Appropriateness of Duplex ultrasound assessment on venous system of the legs: a two-month preliminary analysis

Ann. Ital. Chir., 2017 88: 1-6
pii: S0003469X17026562

Silvia Stegher*, Maria Teresa Occhiuto*, Daniela P Mazzaccaro*, Paolo Carlo Righini*, Alfredo Modafferi*, Giovanni Malacrida*, Giovanni Nano*/**

**First Unit of Vascular Surgery, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy*
***University of Milan, Milan, Italy*

Appropriateness of Duplex ultrasound assessment on venous system of the legs: a two-month preliminary analysis

AIM: *The goal of this study is to evaluate the appropriateness to prescribe venous ultrasound of lower limbs.*
MATERIAL OF STUDY: *Over a two months period, 1005 Duplex scans were performed by our Vascular Surgery Unit; out of the total, 225 exams were conducted on venous system of lower limbs. We retrospectively analyzed appropriateness of prescription (according to Lombardy District indications), urgency of prescription, time-lapse between application for the exams and its execution, positive or negative results, National Health System's sustained cost.*
RESULTS: *During the above mentioned period, 87,5% of the exams were conducted as normal screening with no urgency characteristics, 61 exams (27%) were combined with arterial duplex of the same district. General Practitioners' requests accounted for 76,8% while only 9,7% were from vascular surgeons. Following indications of appropriateness, 117 exams (52%) were judged as appropriate. Combining appropriateness and result (χ^2 test) we found that if the indication was inappropriate the negative result rate was 90,75%; in the group of exams prescribed with an urgent request the rate of appropriateness raised to 60,7% of whose 94.1% were pathologically positive.*
DISCUSSION: *There is no evidence in Literature about appropriateness of prescription of Duplex ultrasound for vascular districts. While Lombardy District recently published guidelines for prescription, neither vascular surgeon societies nor National Health Service ever provided any indication.*
CONCLUSION: *Nowadays there is increasing demand for appropriateness in healthcare. This study delivered such significant data to make it a pivotal study for an extended analysis during 2016.*

KEY WORDS: Appropriateness, Vascular Duplex Ultrasound, Venous System

Introduction

Duplex ultrasound is considered a safe, painless, cost-effective exam, which is widespread everywhere. All these characteristics make it a very frequently requested exam[1-4].

In Italy, Duplex ultrasound is performed by medical doctors of various specialties, in public or private Institutions, through National Health System or private insurances, generating a very high social and economic cost.
Nowadays appropriateness is to be considered one of the best indicator of efficacy in Medicine. In order to obtain efficacy, appropriateness indicators about Duplex scan are necessary but neither in Literature nor in Society's guidelines are present by now.
Since August 2015 Lombardy District Council has published unformal indicators of appropriateness in Vascular Duplex Scan, producing parameters that should be followed to prescribe the right exam in the right patient at the right moment[5]. However, everyday practice in an outpatient Service of Vascular Duplex scan still gives the sensation of a large amount of not appropriate prescriptions.

Pervenuto in Redazione Ottobre 2016. Accettato per la pubblicazione Dicembre 2016
Correspondence to: Silvia Stegher MD, IRCCS Policlinico San Donato, piazza Malan, 20097 San Donato Milanese (MI) Italy (e-mail: silvia.stegher@live.it)

This study is about two months of Duplex scan activity of our Vascular Unit in Lombardy District immediately subsequent to the publication of the guidelines. The aim is to evaluate the appropriateness of prescription of the Duplex scan of the venous system of lower limbs.

Material and Method

We retrospectively analyzed two months activity on 1005 outpatient Duplex scan performed by our Vascular Surgery Unit. We decided to analyze all the subsequent prescriptions for Venous Duplex scan of the lower limb, which were fulfilled from 1st September to 31st October 2015.

We evaluated the prescriptions for this type of exam considering different parameters.

Sex and age of the patients were the only personal information collected. The majority of data were collected about the prescription. First, we considered if the request had an urgent characteristic or not, in fact in Lombardy District each prescriber may indicate a request to be processed within 72 hours.

Requests of single venous Duplex scan and combined venous and arterial exams of the lower limb were considered.

Payment that the patient performed to obtain the exams was classified as: completely sustained by National Health System with no charge for the patient, full payed by the patient in a private fashion, payment of a fee, called "Health ticket", as a compensatory measure for the health care provided by State. We identified the origin of prescribers into three groups: General Practitioners (GPs), Vascular Surgeons, Doctors of other specialties than vascular surgery.

Considering the appropriateness of the prescription, data about the reason of the request as written on it were analyzed following the indications provided in the flowchart of Lombardy District guidelines (Fig. 1)[5].

Positive or negative results for any pathological description, even not directly connected to the reason of the request, were also assessed.

All these data were entered in a database and analyzed using the statistical software JMP 5.1.2 (Sas Institution). Data were reported as median and interquartile range for non-Gaussian outcomes. Chi square test was used as appropriate to assess any statistically significant difference between positive and negative results in the two groups of appropriateness.

Results

A total of 225 exams (22,4%) were performed on venous system of the lower limb out of a total of 1005 exams performed by our outpatient service of vascular duplex scan.

The population results composed of 142 women and 83 men (63% vs 37%) with a mean age of 64 years old,

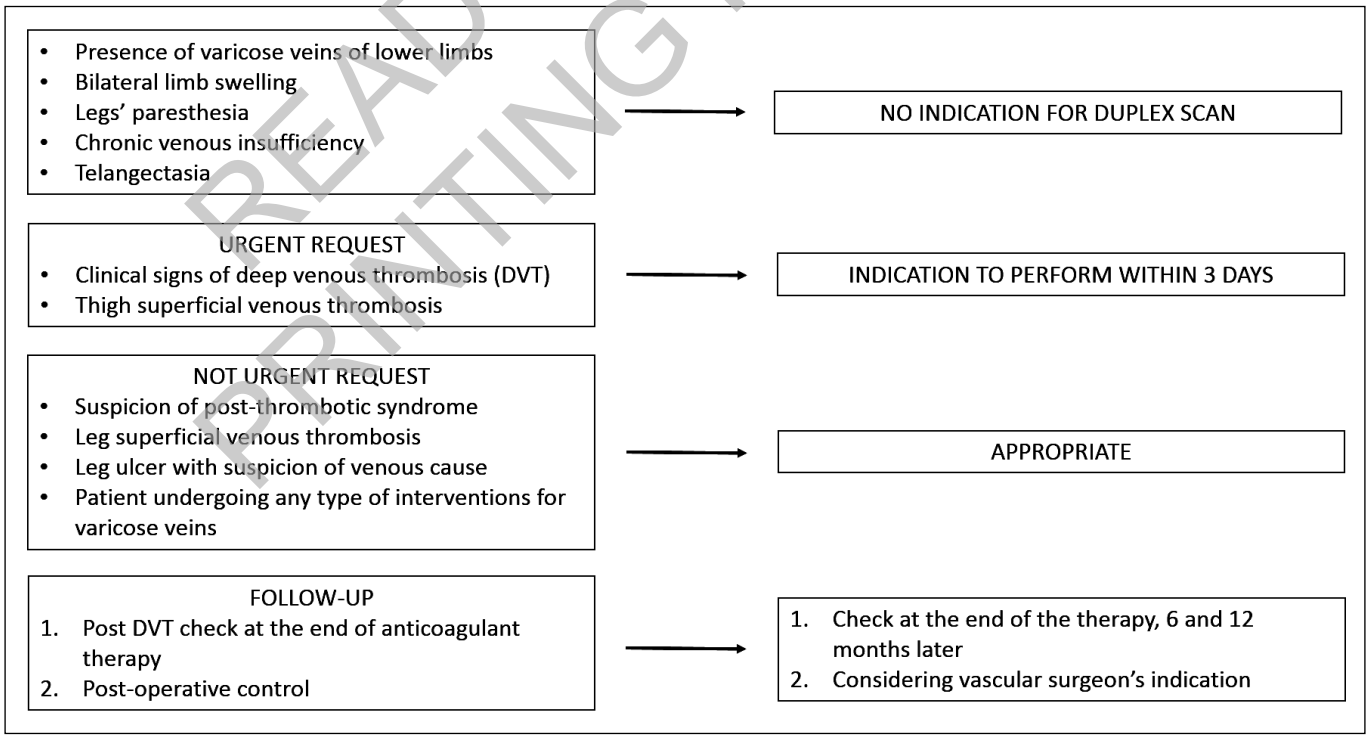

Fig. 1

TABLE I - *Frequencies of sex and distribution of age.*

Distribuition of sex	Female	142 (63,1%)
	Male	83 (36,9%)
Age	Mean	64.5 years
	Median	68 years
	IQR*	54-76 years
	Range	17-93 years

* IQR (interquartile range)

median age of 69 years old (interquartile range 54-76 years) (Table I).
We collected data about the delay between prescription request and booking of the exam, and between booking and Duplex scan execution. 50% of the patients booked the exam within 2 days from the prescription, while another 25% booked it within 15 days. Considering the interval of time between the booking day and the day of the examination the distribution showed a median value of 44 days (interquartile range 35,5-54 days) (Table II).
During the two months, 197 (87,5%) exams were conducted as normal screening with no urgency characteristics, 61 prescriptions (27%) were for a combination of arterial and venous duplex scan of the same district.
141 exams (63,5%) were conducted on patients whose exam was completely paid by National Health Service, because of low personal income or exemption for pathology. The other patients payed to the hospital a fee ("Health Ticket ") of 48,30 €, which corresponds to the amount that the Lombardy District reimburses the hospital for each exam performed. 10 patients (4,5%) had a personal insurance covering for the overall cost of the examination.
General Practitioners' requests accounted for 76,8% while only 9,7% of the prescriptions came from vascular surgeons.
Following the indication of appropriateness from Lombardy District (Fig. 1), 117 exams (52%) were judged as appropriate, and a similar percentage 119 exams) resulted with negative response. Combining appropriateness and result (χ^2 test) we found that if the indication was not appropriate the negative result's rate was 90,75% ($p< 0.0001$); in a similar fashion in the group of appropriate prescription the positive result for any type of pathology was 82% ($p< 0.001$).
The combination of not appropriateness and exemption from ticket payment resulted of 71,9%. The rate of negative exams judged as not appropriately prescribed, in free from ticket patients was 92,2% in this analysis. These inappropriate, negative, free from ticket exams accounted for 31,5% out of the total exams generating a very high waste of economic resources.
In the group of exams prescribed with an urgent request the rate of appropriateness increased to 60,7% of whose 94,1% were pathologically positive.
Another group that drew attention was the one in which the request of exam was combined for arterial and venous system (61 exams out of 225 - 27%). The rate of appropriateness for venous request in this group was 29,5% versus 61,8% in simple venous request. We even noticed that the combined exams came from GP's for 45 cases (73,7%) and from other specialties than vascular surgery for 13 exams (21,3%). Only 3 combined exams were requested by a vascular surgeon. In this group of combined prescriptions from not vascular surgery specialties and GPs, appropriateness resulted of 25,4%.

Discussion and Comments

The discussion about this data is not easy because this analysis seems to have no previous in Literature, even if appropriateness criteria are becoming increasingly important in worldwide health care.
Duplex scan is a safe, noninvasive, cost-effective and reliable test, which is recommended as first diagnostic test for all the patients with suspected Chronic Venous Disorder [1-4]. Considering that in the adult Western population, the prevalence of varicose veins is at least 20% (range 21.8%-29.4%) [6,7], the idea of performing a venous Duplex scan in patient with any signs or symptoms of chronic venous insufficiency would mean a collapse of the system.

TABLE II - *Distribution Of interval between prescription request and booking, and between booking and execution.*

Time interval between prescription request and booking of the exam	Mean	16,4 days
	Median	2 days
	IQR*	0-15 days
	range	0-363
Time interval between booking and duplex scan execution	Mean	45,2 days
	Median	44 days
	IQR*	35,5-54 days
	Range	0-325 days

* IQR (interquartile range)

Unlike cardiac ultrasound indications, for which separate appropriateness criteria exist, the indications for arterial and venous ultrasound are much boarder [8-11], and there is even greater need for appropriateness even today in which Duplex is a tool during intervention [12,13]. In 2012 a report "Appropriate Use Criteria (AUC) for Peripheral Vascular Ultrasound and Physiological Testing part 1: Arterial Ultrasound and Physiological Testing" fills this need about arterial vascular district [14,15]. The report evaluated a total of 225 indications derived from common clinical practice and a panel of 19 experts from various organizations rated 117 (46%) indications as appropriate, 84 (33%) as uncertain and 52 (21%) as inappropriate. The major highlight of the report is that vascular testing is to be considered appropriate when the test is directly related to clinical signs and symptoms. We totally agree with this sentence even if we consider that in everyday clinical practice it can be hardly applied because the patient refers first of all to GPs who could have less time and less skills to correctly evaluate signs and symptoms. A solution could be to address the patient to clinical evaluation by vascular surgeons instead of to Duplex examination, considering that this approach could even spare some money to patient and National Health System because clinical evaluation has, in Italy, a lower reimbursement rate than Duplex scan.

A consideration should be done about the indications for appropriate prescriptions of venous duplex of lower limb, given by Lombardy District. In fact the categories (Fig. 1) provided by the group of experts are totally sharable and easily applicable in everyday clinical practice, although there are so few categories that they could be misunderstood by physicians who have less expertise in vascular surgery.

About our data, considerations should be done about some bias and some points that need major attention for an extensive survey and in order to obtain real world information. This is why we consider this present analysis as a pivotal study for an extensive one, which has been approved by Ethical Committee and is ongoing throughout 2016, analyzing all the prescriptions for vascular ultrasound (supra-aortic vessel, arteriosus and venous Duplex scan of lower limb).

In this present study, we had a bias in the category of prescribers, because considering only those who fill the prescription could result a greater number of GPs than other specialities' doctors. This bias could not be overtaken because of the retrospective analysis of prescriptions could not provide any better data. In our ongoing extensive survey for 2016 this value has been change into "promoter" of the prescription and the patient is asked to specify this information, so that we could even consider the patient himself as a possible actor in the request of the exam.

We consider this data about prescribers a very important one, as soon as a good educational policy, directly addressed to such categories, could really change the number of appropriate prescriptions.

Considering the problem of the combining prescriptions of arterial and venous Duplex scan of lower limb in the same patient, we noticed that one of the prescription is usually inappropriate. The ongoing registry, studying both the arterial and venous exams and giving the appropriateness of both, could confirm this data and provide a definitive result about the value of appropriate combining prescription. The information that has to be associated to this data is the promoter of the combined prescription. In the present study the great majority of combined studies were request by GPs and other specialties doctor than vascular surgeons (95%) giving the sensation that there was not a clear idea of pathology behind the prescription.

Considering the large amount of inappropriate requests of this study, it could even generate an increasing of waiting list. In a Hospital such as our Institution, we usually perform at least 8000 every district duplex scans per year and during 2015, 3130 duplex scans were performed considering arterial or venous Duplex scan of lower or upper limbs, which have the same codification number. The time interval between booking of the exam and Duplex scan execution during this study resulted to be 44 days of median value. Considering this value and comparing it with the waiting list around Lombardy District such a timing does not give our patients a feeling of inefficiency of the system. All around Italy the large amount of inappropriate requests is the cause of lengthen of waiting list, so that reducing the number of this type of requests could have influence on cost-effectiveness and even on perception of good Health System.

Conclusions

We consider that the discussion about appropriateness in vascular ultrasound should be carried on by Vascular Surgery Societies in order to develop clear international indications about the prescription of this type of exam, with specifies about timing and class of risk. Appropriateness criteria act as useful and practical guidelines for the treating physician, leading to an improving of cost-effectiveness too. Waiting for guidelines and appropriateness criteria, we would like to underline immediately that nothing should supersede thoughtful clinical judgment for individual patient.

Riassunto

Uno dei temi che ricorrono oggi più frequentemente nell'ambito della medicina in generale è la ricerca di appropriatezza delle prescrizioni e di tutti gli atti medici. Per appropriatezza si intende l'erogazione di un ser-

vizio al paziente giusto, al momento giusto e nel posto giusto.

Questa problematica si applica a maggior ragione su esami di largo impiego e facile disponibilità come l'ecocolorDoppler vascolare.

La regione Lombardia ha recentemente emesso delle "raccomandazioni per la prescrizione di EcocolorDoppler" (ECD) per la diagnostica delle patologie, tra l'altro, degli arti inferiori. Lo scopo del nostro studio retrospettivo è quello di valutare due mesi di attività del nostro servizio ambulatoriale ECD dell'Unità Operativa di Chirurgia Vascolare I (mesi di Settembre ed Ottobre 2015). In particolare, insieme a dati anagrafici, sono stati raccolti dati a riguardo dell'intervallo di tempo che passa tra la prescrizione dell'esame e la prenotazione da parte del paziente, ed i tempi di attesa per l'esecuzione dello stesso. Abbiamo valutato la provenienza della prescrizione dell'esame e la motivazione della richiesta, crociando i risultati con la positività dei referti ed il successivo destino dei pazienti. L'analisi statistica è stata effettuata utilizzando il software JMP 5.1.2 (SAS Institute).

Nei mesi in esame sono state fornite dalla nostra Unità Operativa, in solo regime ambulatoriale, 1005 prestazioni di ECD di tutti i distretti, di cui 225 (22,4%) eseguite per ECD venoso degli arti inferiori; 87,5% di queste sono svolte come richieste ordinarie senza urgenza differibile. La maggior parte delle richieste è risultata provenire dai medici di medicina generale (MMG) 166 (76,8%), solo 21 (9,7%) direttamente da specialisti in Chirurgia Vascolare. 117 esami (52%) sono stati giudicati con indicazione appropriata, 119 esami (52,8%) hanno avuto un risultato negativo. L'analisi è stata poi eseguita con crossing dei campi di analisi ottenendo risultati molto interessanti a riguardo della percentuale di esami inappropriati eseguiti nei pazienti esenti 71,9%, ed esami inappropriati e negativi 90,75%. Questo studio vuole essere una prima valutazione sull'appropriatezza della prescrizione ECD, i risultati di grande interesse non hanno solo una implicazione economica ma anche di buona politica sanitaria. Nel corso del 2016 stiamo applicando uno studio simile in maniera trasversale a tutti gli ECD di tipo tronchi sovra-aortici, arteriosi e venosi degli arti inferiori, con l'obiettivo poi di linee guida ai medici prescrittori per garantire una più adeguata prescrizione.

References

1. Gloviczki P, Comerota AJ, DAlsing MC, et al.: *The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum.* J Vasc Surg, 2011; 53(5 Suppl):2S-48S.

2. Coleridge-Smith P, Labropoulos N, Partsch H, et al.: *Duplex ultrasound investigation of the veins in chronic venous disease of the lower limbs: UIP consensus document: part I. Basic principles*. Eur J Vasc Endovasc Surg, 2006; 31:83-92.

3. Cavezzi A, Labropoulos N, Partsch H, et al.: *Duplex ultrasound investigation of the veins in chronic venous disease of the lower limbs. UIP consensus document. Part II. Anatomy.* Eur J Vasc Endovasc Surg, 2006; 31:288-99.

4. Chalazonitis AN, Condilis N, Tzovara J, Ptohis N, Laspas F, Neofytou I, Feida E, Tzannetaki A: *Lower limb veins color and spectral Doppler ultrasonography examination. An examination protocol.* Ann Ital Chir, 2008; 79:273-80.

5. *La giunta della Regione Lombardia con Presidente Roberto Maroni. DELIBERAZIONE N° X / 3993 Seduta del 04/08/ Ulteriori determinazioni in ordine alla gestione del servizio sanitario regionale per l'esercizio 2015.* SUB ALLEGATO "Appropriatezza ECD in angiologia".

6. Rabe E, Pannier F: *Epidemiology of chronic venous disorders.* In: Gloviczki P(ed): *Handbook of venous disorders: guidelines of the American Venous Forum*. 3rd ed. London: Hodder Arnold; 2009, 105-10.

7. Quarto G, Amato B, Giani U, Benassai G, Gallinoro E, Apperti M, Furino E: *Comparison of traditional surgery and laser treatment of incontinent great saphenous vein. Results of a meta analysis.* Ann Ital Chir, 2016; 87(1):61-7.

8. Cestaro G, Furino E, Solimeno G, Gentile, M, Benassai G, Massa, S, Quarto, G: *The role* of *superficial epigastric vein sparing in the treatment of chronic venous disease: A retrospective study.* Acta Phlebologica, 2015; 15(3):143-47.

9. Quarto G, Genovese G, Apperti M, Amato B, Benassai G, Furino E: *Is the fibrotic parietal thickening a reliable parameter for diagnosing asymptomatic deep vein thrombosis?* Ann Ital Chir, 2015; 86(5): 427-31.

10. Quarto G, Solimeno G, Furino E, Sivero L, Bucci L, Massa S, Benassai G, Apperti M: "*Difficult-to-treat" ulcers management: Use of pulse dose radiofrequency*. Ann Ital Chir, 2013; 84(2):225-28.

11. Genovese G, Furino, E, Quarto G: *Superficial epigastric vein sparing in the saphenous-femoral crossectomy or in the closures of the saphena magna*. Ann Ital Chir, 2015; 86(5):383-85.

12. Mazzaccaro DP, Stegher S, Occhiuto MT, Muzzarelli L, Malacrida G, Nano G: *Varicose veins: new trends in treatment in a Vascular Surgery Unit.* Ann Ital Chir, 2016; 87:166-71.

13. Mazzaccaro D, Malacrida G, Occhiuto MT, Stegher S, Tealdi DG, Nano G: *Endovascular treatment of iatrogenic axillary artery pseudoaneurysm under echographic control: A case report*. J Cardiothorac Surg, 2011; 6:78.

14. Naqvi TZ, Perese S: *Noninvasive vascular appropriateness criteria. Review and comments on the American College of Cardiology (ACC) Guidelines.* J Am Soc Echocardiogr, 2013; 26(5):A34. doi: 10.1016/j.echo.2013.03.001.

15. American College of Cardiology Foundation (ACCF); American College of Radiology (ACR); American Institute of Ultrasound in Medicine (AIUM); American Society of Echocardiography (ASE); American Society of Nephrology (ASN); Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL);Society for Cardiovascular Angiography and Interventions (SCAI); Society of Cardiovascular Computed

Tomography (SCCT); Society for Interventional Radiology (SIR); Society for Vascular Medicine (SVM); Society for Vascular Surgery (SVS), Mohler ER 3rd, Gornik HL, Gerhard-Herman M, Misra S, Olin JW, Zierler RE, Wolk MJ, Mohler ER 3rd: *ACCF/ACR/AIUM/ASE/ ASN/ICAVL/ SCAI/ SCCT/ SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: arterial ultrasound and physiological testing: a report of the American College of Cardiology Foundation appropriate use criteria task force, American College of Radiology, American Institute of Ultrasound in Me*dicine, *American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery.* J Am Coll Cardiol, 2012; 60:242-76.