

## Medico-legal Issues in Phlebology Dr Louis Loizou

The author will try to simplify as well as offer practical solutions to the complex requirements of the medicolegal issues that face phlebologists.

That is to say that should you be facing litigation- do you have a defensible case? If so then what makes a case defensible?

Litigation and the courts offer no black or white solutions. The so called “court room theatre” that involve an adversarial process with a judge and jury and opposed duelling experts may conclude without logic as you are rarely allowed to express yourself in an understandable manner. It is legally clear that ignorance of the law is no defence. There are legislated acts for everything we do and how they are interpreted is beyond most of us and are very complicated.

In the background of all the cases studied in preparation for this talk is something called the CLINICAL GOVERNANCE. This has two components. Firstly Quality Assurance- that means getting it right more often. Secondly Risk management- that means getting it wrong less often. This relates to preventing an adverse event which is defined as “an event or circumstance leading to unintended harm or suffering”. Basically something goes wrong!

The aim is to reduce the risk of an adverse event. But how? This really depends on your level of knowledge, skill and experience in making an accurate diagnosis and choosing the correct management. To do so requires that you undergo a proper accredited training program such as offered by the ACP and outlined in the training handbook. This talk does not cover frank negligence and the consequences.

**BASIC POINT 1-** why do patients litigate phlebologists? It is not because they have developed a treatment ulcer or matting or even pigmentation. The legal case studies overwhelmingly demonstrate that if there is a failure of the doctor to establish effective communication and hence poor doctor-patient relationship and if coupled to a catalyst such as failure to adequately warn of adverse events then it is this combination that provokes patients to litigate.

Therefore poor communication + failure to warn =Litigation.

If they litigate –this means you need DEFENCE. If you need defence then this means you need DOCUMENTATION. But not just any documentation- you need in particular documentation of the pre-operative

discussion. In other words your only real defence is heavily based on the available documentation that is intimately related to CONSENT.

BASIC POINT 2-The question arises. Do we need to get consent? The simple answer is YES. The reason being is that it is a legal requirement. Make no mistake- you do need to get consent. Here is the statement that says so!

“Every human being of adult years and sound mind has the right to determine what shall be done with his or her own body; and a surgeon/doctor who performs a procedure without the patients consent commits assault and trespass” (Schloendorff v Society of New York Hospital 1914)

BASIC POINT 3-Is having a consent form signed enough? Your patient has signed a 12-page consent form prepared by your solicitor. Are you safe?

NO

“It is a misconception that the so called ‘watertight’ consent form will defeat claims of failure to warn.”

WHY?

Because litigating patients just simply state that they did not understand what they were signing and did not understand the handouts provided and felt pressured to sign because the doctor was in a hurry.

BASIC POINT 4- TAKE HOME MESSAGE

Consent is a **PROCESS**. A signed consent form is but only one part of this process.

BASIC POINT 5- it is clear to me that following assessment of many judgements in medico legal cases that the courts seem to hold the doctor responsible for what takes place in the consultation. It is also the doctor’s responsibility to know when the patient has been given the exact amount of information necessary. How psychic are you feeling?

Let’s summarize.

What have we learned so far?

- (1) That it is on a background of poor doctor patient relationship that failure to warn of an adverse event can lead to litigation.
- (2) That a signed consent forms on its own is inadequate.
- (3) That we must undergo a process of consent, which must be documented.
- (4) That somehow we are required to know when this process has satisfied the patient.

What is the solution?

Firstly we need to determine what will satisfy the MDO. Answer- that there is adequate documented evidence that a process of consent has been undertaken.

Then and only then will a claim of failure to warn have the capacity to be successfully defended.

What constitutes the CONSENT PROCESS? The key to the consent process is to ensure that an individual patient assessment has been made with good communication and discussion to the patients' satisfaction and this has been documented.

The key phrases in the above statement are: -

- (1) Individual patient assessment.
- (2) Adequate communication with discussion.
- (3) To the patients satisfaction.
- (4) Adequate documentation.

Let's start with

- (1) What constitutes -Individual patient assessment: - the venous history involves asking about 120 questions. It covers the following categories.

Presenting complaints and symptoms

Aggravating and relieving factors

Onset of disease

Pelvic congestion history

Past venous history

Past treatment history

Past medical history

Gynaecological history

Family history

Psychological history

Social history

Medication list

Allergic history

Other

Asking all these questions is time consuming and laborious with often-indecisive answers being given by an increasingly fatigued patient and not to mention doctor.

However in reality these questions need to be asked as more is missed by not asking than not knowing! Do you ask and get a response to all relevant questions? If not you are not being thorough. It can be done!

BUT HOW?

PRACTICAL SOLUTION 1- by providing the patient with a comprehensive questionnaire that can be filled out prior to the initial consultation. What are the advantages of doing so?

- Saves considerable time and yet all the questions that need to be asked have been asked.
- Allows the patient to think about their answers and to check their facts and dates.
- Allows the doctor to focus on the important points of interest and to clarify the answers given by the patient in the questionnaire.
- Provides a record that can be filed away.
- Allows for more discussion time.

(2) What constitutes adequate communication and discussion?

A legal fact- “communication and discussion MUST be given by the treating doctor”. For the communication and discussion to be considered adequate must include:-

- Nature of illness.
- The proposed approach to diagnosis, investigation and treatment.
- The benefits of treatment.
- The consequences of not treating the condition.
- The risks and side effects, complications and the MATERIAL RISKS and how they may be treated.
- The alternative options to treatment and their associated risks.

- Specific patient concerns must be addressed and preferably with photographic display.
- Highlight the important precautions and what is expected of the patient before and after treatment.
- The degree of uncertainty of the therapeutic outcome.
- An indication of duration and the number of treatments required treating the condition.
- The cost and out of pocket expense.
- Must not be misrepresentative or biased.

BUT HOW can we cover all this?

PRACTICAL SOLUTION 2- provide the patient with a basic information brochure prior to the consultation. This allows for a more meaningful discussion as the patient has already some insight into the procedures available and may provoke questions that relate back to what they are concerned about (material risk). Then during the consultation present a more detailed information document that can be used as a structured basis for discussion.

Is providing an information brochure or document enough?

NO

What do the MDO feel about the use of brochures and information documents?

MDO suggest that brochures and information documents are useful if they are used as a guide for the doctor during discussion with the patient. They should not be used as a substitute for a face-to-face discussion or as evidence that the patient understood the nature of the risks involved in the procedure.

“The provision of written material will not discharge a doctor’s responsibility and legal duty to disclose”.

(3) What constitutes- to the patients’ satisfaction?

The MDO’s consider that adequate information transfer only occurs when the PATIENT (not the practitioner)

- Considers that they have been given the information and that they have been given every opportunity to have their questions answered.
- Has had the opportunity to understand and consider the information.
- So that they are able to make a decision regarding having the procedure.

BUT HOW do we achieve this?

PRACTICAL SOLUTION 3-the doctor must prompt the patient to ask questions. I use phrases such as “is there anything discussed so far that worries you or is unclear or requires further clarification?”

You must give the patient an opportunity to raise any questions following the discussion. It is essential to document any questions asked and the discussion that followed because this constitutes the material risk to the patient.

(4) How do we document the discussion?

That is to say “that having gone through the discussion with the patient and being satisfied that it is to their satisfaction **it would be counterproductive not to document these discussions**”.

BUT HOW?

PRACTICAL SOLUTION 4- use shortcut keys in a clinical software program such as medical director or the latest in custom designed programs such as offered by Vision Software. This allows the practitioner to document all the discussions and history with a few keystrokes.

I had the pleasure of meeting Merita today wishing to explore the option of a non-surgical approach in the treatment of her veins. They are of considerable concern to her from both a cosmetic and symptomatic viewpoint.

Enclosed are my notes from the initial consultation for your perusal.

**Friday June 20 2008** 13:39:47

Dr. Louis Loizou

HISTORY

Merita presents with a completed questionnaire and has read the information brochure that was sent to them prior to this consultation. The patients presenting complaint and history include **right sided varicose veins / reticular veins and spider veins / recurrence of veins after vein surgery**/ there were no other presenting problems. The patients presenting symptoms included **pain in the legs**/ there were no other symptoms. Specifically the pain in

the legs had the following aggravating associations. Seemed worse after extended periods of standing. The pain had the following relieving factors. Seemed better with rest. **This pattern is suggestive of venous related symptoms from a history viewpoint.** The veins first appeared during pregnancy. On specific questioning regarding pelvic congestion syndrome the patient revealed that there was no heaviness in the abdomen/no pain in the abdomen/no burning sensation in the groin/intercourse was not painful/no haemorrhoids/no urinary urgency/ and no constipation. **Therefore pelvic congestion syndrome is unlikely.** On specific questioning regarding past venous history the patient revealed no history of phlebitis/ or DVT/ or pulmonary embolism/or leg ulcers/ or any bleeding disorder/or easy bruising/ and has never required warfarin or injections in the tummy. **The patient revealed a history of having previous vein treatment by surgery with high ligation and stripping on the right in 2007 but now has a recurrence.** On specific questioning regarding past medical history the patient revealed there was no history of AIDS/HIV/ no hepatitis A, B or C/ has never had a blood transfusion/ no asthma/ not diabetic/not hypertensive/ no history of epilepsy or seizures/ no stroke or TIA/no cancers/ no arthritis or autoimmune disease/no thyroid problems / no heart disease/ and no migraine/ no previous lower limb fractures. **There is no other significant past medical history.** The patient revealed she has been pregnant 3 times and has 3 children. The patient has an intact uterus. The patient is not taking the contraceptive pill. The surgical history is noted. Specific questioning regarding family history revealed the following. There is a family history of varicose veins and spider veins. The patient revealed no family history of phlebitis or blood clots / any bleeding disorders or leg ulcers and no family history of bad circulation. Specific questioning regarding psychological history revealed no history of anxiety/ depression/claustrophobia/ needle phobia or any other psychological problem. The current medication list has been noted and does not preclude the patient from treatment. The patient is taking iron tablets. They are not taking NSAID or aspirin. There is no allergic history of any note. In particular do not suffer with eczema, hives, hay fever or anaphylactic type reactions. Discussion relating to allergic tendencies revealed no known allergies to foods/local anaesthetics or adhesive tapes. The patient will consider varicose vein surgery only if there is no alternative. There are no pending travel arrangements. There have been no problems with previous travel.

#### EXAMINATION

On examination the patient general looks well and BP is 130/75. Foot posture appeared normal. There are right sided varicose veins with posterior thigh varicose vein distribution but also reticular veins and spider veins and there appears to be underlying vein pathology. There were no significantly suspicious skin lesions for malignancy in the lower limbs. There was no evidence of a pelvic mass on palpation. There was no evidence of chronic venous hypertension in particular any skin changes of venous dermatitis, lipodermatosclerosis, atrophie blanche or active ulceration. Peripheral pulses were palpable and strong and there was little evidence clinically of arterial disease. There is nothing in the history or examination that suggests a thrombophilia or an increased risk of clotting.

#### INVESTIGATION

The patient does not require a thrombophilia screen in this presentation. The patient underwent venous doppler scan which demonstrated several incompetent veins suggesting the need for a full duplex scan. As the findings appear complex the patient was referred for a diagnostic duplex scan to clarify the venous pathology so that the best treatment option can be offered. This demonstrates a recanalised great saphenous vein with abnormal channels and neovascularisation in the saphenous sheath with multiple incompetent calf perforators.

#### DIAGNOSIS

**Recanalised great saphenous vein with abnormal channels following vein surgery.**

#### PATIENT DISCUSSION

The mechanism of venous incompetence was demonstrated and discussed with the aid of diagrams. The non-surgical procedure was explained in detail and how this procedure will be applied to their specific presentation. The patient was given a brochure (Information document) to read after it was discussed. The possible complications and the most likely complications in their presentation were highlighted & the possible but rare complication of DVT and Anaphylactic reaction was discussed and their treatment was explained. Several photographs of the possible complications were demonstrated. I expressed a concern regarding pigmentation and they were informed that in 95% of cases any pigmentation disappears within 12 months. In about 5% of cases the pigmentation lasts more than 12months. They were informed to cease all Vitamins that may contain Iron supplements. I

also indicated that in view of this concern that close attention to drainage of trapped blood would be important and to avoid missing review appointments. I also indicated that I could not guarantee no pigmentation even if all measures are taken. The patient was invited to ask questions. The cost of treatment coupled to the projected treatment course was provided in written form. A consent form was discussed and highlighted given to the patient to read prior to their treatment. Ample time was provided for any further questions. In my view there is no surgical option for this presentation and this was conveyed to the patient. I also informed the patient that if treatment is delayed that her condition will worsen with time.

#### RECOMMENDATION

In my assessment, given the history and examination findings I consider Merita to be an excellent candidate for non-surgical treatment and a successful outcome is expected but not guaranteed with a combination of ultrasound guided sclerotherapy and standard sclerotherapy. Merita may require maintenance treatment in the future. Should Merita proceed with treatment I will keep you informed of the progress.

With Kind Regards  
Dr Louis Loizou (FACP)  
Fellow Australasian College Phlebology

The above is an example of pre-treatment notes that took about 1 minute to produce using short cut keys. I basically made a list of medicolegal requirements and Medicare requirements and made sure I accommodated the requirements in my notes.

Alternatively documentation can take various forms. One can make reference to the discussion in the patient's record. A detailed note can be made or simply record "discussed risks and complications as per information document" PROVIDED you ensure that:-

- (1) A more detailed record of your notes and or discussions is included in correspondence to the patients GP.
- (2) Alternatively write to the patient confirming your advice, and their agreement and send a copy to the GP.
- (3) Document any written material provided to the patient.

**PRACTICAL SOLUTION 5-**You could dictate the letter. Or by using computer generated notes that can be easily included in a letter to either patient or GP.

This brings me to **WHAT CONSTITUTES AN ADEQUATE CONSENT FORM?**

Must include; -

- Name and full identification of patient
- Name of the procedure agreed to.
- Statement acknowledging the possible need for emergency treatment.

- Contain the general complications that can occur.
- Lists specific and material risks of the procedure.
- Name of the practitioner performing the procedure.
- Should be written in easy language.

PRACTICAL SOLUTION 6- I give the patient the consent form to read at home after I have highlighted the complications and emphasised the most likely complications in their presentation.

Why bother?

Because the patient must have time to determine their concerns and hence the material risks become evident which must be addressed before treatment begins.

The following are examples of common questions that indicate what in fact the patient is worrying about or what the doctor is worrying about. Such concerns must be documented. This can be easily done with short cut keys.

The patient expressed a concern regarding pigmentation and they were informed that in 95% of cases any pigmentation disappears within 12 months. In about 5% of cases the pigmentation lasts more than 12months. They were informed to cease all Vitamins that may contain Iron supplements. I also indicated that in view of her concern that close attention to drainage of trapped blood would be important and avoid missing review appointments. I also indicated that I could not guarantee no pigmentation even if all measures are taken.

I expressed a concern that with her vein pattern and skin type that there is a risk of her developing matting. I explained that matting is new vessels growth so fine that I cannot inject it when it first appears. I explained that there appeared to be a link with female hormone, as matting is not seen in men who have their veins treated. I further indicated that despite further treatment when appropriate matting can persist.

I expressed a concern regarding the possibility of the development of a treatment ulcer. I explained that with her veins it is possible that abnormal connection exist that cannot be visualized. I explained that despite great care a small treatment ulcer might develop. If such an ulcer does develop they heal with time and often leave a small scar that becomes less obvious with time.

The consent form then needs to be signed by the patient immediately after a paragraph stating that an explanation has been given, that the form has

been read and understood, that the patients questions have been answered and that the patient wishes to proceed and that the post treatment instructions have been provided and discussed.

The consent form then needs to be signed by the treating doctor immediately after a short paragraph which states that the treating doctor has explained the treatment and has answered the patients' questions and believes the patient understands and wishes to proceed.

It must be then dated.

The following is an example of the notation regarding the signing of the consent form.

“The patient was prompted to ask any questions following our last discussion and whether anything in the reading material provided produced confusion. The patient seemed satisfied and signed the consent form. We then proceeded to the ultrasound guided sclerotherapy procedure.”

Documenting any post treatment advice is also very important. For example: -

“The patient then had a class 11 compression stocking applied and asked to walk for a minimum of 30 minutes and to do so daily as per the post treatment instruction sheet provided as discussed. They were asked to report any persisting calf pain or swelling that would not settle with walking and any stabbing chest pains that may indicate a pulmonary embolus. A review appointment was emphasised for 2 weeks time. The post treatment instruction sheet was provided and discussed and my contact number was provided should they have any concerns prior to their next appointment. The patient was given the opportunity to ask any questions and there did not appear to be any concerns. They were instructed that if anything comes to mind that is not answered in the material provided to then contact me for clarification.”

If you adopt this method for gaining consent then if anything should go wrong during the procedure, the doctor will be able to demonstrate that as far as was possible the patient was both informed and forewarned and should be able to accept the consequences of the adverse outcome

without complaint or litigation. In the event of litigation, however, the doctor is more likely to be defended because of the documentation.