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

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ABSTRACT

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Results: A positive diagnosis for acute phlebopathy in progress of patients undergoing urgent instrumental assessment, with detailed unilateral CUS technique, was detected in 7400 cases, which specifically concerned the deep tract more than the superficial one. The therapy was obviously diversified according to the pathology detected.

Conclusions: Based on the clinical experience conducted, it is clear that the thrombo-embolic pathology was found only in about a quarter of the cases sent to the specialist doctor, of which only a small number of patients needed hospitalization.

Keywords: venous thrombosis, venous ultrasonography, emergency department.

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I. INTRODUCTION

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". The validity of the ultrasonography (US) approach is well established in the diagnosis of thrombotic diseases, either deep or superficial, by several worldwide clinical trials. Indeed, only a few cases are left to contrast-based tests. Thus, the US test is the diagnostic method recognised by worldwide Guidelines as the gold-standard in venous diseases (Grade A), while venography should be considered only in a small number of patients with anatomical anomalies, malformations or when there is an indication for surgery on the deep venous system (Grade B)¹.

Deep vein thrombosis (DVT), and the thromboembolic complications that may ensue (pulmonary embolism, PE), is a potentially fatal disease, which often complicates the clinical

course of patients already suffering from other diseases, but is also able to affect apparently healthy individuals.

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

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

The purpose of this study is to report and analyze the experience gained over ten years with patients sent to the emergency room of the Santa Maria alle Scotte Hospital (Siena) with the presumed diagnosis of deep vein (DVT) or superficial (TVS) thrombosis of the lower limbs.

II. MATERIALS AND METHODS

Between March 2001 and December 2011, at the Centre for Phlebology of the University of Siena, 3035 patients were considered with ecocolordoppler (ECD) (Siemens with 6.5-8.5 MHz linear probe), in the emergency room. 2160 were female (69.7%) and 9190 male (30.3%). The examined patients had come to the emergency room according to three referral modes: the urgent request of a general practitioner (45.2%), independently and later referred by the medical practitioner on duty in the emergency room (50.6%) or from a nearby centre not suited to carry out such an instrumental diagnosis (5.4%). All were administered a specific visit that included a thorough medical history to assess the Wells score, and ECD venous examination of the lower limbs by a medical specialist, with detailed technical CUS only focused on the lower limb involved.

The considered patient pool had a mean age of 65 years, ranging between 3 and 98 years, and if the seventh decade was the most representative for the female population, for the male it was the sixth. The requests sent to a trusted phlebology specialist turned out by 75,2% to be suspected DVT, 17.8% VBS and 7% other related diseases, with a slightly higher percentage in the right lower limb (52% right vs. 48% left). The ECD test was performed with the patient in the supine position for the investigation of the proximal femoral artery, and then in the prone position (with one leg above the other, alternately) for the popliteal portion and finally in a sitting position on the edge of the bed to examine the distal deep veins (stretching the veins promotes the display of anatomical detail). The posterior tibial compartment is visualised in the medial retromalleolar region, mostly in cross section, and the veins are displayed by squeezing the sole of the foot, while the anterior tibial veins are identified on the neck of the foot. You can directly and comprehensively examine the common femoral vein, deep femoral artery to the confluence with the common femoral vein, the superficial femoral artery, the popliteal artery, the sub-popliteal arteries at the convergence with the popliteal artery and, finally, the venous plexus of the calf. The exploration of the veins in the calf is quite time consuming, as it requires the examiner to have a special skill and to use suitable latest-generation equipment².

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 you to determine if the walls of the vein fall into place or not, in fact, a fully compressible vein certainly does not contain any thrombi. It should be noted, however, that for various reasons some venous portions are difficult to compress (superficial femoral by Hunter's canal and deep femoral) and this can occur due to anatomical location, depth, overlap of bone and tendon structures, or, finally, for the presence of surrounding sclerotic tissue.

The compression test was performed both with a longitudinal and transverse scan. Its diagnostic accuracy is reduced at the distal end, where it has

sensitivity by 33%, specificity by 91% and a positive predictive value of 58%³. For all the examined patients Wells' score was used to calculate the level of clinical likelihood (pre -test) to suffer from an ongoing thrombotic process in place.

III. RESULTS

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

The diagnosis of patients undergoing urgent venous Doppler ultrasound of the lower limbs, using the described unilateral detailed CUS technique, was:

- In 64.4% of the sample, amounting to 19570 cases, no detectable pathology was in place;
- In 24.5% of the sample, or 7400 cases, an 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.

The therapy was obviously varied according to the disease: the 2580 proximal DVT were admitted to the Siena hospital in a medical ward, in order to administer the appropriate anticoagulant therapy.

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

IV. DISCUSSION

The clinical manifestations of DVT of the lower limbs are multiple (spontaneous pain or caused by the stretching of the muscles, redness, cyanosis, increased skin temperature, cramps, increase in the size of the limb, full fledged oedema, development of collateral circulation, phlegmasia alba dolens) however the clinical DVT diagnosis is not accurate because it is based on symptoms and signs (Bauer and Homans) which, individually or together, are not sufficiently sensitive and specific⁴.

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

Ultrasonography with compression ECD (CUS) is one of three specific tests, together with clinical likelihood and D-dimer dosage, which constitute the diagnostic algorithm⁵⁻⁶.

With regard to clinical likelihood, there are many factors associated with DVT, either predisposing or triggering, which affect onset, evolution and response to treatment, such as: history of previous DVT or pulmonary embolism episodes, recent surgery, immobilization, age, concomitant neoplastic disease, heart failure, trauma with tissue destruction, and/or fractures, oestrogen hormone therapy, pregnancy, obesity, genetically determined or acquired thrombophilia.

The existence of predisposing conditions or triggers should be considered in each individual patient, as they contribute in varying degrees to define the risk profile. This is clinically important to define, since performing the instrumental test to examine if the subject belongs to a high or low risk group affects the predictive value of the instrumental assessment from which the definitive diagnosis depends. The definition of risk is therefore critical to the decision-making process regarding the diagnostic process to be focused on each patient individually.

Different systems have been offered to quantify the clinical probability of DVT in individual patients. More specifically, in 1997 Wells developed a scoring system, which allows us to identify three categories of clinical probability: high, medium, low. This system combines medical records (neoplastic disease, immobilization of the lower limbs, bedding), data derived from physical examination of the patient (pain, swelling, venous collateralization), and an opinion as to the likelihood of an alternative diagnosis⁷. It all has been validated in a cross-sectional study based on systematic comparison with venography as the diagnostic standard of reference and in a longitudinal study based on the occurrence of clinical events, where it has been demonstrated that it can minimize the use of invasive procedures (venography) or non-invasive repeated (ultrasonography), without increasing the risk associated with false-negative diagnosis.

The ECD is a non-invasive method of choice for the diagnosis of proximal DVT of the lower limbs, as it has high diagnostic accuracy (sensitivity and specificity), ease of use, cost effectiveness and repeatability⁸.

It allows the visualization of the venous system (venous wall and valves) and the representation of the real-time flow in various ways and in static conditions or during dynamic manoeuvres. The use of simple continuous wave Doppler device (CW Doppler) has been practically abandoned, because of its poor diagnostic accuracy⁹. The introduction of EDC has undoubtedly increased the possibility of recognizing and properly reviewing the venous structures at the distal

level¹⁰. It should be pointed out, though, that especially for the examination of the distal veins, the ability of the operator and the use of suitable latest-generation equipment are key determinants in terms of the quality of the results of the US assay.

Additional diagnostic criteria are the absence of the Doppler and colour signal, spontaneous and/or caused, and direct visualization of the thrombus. Additional assays allow to assess the degree of echogenicity of the thrombus, its adhesion to the vessel wall (in particular, the presence of a floating proximal end) and its organization, although none of these issues has proven significant in the definition of the risk of pulmonary embolism¹¹⁻¹².

Several scholars have offered the opportunity to examine not only the symptomatic limb, but also the contralateral one. As a matter of fact, a Canadian study performed on a large series showed that 80% of all DVT were unilateral and in the symptomatic limb, 15% were bilateral and only 5% were asymptomatic unilateral in the limb, but with thrombi limited to the sub-popliteal portion¹³. Therefore, it seems reasonable to conclude from these data that the presence of symptoms requires unilateral examinations, while a bilateral assessment seems appropriate only in patients with unilateral, though high-risk, symptoms or bilateral, as was the case in our diagnostic protocol.

The method is particularly accurate in the diagnosis of symptomatic proximal DVT and less satisfactory in the distal portion and asymptomatic patients in general. In the distal district it is possible to obtain substantial improvements with the growing experience and skill of the operators and the use of ecocolor Doppler³⁻¹⁰ that will produce, according to some authors, sensitivity values up to 100% and specificity by 79%, a positive predictive value (PPV) by 71% and negative predictive value (NPV) by 100%. It should be noted, however, that, to this day, we still lack a validation study concerning the proper exploration of the distal portion.

Recording a complete re-channelling or the persistence of a residual thrombus was crucial for

Recording a complete re-channelling or the persistence of a residual thrombus was crucial for a proper diagnosis in cases of suspected recurrence. Indeed, the detected compressibility of a previously free venous segment is a definitive diagnostic element, though it is not possible if there is no certainty about the previous framework to the onset of symptoms related to recurrent thrombosis. In addition, a significant change in the scale of a residual thrombus is a useful diagnostic element. The diagnosis of venous thrombosis in the superficial veins (SVT) is essentially clinical: inflammation, hardening, erythema, and tenderness along the course of the superficial veins makes it easy to tell this anatomical condition.

The US study (CUS) is especially suitable to evaluate the extent of the thrombotic process, which may not coincide with the extension of the inflammatory process¹⁴, but especially to exclude its propagation to the deep veins of the system, which has been estimated to vary from 17 to 40%¹⁵⁻¹⁶.

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

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

It has been calculated that, in the absence of anticoagulation, the risk of recurrent venous thrombo- embolism (VTE) is approximately 40%

during the first month after the primary event and a further 10% in the second and third month¹⁷, and every day spent without anticoagulation during the first month after the event is associated with a 1% absolute increase in the risk of relapse¹⁸

Some authors have shown that the quality of heparin anticoagulation during the first days of therapy after diagnosis of DVT significantly influenced the incidence of thromboembolic recurrence in the long term, as insufficient heparin treatment in the first 24 hours associated with a greater frequency of relapses in the long run, even in the presence of a suitable oral anticoagulant therapy¹⁹. These results are in agreement with what was found in a randomised, where it has been shown that the absence of initial heparin treatment is associated with an unacceptably high frequency of relapses in the long - term²⁰⁻²¹.

The use of compression therapy in the course of DVT and for the prevention of SPT has become a well-established practice. Indeed, the usefulness of elastic compression, with anti-embolic stocking or permanent bandage in the initial phase and therapeutic elastic stocking (40 mmHg) for gait has been confirmed by observational studies. After 5 years of follow-up in patients with DVT, moderate post-thrombotic syndrome was observed in only 12% of the controlled population, while larger cases (ulcer or recurrent DVT) were detected only in 6% of the patients²². More recently it has been shown that the early application of elastic compression (within two-three weeks from the onset of the disease) reduces the incidence of post-thrombotic syndrome up to 57%²³, as later confirmed by a randomized trial in which therapeutic elastic stockings were used with high compression (30-40 mmHg) up to the highest point where the presence of a thrombotic process was detected²⁴.

Elastic compression maintains a crucial value even when the SPT was fully formed, thus reducing the severity and delaying its inevitable unfavourable development; indeed, recent evidence support higher incidence of thrombotic recurrence in those patients in whom the complete re-channelling of the veins affected by

the thrombotic process has not been obtained. To confirm this, the early application of elastic compression (2nd class therapeutic elastic stockings) since the DVT diagnosis, promotes faster and more complete re-channelling of the thrombus and therefore a lower risk of thrombotic recurrences and remote sequelae²⁵⁻²⁶.

It is possible to conclude that in patients treated early with anticoagulant drugs and protected by therapeutic elastic stockings, the incidence of SPT is considerably lower than generally believed in the past, while there seems to be no correlation between the severity of the SPT and the extension of the initial thrombosis²⁷.

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

It is estimated that the percentage of cases in which a clinically suspected DVT is confirmed to be less than 50%²⁸⁻²⁹⁻³⁰⁻³¹⁻³²; this value is reduced to 30% if we limit ourselves to considering outpatient cases only³³⁻³⁴⁻³⁵⁻³⁶⁻³⁷.

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

Finally, a Doppler ultrasound study is warmly suggested by various clinical trails for a true evaluation of the extent of the thrombotic process in superficial phlebitis (especially in case of a thrombophlebitis of the great saphenous vein above the knee), in fact some authors consider it essential to repeat the test after a maximum of seven days for the possible proximal spread³⁸.

Even if such a theory does not yet exist a general consensus (this is an assessment that can also be entrusted only to the clinical inspection) in our study protocol was performed on all patients suffering from this disease³⁹.

V. CONCLUSIONS

Based on clinical experience applied to 30350 symptomatic patients in an outpatient setting, evaluated with unilateral CUS detailed EcoColorDoppler ultrasound method, we saw that the thromboembolic disease was found only in 24.5% of cases referred to a specialist, of which only 9.8% of patients required hospitalization for adequate oral anticoagulant therapy. Thus, from our prospective study, which last approximately 10 years, it appears that the request for an instrumental examination for suspected ongoing deep vein thrombosis of the lower limbs was definitely quite unnecessary (perhaps an excess of zeal for our patients or poor accuracy of the clinical signs) and should be rationalized in a better way. It is certain, though, that 4420 proximal and distal DVT detected in the first hours after the onset of appropriate therapy have benefited from the suitable therapy administered from the very beginning, thus presenting a significant reduction in morbidity and mortality associated with acute thrombotic event such as the incidence of periodic recurrences and/or the onset of venous skin ulcers and post-thrombotic aetiology, which in the literature represent about 60% of the total number of people affected by this condition⁴⁰⁻⁴¹.

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Table I: Distal DVTs

Popliteal vein	500	27.2%
Twin veins	770	41.8%
Solenoid veins	380	20.7%
Tibial veins	190	10.3%

Table II: Superficial Venous Thrombosis

Great Saphenous Vein	960	32.1%
Small Saphenous Vein	190	6.4%
Accessory Saphenous Vein	90	3.2%
Collateral vein	1740	58.3%

Table III: Non-Venous Clinical Pictures

Baker's cyst	1470	43.9%
Erysipelas/Lymphangitis	1000	29.8%
Hematoma	640	19.1%
Muscle tear/Lymphedema	240	7.2%