs in the Emergency Department
62 The compression test was performed both with a longitudinal and transverse scan. Its diagnostic accuracy
63 is reduced at the distal end, where it has The therapy was obviously varied according to the disease: the 2580
64 proximal DVT were admitted to the Siena hospital in a medical ward, in order to administer the appropriate
65 anticoagulant therapy.

66 Conversely, the 1840 distal cases were discharged with a therapeutic dose LMWH, compression bandaging and
67 diagnostic check after three to five days. Instead, all the 2980 cases of SVT were discharged with LMWH at
68 therapeutic dose and prescribed a 2 nd class therapeutic elastic stocking compression (single stocking or knee-high
69 depending on the extent of the thrombotic disease) and control after an average of about five to seven days.

70 4 IV. DISCUSSION

71 The clinical manifestations of DVT of the lower limbs are multiple (spontaneous pain or caused by the stretching
72 of the muscles, redness, cyanosis, increased skin temperature, cramps, increase in the size of the limb, full fledged
73 oedema, development of collateral circulation, phlegmasia alba dolens) however the clinical DVT diagnosis is not
74 accurate because it is based on symptoms and signs (Bauer and Homans) which, individually or together, are
75 not sufficiently sensitive and specific 4 .

76 Precisely for this reason it is necessary to use a standardized diagnostic procedure to either confirm or rule
77 out DVT, which must be administered rapidly, non-invasive, reproducible, sensitive and specific.

78 Ultrasonography with compression ECD (CUS) is one of three specific tests, together with clinical likelihood
79 and D-dimer dosage, which constitute the diagnostic algorithm . For all the examined patients Wells' score was
80 used to calculate the level of clinical likelihood (pre -test) to suffer from an ongoing thrombotic process in place.

81 5 III. RESULTS

82 All patients were examined within a maximum of six hours from the arrival in the emergency room, with an
83 average waiting time of about 2 hours. Surprisingly, this resulted in a final average value by -1.14 (low pre-test
84 grade) while D-dimer dosage was not assayed for a statistically significant number of patients.

85 The diagnosis of patients undergoing urgent venous Doppler ultrasound of the lower limbs, using the described
86 unilateral detailed CUS technique, was: The existence of predisposing conditions or triggers should be considered
87 in each individual patient, as they contribute in varying degrees to define the risk profile. This is clinically
88 important to define, since performing the instrumental test to examine if the subject belongs to a high or low risk
89 group affects the predictive value of the instrumental assessment from which the definitive diagnosis depends.
90 The definition of risk is therefore critical to the decision-making process regarding the diagnostic process to be
91 focused on each patient individually.

92 Different systems have been offered to quantify the clinical probability of DVT in individual patients. More
93 specifically, in 1997 Wells developed a scoring system, which allows us to identify three categories of clinical
94 probability: high, medium, low. This system combines medical records (neoplastic disease, immobilization
95 of the lower limbs, bedding), data derived from physical examination of the patient (pain, swelling, venous
96 collateralization), and an opinion as to the likelihood of an alternative diagnosis 7 . It all has been validated in
97 a cross-sectional study based on systematic comparison with venography as the diagnostic standard of reference
98 and in a longitudinal study based on the occurrence of clinical events, where it has been demonstrated that it
99 can minimize the use of invasive procedures (venography) or non-invasive repeated (ultrasonography), without
100 increasing the risk associated with false-negative diagnosis.

101 The ECD is a non-invasive method of choice for the diagnosis of proximal DVT of the lower limbs, as it has
102 high diagnostic accuracy (sensitivity and specificity), ease of use, cost effectiveness and repeatability 8 .

103 It allows the visualization of the venous system (venous wall and valves) and the representation of the real-time
104 flow in various ways and in static conditions or during dynamic manoeuvres. The use of simple continuous wave
105 Doppler device (CW Doppler) has been practically abandoned, because of its poor diagnostic accuracy 9 . The
106 level 10 . It should be pointed out, though, that especially for the examination of the distal veins, the ability of
107 the operator and the use of suitable latest-generation equipment are key determinants in terms of the quality of
108 the results of the US assay.

109 Additional diagnostic criteria are the absence of the Doppler and colour signal, spontaneous and/or caused, and
110 direct visualization of the thrombus. Additional assays allow to assess the degree of echogenicity of the thrombus,
111 its adhesion to the vessel wall (in particular, the presence of a floating proximal end) and its organization, although
112 none of these issues has proven significant in the definition of the risk of pulmonary embolism [11][12] .

113 Several scholars have offered the opportunity to examine not only the symptomatic limb, but also the
114 contralateral one. As a matter of fact, a Canadian study performed on a large series showed that 80% of all DVT
115 were unilateral and in the symptomatic limb, 15% were bilateral and only 5% were asymptomatic unilateral in
116 the limb, but with thrombi limited to the sub-popliteal portion 13 . Therefore, it seems reasonable to conclude
117 from these data that the presence of symptoms requires unilateral examinations, while a bilateral assessment
118 seems appropriate only in patients with unilateral, though high-risk, symptoms or bilateral, as was the case in
119 our diagnostic protocol.

120 The method is particularly accurate in the diagnosis of symptomatic proximal DVT and less satisfactory in
121 the distal portion and asymptomatic patients in general. In the distal district it is possible to obtain substantial
122 improvements with the growing experience and skill of the operators and the use of ecocolordoppler 3-10 that will
123 produce, according to some authors, sensitivity values up to 100% and specificity by 79%, a positive predictive
124 value (PPV) by 71% and negative predictive value (NPV) by 100%. It should be noted, however, that, to this
125 London Journal of Medical and Health Research Recording a complete re-channelling or the persistence of a
126 residual thrombus was crucial for Recording a complete re-channelling or the persistence of a residual thrombus
127 was crucial for a proper diagnosis in cases of suspected recurrence. Indeed, the detected compressibility of a
128 previously free venous segment is a definitive diagnostic element, though it is not possible if there is no certainty
129 about the previous framework to the onset of symptoms related to recurrent thrombosis. In addition, a significant
130 change in the scale of a residual thrombus is a useful diagnostic element. The diagnosis of venous thrombosis in
131 the superficial veins (SVT) is essentially clinical: inflammation, hardening, erythema, and tenderness along the
132 course of the superficial veins makes it easy to tell this anatomical condition.

133 The US study (CUS) is especially suitable to evaluate the extent of the thrombotic process, which may not
134 coincide with the extension of the inflammatory process 14 , but especially to exclude its propagation to the deep
135 veins of the system, which has been estimated to vary from 17 to 40% 15- 16 .

136 The most important clinical goals of timely and correct diagnosis and treatment of VTE focus on to reducing
137 morbidity and mortality associated with its acute manifestations, reducing the incidence of further acute events,
138 and finally contrasting the incidence of remote sequelae represented by the post-thrombotic syndrome, often
139 highly debilitating and with high social costs (skin ulcers).

140 As reported in clinical trials worldwide, it is estimated that only around 30% of outpatient cases in which
141 suspected DVT is actually confirmed by objective investigations. This data expresses the need to implement
142 a proper diagnostic procedure to ensure an adequate and absolutely crucial -though not risk-free- treatment for
143 those, and only those, who have an ongoing DVT. The awareness of this clinical issue is already widely spread,
144 but the awareness of the importance of early diagnosis is much less widespread.

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146 It has been calculated that, in the absence of anticoagulation, the risk of recurrent venous thrombo-embolism
147 (VTE) is approximately 40% during the first month after the primary event and a further 10% in the second and
148 third month 17 , and every day spent without anticoagulation during the first month after the event is associated
149 with a 1% absolute increase in the risk of relapse. 18 Some authors have shown that the quality of heparin
150 anticoagulation during the first days of therapy after diagnosis of DVT significantly influenced the incidence of
151 thromboembolic recurrence in the long term, as insufficient heparin treatment in the first 24 hours associated
152 with a greater frequency of relapses in the long run, even in the presence of a suitable oral anticoagulant therapy
153 19 . These results are in agreement with what was found in a randomised, where it has been shown that the
154 absence of initial heparin treatment is associated with an unacceptably high frequency of relapses in the long
155 -term [20][21] .

156 The use of compression therapy in the course of DVT and for the prevention of SPT has become a well-
157 established practice. Indeed, the usefulness of elastic compression, with anti-embolic stocking or permanent
158 bandage in the initial phase and therapeutic elastic stocking (40 mmHg) for gait has been confirmed by
159 observational studies. After 5 years of follow-up in patients with DVT, moderate post-thrombotic syndrome
160 was observed in only 12% of the controlled population, while larger cases (ulcer or recurrent DVT) were detected
161 only in 6% of the patients 22 . More recently it has been shown that the early application of elastic compression
162 (within two-three weeks from the onset of the disease) reduces the incidence of post-thrombotic syndrome up to
163 57% ??3 , as later confirmed by a randomized trial in which therapeutic elastic stockings were used with high
164 compression (30-40 mmHg) up to the highest point where the presence of a thrombotic process was detected 24 .

7 V. CONCLUSIONS

165 Elastic compression maintains a crucial value even when the SPT was fully formed, thus reducing the
166 severity and delaying its inevitable unfavourable development; indeed, recent evidence support higher incidence
167 of thrombotic recurrence in those patients in whom the complete re-channelling of the veins affected by the
168 thrombotic process has not been obtained. To confirm this, the early application of elastic compression (2nd
169 class therapeutic elastic stockings) since the DVT diagnosis, promotes faster and more complete re-channelling
170 of the thrombus and therefore a lower risk of thrombotic recurrences and remote sequelae [25][26].

171 It is possible to conclude that in patients treated early with anticoagulant drugs and protected by therapeutic
172 elastic stockings, the incidence of SPT is considerably lower than generally believed in the past, while there seems
173 to be no correlation between the severity of the SPT and the extension of the initial thrombosis 27.

174 From the above it must be concluded that the timeliness and adequacy of heparin anticoagulation to be
175 administered in the early days until valid anticoagulation with warfarin, is a key factor to reduce the recurrence
176 of VTE not only during the first period after the acute event, but also after months, and also to reduce the
177 severity of the post-thrombotic syndrome strongly influenced by the number of recurrences.

178 It is estimated that the percentage of cases in which a clinically suspected DVT is confirmed to be less than
179 50% ; this value is reduced to 30% if we limit ourselves to considering outpatient cases only 33-34-35-36- 37 .

180 Recently, a simplified mode of execution of the CUS has been offered, which provides only the examination of
181 the common femoral vein in the groin and the popliteal vein at the popliteal fossa to its trifurcation, repeating
182 the test after a week in the case of initial normality, or earlier in case of disorder worsening or the onset of new
183 symptoms. The procedure has been validated in a prospective study including 1702 patients, with follow-up at 6
184 months, which showed a low overall incidence of thromboembolic complications (0.7%). The investigation thus
185 conceived seems safe and effective, but requires to repeat the test in 70% of cases. However, it should also be
186 noted that these results are attributable only to symptomatic outpatient cases, which prevent them from being
187 adopted as standard protocol in our study.

188 Finally, a Doppler ultrasound study is warmly suggested by various clinical trials for a true evaluation of the
189 extent of the thrombotic process in superficial phlebitis (especially in case of a thrombophlebitis of the great
190 saphenous vein above the knee), in fact some authors consider it essential to repeat the test after a maximum of
191 seven days for the possible proximal spread 38 .

192 Even if such a theory does not yet exist a general consensus (this is an assessment that can also be entrusted
193 only to the clinical inspection) in our study protocol was performed on all patients suffering from this disease 39
194 .

195 7 V. CONCLUSIONS

196 Based on clinical experience applied to 30350 symptomatic patients in an outpatient setting, evaluated with
197 unilateral CUS detailed EcoColorDoppler ultrasound method, we saw that the thromboembolic disease was
198 found only in 24.5% of cases referred to a specialist, of which only 9.8% of patients required hospitalization for
199 adequate oral anticoagulant therapy. Thus, from our prospective study, which last approximately 10 years, it
200 appears that the request for an instrumental examination for suspected ongoing deep vein thrombosis of the
201 lower limbs was definitely quite unnecessary (perhaps an excess of zeal for our patients or poor accuracy of
202 the clinical signs) and should be rationalized in a better way. It is certain, though, that 4420 proximal and
203 distal DVT detected in the first hours after the onset of appropriate therapy have benefited from the suitable
204 therapy administered from the very beginning, thus presenting a significant reduction in morbidity and mortality
205 associated with acute thrombotic event such as the incidence of periodic recurrences and/or the onset of venous
206 skin ulcers and post-thrombotic aetiology, which in the literature represent about 60% of the total number of
people affected by this condition [40][41] . London Journal of Medical and Health Research ¹



7

Figure 1: © 7 Clinical

instrumental framework of acute phlebopathy was detected, involving the deep portion in 59.8% and the surface in 40.2%;

? In 11.1% of the sample, or 3380 cases, a correlated non-venous disease; Going into more detail, taking into account only the 7400 acute phlebopathy cases, the thrombotic process was detected in different locations in the following percentages (considering only the most serious and the most proximal in the concomitant thrombosis):

? In 34.8% of 2580 cases, proximal DVT was detected (common femoral, superficial and deep);

? In 24.8% of the sample, 1840 cases, distal DVT was detected (Tab. I);

? In 40.2% of the sample, 2980 cases, SVT was detected (Tab. II).

As previously mentioned, an alternative diagnosis was achieved only in 11.1% (in the remaining percentage patients were referred to the emergency room without a definitive diagnosis) and, taking into account only related venous diseases, they were those described in Table III in

order of frequency.

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Figure 2: ?

Figure 3: 28-29-30-31-32

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