

**A Decision by the
Aged Care Commissioner
(Case 20HDC01268)**

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Introduction

1. This report is the opinion of Carolyn Cooper, Aged Care Commissioner, and is made in accordance with the power delegated to her by the Health and Disability Commissioner.
2. The report discusses the care provided to Mrs A by Dr B, a vocationally registered general practitioner with a sub-specialty in procedural phlebology.¹
3. Mrs A (then aged in her seventies) presented to Dr B for treatment of varicose veins² in her legs on 22 January 2020. The agreed treatment was for radiofrequency endo-venous ablation³ under local anaesthetic, and ultrasound-guided foam sclerotherapy (a treatment to eradicate varicose veins by injecting a chemical (known as sclerosant) into the vein). During the sclerotherapy on 19 February 2020, Dr B suspected that he might have inadvertently injected the dorsalis pedis artery (the main artery in the foot) on the right-hand side. He assessed both feet and considered that there did not seem to be anything outwardly different between them. Despite this finding, Dr B assumed that it was still a unilateral issue (affecting only the right foot). It was only after speaking with Mrs A later that

¹ A branch of medicine concerned with the veins.

² Enlarged and twisted veins.

³ A technique for destroying larger faulty veins.

evening, when she reported that both feet were painful and blotchy, that Dr B realised that the issue was bilateral (affecting both sides).

4. On 25 February 2020, Mrs A was admitted to a public hospital under Te Whatu Ora (formerly a district health board⁴). She was admitted under the vascular service for discoloured and painful feet and was diagnosed with '[b]ilateral ischaemic⁵ feet secondary to private varicose vein surgery'. On 2 March 2020, Mrs A was transferred to a main centre hospital. On 6 March 2020 she underwent a bilateral below-the-knee amputation, due to tissue necrosis (tissue death) as a result of the ischaemia in her feet.
5. The following issue was identified for investigation:
 - *Whether Dr B provided Mrs A with an appropriate standard of care in January and February 2020.*
6. The parties directly involved in the investigation were:

Mrs A	Consumer
Dr B	General practitioner
7. ACC advisor Dr C is also mentioned in this report.

Background

8. On 22 January 2020, Mrs A had a consultation with Dr B at his clinic for longstanding varicose veins in both legs that were 'painful and causing heavy, restless legs and cramps at night'. She had undergone varicose vein surgery about 40 years previously, but the varicose veins had returned gradually since then. Mrs A also suffered from superficial thrombophlebitis⁶ in her varicose veins, which Dr B said was 'debilitating' and ran the risk of escalating to deep vein thrombosis. Dr B performed a diagnostic duplex ultrasound⁷ scan, which confirmed that she had long saphenous vein incompetence⁸ in both legs.
9. Following the ultrasound, Dr B discussed treatment options with Mrs A. Dr B recommended radiofrequency endo-venous ablation under local anaesthetic, and ultrasound-guided foam sclerotherapy using Fibrovein sclerosant. Dr B explained these treatment processes to Mrs A and discussed possible complications with her, including the risk of inadvertent intra-arterial injection. During their discussion, Mrs A was provided with an information sheet that described intra-arterial injection as 'an extremely uncommon complication that may

⁴ On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora | Health New Zealand.

⁵ A lack of adequate arterial blood flow to the affected area.

⁶ Inflammation of a vein just below the surface of the skin, which results from a blood clot.

⁷ Duplex ultrasound uses high-frequency sound waves to look at the speed of blood flow and structure of veins.

⁸ The great saphenous vein no longer functions normally. Great saphenous vein insufficiency is the most common type of varicose vein.

result in muscle and skin damage'. Dr B said that in his discussion with Mrs A he described it as a 'very rare complication'.

10. At 11.15am on 19 February 2020, Mrs A attended an appointment with Dr B for the procedures to be carried out. Prior to the procedures, Dr B obtained informed consent from Mrs A, photographed the veins, and performed a further duplex ultrasound scan, which confirmed his impressions from the consultation scan. Dr B and the nurse manager, an enrolled nurse, performed the radiofrequency ablation, which Dr B said progressed smoothly.
11. Dr B then performed the ultrasound-guided foam sclerotherapy. He stated that the procedure was done first on the left leg, which was 'uneventful', and that Mrs A appeared to tolerate the procedure well. Dr B documented that during the sclerosant injection at the right ankle, Mrs A experienced pain and he stopped the injection immediately.
12. Mrs A recalls that Dr B treated her right leg first, and that it was when he was injecting her left ankle that he had to stop because of the pain. However, both Dr B and Mrs A agree that it was during the injection on the second leg that Dr B had to stop the procedure.
13. Mrs A also recalls that although the injection at the ankle in the first leg was not painful immediately, the pain was building, and then Dr B injected the ankle in the second leg. Mrs A stated that just as she was about to tell Dr B about the pain from the first ankle, the ankle of the second leg 'exploded in pain' when injected, and she swore.
14. Dr B stated that a painful injection during sclerotherapy 'immediately alerts the practitioner to a possible inadvertent, arterial injection'. Dr B assessed Mrs A's feet and documented that her toes on both feet were pale, and that he saw foam bubbles in the right dorsalis pedis artery (although he told HDC that he was unsure whether these were 'artifacts, blood cells or foam sclerosant'). Dr B's documented impression was that there had been an inadvertent injection of foam into the artery in Mrs A's right foot. Dr B also documented:

'Pain settled quickly followed by numbness bilaterally that resolved on standing and arterial return started to improve. Discussed that foam may have got into wrong place and that we should review tomorrow. Also anticoagulated with Xarelto⁹ 10mg [once daily for three weeks]. Below knee [compression] stockings to remove at night when lying in bed so as not to compromise arterial flow when horizontal. Review tomorrow and clear instructions given re emergency contact with me overnight if problems.'

15. Dr B told HDC that he applied thigh-length compression stockings to both legs (although his clinical record states that below-the-knee stockings were provided). However, Mrs A is adamant that stockings were not applied or provided at this time, and stated that following the appointment, she went for a walk, as advised, and met up with two people who saw her remove her sneakers and would attest to the fact that she was not wearing compression

⁹ An anticoagulant medication used to treat and prevent blood clots.

stockings. Mrs A stated that she was given stockings the following day, at the appointment on 20 February 2020.

16. Dr B stated that both feet were assessed for vascular return after compression; that pulses were identified in both feet by ultrasound and were 'not pronounced but they were equal'; and that there 'did not seem to be anything outwardly different' between the two feet or legs. While Dr B also stated that Mrs A's feet appeared to improve in colour once she was standing, Mrs A disagrees and stated that her feet had a 'horrible yellowish, bloodless look' when she stood.
17. Dr B told HDC that he was 'slightly confused' by the bilateral findings, but still suspected that there had been an inadvertent intra-arterial or arteriole¹⁰ injection in the second leg. He thought that this was a unilateral problem as Mrs A had not reported any issues during the treatment on the first leg.
18. At 5pm that evening, Dr B called Mrs A to check on her progress. Dr B's notes from the call state: 'Feet are very sore despite massage with deep heat. She is walking but also elevating them. Colour is improving.' Mrs A recalls that she reported ongoing high levels of pain, and that colour blotches had appeared. At this point Dr B recognised that the issue was bilateral. He prescribed nifedipine¹¹ and prednisone,¹² and codeine¹³ for pain relief, and advised Mrs A to avoid elevation. He scheduled a review appointment for the next day.
19. At 7.30pm, Dr B called Mrs A again. He documented that her pain had reduced to 5/10, but she had vomited after taking pain medication, and he advised her to remove her compression stockings until the next day. Dr B reiterated to Mrs A that she contact him overnight if concerned. At 8.04am the following morning, Dr B sent Mrs A a text message, which stated: 'Hi [Mrs A] Don't wear your stockings today.'
20. At 12.15pm on 20 February 2020, Mrs A attended a review appointment with Dr B. Mrs A recalls that it was at this appointment that Dr B gave her compression stockings to wear. Dr B documented that her pain was at 8/10 and the soles of both feet had a mottled appearance. Dr B explained that intra-arterial injection had occurred and used diagrams to describe this. He told Mrs A that the final outcome would not be known for about six weeks, and that he had seen this once before where the skin on the foot had peeled and the blood flow and function of the foot had returned. Dr B apologised for the complication, and 'tried to explain the difficulties with 2D ultrasound and 3D bodies and how that can lead to mistakes'. He prescribed gabapentin¹⁴ for pain management and made a plan to keep in contact with Mrs A over the weekend, and arranged to review her again the following Tuesday (25 February 2020).

¹⁰ Small blood vessels that carry blood from the heart to tissues and organs and connect arteries and capillaries.

¹¹ Antihypertensive (to lower blood pressure).

¹² A medication mostly used to suppress the immune system and decrease inflammation.

¹³ An opiate mainly used to treat pain.

¹⁴ Medication commonly used for the treatment of nerve pain.

21. Dr B called Mrs A on the morning of 21 February 2020. He documented that her feet were tender on the sole but only the toes were painful now, and she felt that the colour had improved. However, Mrs A presented to the Emergency Department at the public hospital that evening due to pain at the base of both feet. She was assessed, given pain management, and advised that if the discoloration and pain worsened, she should return.
22. Between 21 and 25 February 2020, Dr B continued to be in regular contact with Mrs A via text message with regard to managing her pain.
23. On the morning of 25 February 2020, Mrs A was admitted to the public hospital under the vascular service, as her feet were still painful and discoloured. She was diagnosed with 'bilateral ischaemic feet secondary to private varicose vein surgery'.
24. On 2 March 2020, Mrs A was transferred to a main centre hospital. On 6 March 2020, she underwent a bilateral below-the-knee amputation due to tissue necrosis as a result of the ischaemia in her feet.
25. A treatment injury claim was lodged with ACC and accepted on 1 May 2020.

Responses to provisional opinion

26. Dr B was given the opportunity to comment on the provisional opinion. He stated that he sold his practice and has retired from phlebology practice. He no longer performs any vein procedures.
27. Mrs A was given the opportunity to comment on the provisional opinion. She stated that with his credentials, she feels that Dr B should have been aware of all the possible outcomes of the sclerotherapy and that instead of adopting a 'watch and see' approach, any steps that could have been taken, should have been taken. Mrs A realises that other treatments may not have worked but stated that she will never know what the outcome would have been with the earlier assistance of a vascular specialist.

Opinion: Dr B — breach

28. Dr B treated Mrs A for varicose veins on 19 February 2020 and oversaw the management of her after-care until she was admitted to the public hospital on 25 February 2020. I have undertaken a thorough assessment of the information gathered in light of Mrs A's concerns, and I am critical that Dr B did not refer Mrs A to an emergency facility immediately when he recognised that a significant arterial event might have occurred. I am also concerned that Dr B instructed Mrs A to use compression stockings in the hours following the suspected intra-arterial injection.
29. It is important to note that the outcome of care provided is not a relevant factor when assessing the standard of care provided, as sometimes even an appropriate standard of care can result in an adverse outcome. ACC obtained external clinical advice from a vascular and endovascular surgeon, Dr C, and I sought independent advice from a phlebologist, Dr Peter Paraskevas. It is of note that both Dr C and Dr Paraskevas referred to a study that found that

critical ischaemia that required amputation occurred in 52.5% of cases of intra-arterial injection of scleroscant, despite varying levels of intervention. Dr Paraskevas stated:

‘There are many approaches to managing [intra-arterial injection] and as has been illustrated in the literature, there is no guarantee that it will not lead to critical ischaemia and limb amputation. The goal is to institute early therapeutic management, aiming to relieve the patient’s symptoms and re-establish macro and micro vascular perfusion of the affected tissues.’

30. At the end of this report, I make several recommendations for improvements and follow-up actions that could prevent similar events recurring in the future.

Documentation of pre-procedure lower limb assessment — adverse comment

31. Dr Paraskevas advised that Dr B appeared to follow the correct protocol for pre-procedural assessments. However, Dr Paraskevas queried the adequacy of the assessment of Mrs A’s arterial system. He raised this particularly given her risk factors for cardiovascular disease and peripheral arterial disease, such as her history of smoking, hypertension, hypercholesterolaemia and age. Dr Paraskevas advised:

‘A basic arterial examination of the lower limbs in a patient who presents for assessment of their peripheral venous system is usually carried out if there are obvious symptoms on history or signs on physical examination that are suggestive of peripheral arterial disease of the lower leg. In the absence of any obvious signs of arterial disease, omitting a detailed arterial examination would generally not be considered a significant departure from standard practice. However, if for example the patient complained of intermittent claudication¹⁵ or there were obvious pallor/skin changes in the feet suggestive of arterial disease, then in this case, an arterial examination would be mandatory. There is no way of knowing this as it was not indicated in the clinical notes.’

32. Dr B agreed that an arterial system examination is a standard part of the lower limb assessment and stated that Mrs A had no obvious signs of arterial disease when he completed a lower limb assessment at her consultation appointment. Dr B also explained that he would record only abnormal findings.
33. Dr B did not document that he assessed Mrs A for any signs of arterial disease, or his finding that Mrs A had no obvious signs of arterial disease. The Medical Council of New Zealand’s statement on the maintenance and retention of patient records (August 2008) (Appendix B), which was in effect in February 2020, states: ‘You must keep clear and accurate patient records that report: relevant clinical findings.’ I consider the absence of any signs of arterial disease to be a relevant finding, as vascular health is highly relevant to a patient’s suitability for sclerotherapy. In my view, it would have been appropriate for Dr B to have documented that he assessed Mrs A for signs of arterial disease, and his findings.

¹⁵ Pain caused by too little blood flow to the muscles.

Sclerotherapy procedure — other comment

34. Dr C advised ACC that severe tissue necrosis has been recognised as an uncommon, but serious, complication of sclerotherapy for more than 30 years. He stated that even with ultrasound guidance, inadvertent intra-arterial injection is recognised as a risk, and this is more likely to occur around the ankle and foot.
35. Dr C made the following conclusions:
- The cause of the ischaemia was intra-arterial injection of sclerosant.
 - Both the radiofrequency endo-venous ablation and sclerotherapy were performed using a completely standard technique and with the benefit of duplex ultrasound guidance. Dr C acknowledged that technical difficulties of exact 3D positioning using a 2D ultrasound scan is a weakness in current imaging modalities, and it can be difficult to distinguish between an adjacent artery and a vein.
 - Dr B correctly identified the problem immediately, and his initial management was reasonable.
 - On the basis of Mrs A's medical history, Mrs A did not have significant peripheral vascular disease at the time of treatment.
36. It is important to note that the purpose of Dr C's advice was to assist ACC to determine whether a treatment injury had occurred. The role of this Office is to determine whether an appropriate standard of care was provided by Dr B. Further, as a vascular and endovascular surgeon, Dr C is not a peer of Dr B. Therefore, to assist in my assessment of the standard of care provided to Mrs A by Dr B, I sought independent advice from phlebologist Dr Paraskevas.
37. Like Dr C, Dr Paraskevas advised that the ankle is a high-risk area for intra-arterial injection.
38. Dr Paraskevas advised that it is difficult to make an assessment as to whether the sclerotherapy procedure was performed appropriately, and he cannot directly comment on Dr B's technique without having observed it. However, Dr Paraskevas noted that it is 'extremely difficult, if not impossible to inject a major artery, during Ultrasound Guided Sclerotherapy', and he would be very concerned if an intra-arterial injection occurred while using ultrasound to guide the needle. To clarify this further, Dr Paraskevas stated that it is important to recognise the anatomy of the lower leg, and due to the anatomical position of veins and arteries, it is very unlikely for intra-arterial injection to occur while using ultrasound guidance.
39. After reviewing Dr Paraskevas' advice, Dr B agreed with Dr Paraskevas that bilateral inadvertent arterial injection was **not possible** when using ultrasound guidance. He stated: 'If unilateral inadvertent injection is **virtually impossible** then bilateral inadvertent injection must be completely impossible.' For this reason, he is certain that he did not inject the dorsalis pedis arteries, and therefore his initial impression that he had injected them was incorrect and born out of circumstantial evidence only.

40. Dr B stated that when he is injecting at the ankle, he leaves the colour Doppler¹⁶ on the target area to ensure that there is no arterial pulsation close to the target vein and/or tip of the needle. Dr B described his protocols for injection as follows:

‘1. Ensure that the tip of the needle is clearly visualised in the lumen¹⁷ of the vein to be treated on the ultrasound.

2. Ensure no pulsatile flash back of blood from inadvertent arterial placement. [Draw in] dark venous blood into the hub of the needle to ensure correct placement prior to injection.

3. Follow the sclerosant foam injection with ultrasound imaging to ensure no [leakage from the blood vessel into the tissue around it] and passage of foam [inside] the vein.

If the three tenets are not met, then that injection is abandoned in favour of another attempt in a different position.’

41. Dr B stated that this is exactly what happened with Mrs A’s treatment, and in retrospect it seems impossible that intra-arterial injection was to blame in this case. He also stated that the amount of sclerosant injected at the second ankle was no more than 0.1ml, and so even if he injected the sclerosant into the artery, then that could ‘in no way explain the severity and bilateral nature of the tissue necrosis’.

42. Since the procedure and the subsequent complaint, Dr B has reflected on and researched this situation. He stated that he has realised that there are other potential causes of this complication, many of which he was not aware of at the time. These include arteriovenous malformations¹⁸ and veno-arterial thermoregulatory shunts¹⁹ damaged by venous hypertension. Dr B cited a study that discusses cases where extensive tissue necrosis occurred following sclerotherapy and had been ascribed to intra-arterial injection, but further study showed that the injections had been intravenous. The study proposes a theory of distribution of the sclerosant into the arterial arborisation.²⁰ Dr B also said that the effect of sclerosant in the general circulation is unknown and may contribute to the occurrence of arterial spasm²¹ and lasting ischaemia in a microvasculature²² that has been damaged by smoking and high cholesterol.

¹⁶ This type of Doppler uses a computer to change sound waves into different colours. The colours show the speed and direction of blood flow in real time.

¹⁷ The hollow cavity.

¹⁸ An abnormal connection between arteries and veins.

¹⁹ A connection between an artery and a vein that can minimise blood flow to certain areas for body temperature control.

²⁰ Terminal branching of blood vessels in a tree-like pattern.

²¹ The sudden contraction of arteries.

²² Consists of three types of small vessels: arterioles, capillaries, and venules. These form a network that regulates local blood flow and conducts blood–tissue exchange.

43. Dr B stated:

‘After much consideration, I believe this arterial spasm followed treating [Mrs A] with [ultrasound guided sclerotherapy], but that it was not provoked by inadvertent intra-arterial injection. At the time I was perplexed as I did not believe I had injected the arteries but did not have any other explanation, either for myself or for [Mrs A].’

44. Further, Dr B suggested that the venoarteriolar reflex (VAR), where arteries constrict in response to rapid dilatation of their corresponding veins, could explain how arterial spasm and subsequent ischaemia can occur despite obvious intravenous injection of sclerosant. He stated:

‘One has to suspect that with the damaging effects of many years of smoking, high cholesterol and hypertension and the addition of even a relatively mild VAR provoked by sclerotherapy, there might have been serious and unforeseen consequences for the microcirculation of [Mrs A’s] feet.’

45. Dr B also noted that the data sheet for Fibro vein sclerosant states that ‘[a]rterial spasm can occur despite intravenous injection’, and this is described as ‘very rare’. Therefore, it is known that sclerotherapy can induce arterial spasm and subsequently ischaemia, despite correct placement of sclerosant in the varicose veins.

46. Although the cause remains uncertain, Dr B stated that this is a unique and probably ‘first of its kind’ case of bilateral arterial spasm associated with ultrasound-guided sclerotherapy.

47. Dr Paraskevas advised that with regard to the possibility of sclerosant ‘leaking’ from blood vessels,²³ theoretically it is possible to cause inadvertent arterial spasm if sclerosant leaks into the tissue in the blood vessel space. He stated that it is difficult to determine whether this was the case in this instance, but it highlights the importance of using ultrasound guidance when injecting veins in high-risk areas to avoid leakage from blood vessels. Dr Paraskevas also noted that most of the cases where this happened have involved the posterior tibial artery²⁴ above the medial malleolus.²⁵

48. I acknowledge Dr C’s findings that Mrs A’s ischaemia was caused by intra-arterial injection of sclerosant. However, I accept Dr Paraskevas’ advice that it is difficult to make an assessment as to whether the sclerosant procedure was performed appropriately, and that it is possible for inadvertent arterial spasm to occur if sclerosant leaks into the tissue in the blood vessel space. I also acknowledge that Dr B believes his initial impression that an intra-arterial injection occurred was incorrect and based on circumstantial evidence. For these reasons, I have been unable to determine whether or not an intra-articular injection occurred and, consequently, whether Dr B provided Mrs A with the expected standard of care with regard to the ultrasound-guided sclerotherapy.

²³ Including arteries, veins and capillaries.

²⁴ The artery that runs down the back of the lower leg.

²⁵ The small prominent bone on the inner side of the ankle.

Care after suspected intra-arterial injection — breach

49. As discussed above, it is not clear whether an intra-arterial injection did occur. However, this had not been ruled out, and it was Dr B's impression at the time. I have borne this in mind in my consideration about whether the expected standard of care was followed after the suspected intra-arterial injection.
50. Because Mrs A expressed that she felt pain when the ankle of the second leg was being injected, Dr B suspected an intra-arterial injection had occurred and stopped injecting immediately. He assumed that this was unilateral because Mrs A had complained of pain only when he was injecting in that spot, and so he assessed her feet to see whether there was a difference between the two. Dr B was confused by his finding that the feet appeared the same, but due to the possibility of an intra-arterial injection, he administered an anti-coagulant, and said that he applied thigh-length compression stockings to Mrs A's legs. I address the use of stockings separately, below.
51. Dr Paraskevas advised:
- 'It appears that [Dr B] took several reasonable steps to manage what is considered a rare complication, by
- a. immediately stopping the injection procedure
 - b. prescribing anticoagulation
 - c. performing an arterial examination and duplex assessment.'
52. Dr Paraskevas said that the 'watch and wait' management plan adopted by Dr B is generally accepted for injection of arterioles or veno-arteriolar spasm events resulting in localised (minor) dermal necrosis. However, Dr Paraskevas advised:
- 'If there is evidence of a major arterial injection involving the dermis, that could result in major skin loss, then management under a Vascular or Plastic/Reconstructive Unit may be required.'
53. Dr Paraskevas also advised that although there is no clear consensus on how to approach such a complication, generally it is considered appropriate to seek emergency care under a Vascular Unit. He stated:
- 'In my opinion, the patient should have been referred immediately to an emergency facility upon recognition of an arterial event of such significance. Not doing so, may be considered a significant departure from standard practice. A major arterial injection is considered one of the most devastating complications of ultrasound guided sclerotherapy and as such, is a clinical emergency that requires immediate attention.'
54. Dr B stated that he did not refer Mrs A to a vascular surgeon immediately when the complication occurred because he was not certain what had happened until it was too late for a referral to make a difference to the outcome. He said that there are many potential causes of a painful injection, such as missing the vein and placing the foam in the tissues, or

touching a nerve with the needle. He also noted that the Fibro vein datasheet states that '[p]ain or burning (short term at the injection site) is common'.

55. Dr B stated that he did consider the possibility of an intra-arterial injection, but the lack of material difference between the appearances of the feet meant that he found it difficult to be sure what had happened. Although both feet had seemed pale while elevated, Dr B considered that there had not been bilateral ischaemia at the time because, to his knowledge, this has never happened before. He also considered that he might have injected a small dermal arteriole, which would be 'of no significant consequence', and he had had a similar patient in the past who had responded well to expectant waiting.
56. It was only when Dr B spoke to Mrs A on the phone around 5pm that evening, when she reported that both feet were painful and had a mottled appearance, that the significance of the complication and the bilateral nature became clear to him. Dr B stated that by this time, referral to a vascular surgeon would have made no difference to the outcome because 'the first 6 hours are the critical period for any potential intervention'. Dr B also explained that the reason for referring a patient to a vascular surgeon would be to attempt thrombolysis,²⁶ and there is no evidence that this has any more success than other interventions in preventing amputation. He stated that likewise, intravenous infusion of prostanooids,²⁷ as given to Mrs A by the vascular team once she was admitted to the public hospital, have shown some positive effects, but no long-term results have been obtained.
57. Dr B said that in retrospect, if he had been more aware of the potential for bilateral extensive tissue necrosis despite correctly placed injections, he would have recognised the problem sooner and treated Mrs A differently. Dr B stated that although there are no guiding protocols for management of a suspected intra-articular injection — with the nature of treatment left up to the treating clinician — ideally there would have been a protocol in place for 'suspected' intra-arterial injection, which would have included immediate referral to a vascular surgeon. However, he also reiterated that no one intervention has been proven to be better than any other in cases of intra-arterial injection.
58. Dr B further stated:
- '[I]f this is truly the first and only case of bilateral ischaemia associated with sclerotherapy ever recorded, then it would be setting an extremely high bar to expect anyone to consider and recognise it.'

Stockings

59. Dr B stated that he applied thigh-length compression stockings to Mrs A's legs following the sclerotherapy procedure, and that he advised Mrs A to remove these when lying in bed so as not to compress the arteries. Dr B's notes from this appointment state that these were below-the-knee stockings.

²⁶ A procedure that uses medications or a minimally invasive procedure to break up blood clots and prevent new clots from forming.

²⁷ Used to regulate inflammatory response.

60. Mrs A is adamant that she was not given any compression stockings at this time. She stated that following the appointment, she went for a walk, as advised, and met up with two people, who saw her remove her sneakers and would attest to the fact that she was not wearing compression stockings. Mrs A stated that she was given stockings the following day, at the appointment on 20 February 2023.
61. Dr B documented that when he spoke to Mrs A at 7.30pm on the night of the sclerotherapy procedure, he advised her to remove the stockings until the following day. Dr B then also sent a text message to Mrs A at 8.04am the following day, which said: 'Hi [Mrs A] Don't wear your stockings today.'
62. Given the contemporaneous documentation that discusses the use of compression stockings on 19 February and early on 20 February 2020, and the absence of any documentation regarding the use of compression stockings at or after the review appointment on 20 February 2020, I consider it more likely than not that Mrs A was given compression stockings before leaving her appointment with Dr B on 19 February 2020.
63. Dr Paraskevas advised:

'If there was a recognised arterial event or suspicion of an arterial event, compression stockings could have potentially aggravated the situation by further compromising peripheral arterial microcirculatory flow. Peripheral arterial injections are such a rare event that there is no documented, agreed upon consensus, regarding immediate management. However, it is well documented that compression stockings are contraindicated in moderate to severe Peripheral Arterial Disease. It is in this context that upon recognition of an arterial injection, where there has been intimal damage and microthrombus²⁸ obstruction to the peripheral circulation of the foot, stockings would be highly contraindicated; and as such to apply compression stockings would be considered a departure from accepted practice amongst Phlebologists.'

64. Dr B stated:

'With the benefit of hindsight, I agree that the use of compression stockings was not the best decision during the events that unfolded. As above, advice was provided that they should be removed when the limbs were horizontal to mitigate any minor ischaemia that I suspected from the treatment. When I realised the significant degree of the ischaemia, I immediately instructed [Mrs A] to remove them.

Again, it is uncertain what role compression stockings would play following arterial spasm and tissue ischaemia, but they may not have been helpful. It is noteworthy, however, that more and more physicians are finding compression helpful in healing ischaemic leg ulcers and improving the ankle brachial index while compression may improve the microcirculation in many people.'

²⁸ A very small blood clot within a blood vessel, remaining attached to its place of origin.

Conclusion

65. I accept Dr Paraskevas' advice that it was reasonable for Dr B to manage an intra-arterial injection by immediately stopping the injection, prescribing anticoagulation, and performing an arterial examination and duplex assessment. However, I also accept Dr Paraskevas' advice that Dr B should have referred Mrs A to an emergency facility immediately when he recognised that a significant arterial event had occurred.
66. I acknowledge that Dr B did not realise the significance of the event until several hours after the event when he spoke to Mrs A over the phone, and he felt that at that stage there would have been no further benefit in intervention from a vascular surgeon. However, intra-arterial injection is considered one of the most significant complications of sclerotherapy, and Dr B knew that 'the first 6 hours are the critical period for any potential intervention'. Although Dr B did not realise the significance of the event until later, he still documented that his impression during the appointment was an inadvertent injection of sclerosant foam into the dorsalis pedis artery, and he was sufficiently concerned about the possibility of this that he started Mrs A on an anti-coagulant. Given the significance of the potential outcomes of intra-arterial injection, I consider that the most conservative treatment options were warranted. I am concerned that Dr B did not refer Mrs A to an emergency facility to be seen by a vascular surgeon as soon as he could not rule out that an intra-arterial injection had occurred.
67. Further, I acknowledge that Dr B was not sure that an arterial event had occurred until later that evening, at which point he advised Mrs A to stop wearing the compression stockings; however, given that Dr B suspected intra-arterial injection may have occurred, and the fact that compression stockings could aggravate the effects of this, I am concerned that Dr B instructed Mrs A to use compression stockings in the hours following the suspected intra-arterial injection.
68. Given my concerns outlined above, I consider that Dr B did not provide Mrs A with services with reasonable care and skill, and therefore breached Right 4(1)²⁹ of the Code of Health and Disability Services Consumers' Rights.

Changes made since events

69. Dr B stated that he is truly sorry for the 'devastating complication' that happened under his care, and that he often reflects on this case. He also stated that it caused him to make changes to his practice and the way he teaches procedural phlebology. The changes he made include the following:
- His focus is now to exclude peripheral artery disease, wherever possible, in the lower limb prior to injection with sclerotherapy.
 - His practice has designed and instituted a pre-consultation, online questionnaire for patients to complete prior to their visit, so that this is available for discussion at the consultation. The questionnaire includes a section on smoking, and requests more

²⁹ 'Every consumer has the right to have services provided with reasonable care and skill.'

information about the quantity and duration of the habit even if an ex-smoker. The number of years of smoking and number of cigarettes per day is also noted, as Dr B is now very aware of how that may adversely affect the microvasculature during treatment.

- During history-taking, he questions the patient even more thoroughly to exclude peripheral arterial disease and differentiates venous from arterial symptoms. He also makes note of risk factors such as smoking, high cholesterol, and hypertension.
- During duplex scans, he now thoroughly investigates and records the arterial Dopplers with both phasicity³⁰ and velocity and has redesigned his scan form template to include those readings. The focus is now to exclude peripheral artery disease, wherever possible, in the lower limb prior to injection with sclerotherapy.
- If a case of suspected ischaemia, regardless of the cause, were to occur again, he would immediately anticoagulate the patient and organise their transfer to a vascular unit.
- He has changed the sclerotherapy information sheet as follows with regard to the risk of intra-arterial injection:

‘Before: *Intra-Arterial Injection. This is an extremely uncommon complication that may result in muscle and skin damage.

Now: *Intra-Arterial Injection. This is a very rare complication that may result in extensive tissue necrosis and gangrene. The resultant muscle and skin damage have a 50% amputation rate. The exact mechanisms of this complication are unknown and it can happen even with extremely experienced physicians.’

70. Dr B said that he firmly believes that ‘everything that can be done, must be done to try to prevent this complication happening again, not only in New Zealand but worldwide’. He stated:

‘[Mrs A’s] case has completely changed the way I approach procedural phlebology and especially with respect to the arterial side of the circulation. In the many months since that terrible day, I have read all the relevant literature I could find, discussed the case with my staff, colleagues and peer group ...’

71. Dr B also stated that he is grateful to Dr Paraskevas for his clinical advice, which he has found to be ‘pertinent, professional, and thought provoking’.

Recommendations

72. Taking into account the changes made since the time of events, I recommend that Dr B provide HDC with an audit report on his documentation of the outcome of vascular assessments from the last three months of his practice. This should be provided to HDC within three months of the date of this report.

³⁰ The condition of existing in phases, typically used of blood flow.

73. Further, should Dr B resume phlebology practice, I recommend that he ensure that he documents the outcome of any vascular assessments, regardless of whether or not there are abnormal findings.
74. In response to a recommendation in the provisional decision, Dr B provided an apology to Mrs A, which has been forwarded to her.
75. Taking into account the changes made since the time of events, I recommend that the Australasian College of Phlebology and the Royal Australasian College of Surgeons formulate and adopt an emergency protocol for cases of actual and suspected intra-arterial injection. A report is to be provided to HDC on the actions taken in relation to this recommendation within six months of the date of this report.

Follow-up actions

76. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.
77. A copy of this report with details identifying the parties removed, except the advisor on this case, will be sent to the Australasian College of Phlebology, the Royal Australasian College of Surgeons, the Royal New Zealand College of General Practitioners, the Australasian College of Dermatologists, and the Royal Australian and New Zealand College of Radiologists, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from a phlebologist, Dr Peter Paraskevas:

‘Thank you for requesting an independent opinion with respect to an investigation by the Health and Disability Commissioner.

I can confirm that I have no professional, social, family or financial conflict in providing an expert opinion in this case.

I have read the following documents in preparation:

1. Letter of complaint dated 15 July 2020
2. [Dr B’s] response dated 26 August 2020
3. Clinical Records from [Dr B] covering the period 22 January 2020 to 17 March 2020

My understanding is that [Dr B] consulted the patient, [in her seventies], on the **22nd of January 2020**. She had a history of bilateral varicose veins and a history of vein surgery 40 years ago. Her symptoms included heaviness, restlessness and leg cramps at night. She reported a history of Hypertension, Hypothyroidism and Hypercholesterolaemia and her medications included Ezetimibe (cholesterol tablet), Cetrizine (antihistamine), Cilazaryl (ACE Inhibitor — Hypertension), Bendrofluazide (Diuretic), Statin (medication not listed) and Thyroxine (Hypothyroidism). The patient was flagged as a smoker, however, there is no documentation as to the duration or number of cigarettes smoked per day. There was also a report of previous Superficial Thrombophlebitis in her varicose veins. I do not have access to a formal duplex ultrasound report but on examination of the venous mapping scan provided, it appears that the patient had previous high Ligation of the Saphenofemoral Junction with resultant neovascularization in the groin, refluxing into large diameter Great Saphenous Veins (9.9 mm on the Right and 8.9 mm on the left). Tributaries of the Great Saphenous Veins were shown to extend into the lower leg and ankle bilaterally.

On the **19th of February**, the patient underwent bilateral Radiofrequency Ablation of the Great Saphenous Veins. This was followed by Foam Sclerotherapy of the thigh and lower leg tributaries. The patient reported the following in her “Notification” that the foam treatment was initially pain free but then felt excruciating pain when injecting occurred at the ankle on both right and left feet. The patient reports that the right leg was treated first followed by the left leg. According to [Dr B’s] notes, the treatment on the left occurred first and was unremarkable but that there was pain during injection at the right anterior ankle, presumably in the region of the Dorsalis Pedis Artery and it was at this time that he ceased the treatment and withdrew the injecting needle. There was no mention of whether this injection was Direct Vision or Ultrasound Guided. At this time, **Pallor of the toes were visualised bilaterally**, and foam was visualised in the distal dorsalis pedis artery. It is at this stage, [Dr B], according to his notes, realised that there was inadvertent injection of foam into the right Dorsalis Pedis Artery. The patient was placed on Xarelto 10 mg daily, given below knee stockings that she could remove at

night and given clear instruction to contact [Dr B] if there were any problems. Review was organised for the next day.

Communication occurred later that day at which point the patient reported that her feet were very sore despite massage with deep heat. She was walking but also elevating her legs and the colour was improving. The patient reported that “colour blotches had appeared” and that there were “still high levels of pain”. [Dr B] at this stage, prescribed Nifedipine, Prednisolone and Codeine and scheduled the review the next day. There is no dispute that [Dr B] acknowledged inadvertent injection of the artery and that he had seen this before, at which time the skin had peeled on the foot and blood returned as did the function of the foot.

The patient was reviewed in person on the Thursday, **20th of February**, and was still in a lot of pain (8/10) in the feet and limping. Gabapentin was added for pain relief. She was asked to keep contact over the weekend and review for Tuesday was organised.

The following day on the **21st of February**, during a morning teleconference with [Dr B], the patient had reported some improvement with reduced pain in the feet but still pain in the toes. By the evening, the patient had presented to Emergency with increasing pain. At this point, direct care of the patient was transitioned to the Vascular Department under the care of Dr ...

Initial arteriograms (according to [Dr B]) showed normal flow, but an arteriogram performed on or just before the 27th of February showed no flow distal to the Dorsalis Pedis. Iloprost Infusions were initiated but despite this, the patient’s condition worsened necessitating bilateral below knee amputations.

This is a devastating but rare event following sclerotherapy. It highlights the importance of a coordinated effort amongst the Australasian College of Phlebology, Royal Australian College of Surgeons, College of Dermatology and College of Radiologists to formulate a management plan to deal with this complication when it arises.

1. It seems that [Dr B] followed the correct protocol for pre procedural assessments. What can be brought into question is whether there was an adequate assessment of the patient’s arterial system, taking into consideration the patient’s risk factors for Cardiovascular Disease and Peripheral Arterial Disease, namely her history of Chronic Smoking, Hypertension, Hypercholesterolaemia and her advancing age. The standard part of a lower limb assessment, particularly in a patient with extensive risk factors such as these, should include an arterial system examination. At a minimum, the lower limbs should be examined for colour (peripheral cyanosis, mottled discolouration), loss of hair and any ulcers. They should also be palpated assessing the temperature, capillary refill time of the toes, and pulses including the Femoral, Popliteal, Dorsalis Ped and Posterior Tibial Pulses. In cases where there is concern, particularly when **assessing the patient’s suitability for compression stockings**, an ABI (Arterial Brachial Index) study may be carried out. This can usually be carried out in the office or in a Vascular Department and if in the latter, an arterial

duplex scan may also be ordered to further examine the peripheral arterial system. Examination of the Peripheral Arterial System by way of inspection, palpation and often doppler, is considered standard and mandatory practice for Fellows of the Australasian College of Phlebology at the initial consultation and is also considered standard practice in patients presenting to their GPs with lower limb concerns and a strong Cardiovascular Risk Factor Profile. In the event that there is disease, this does not preclude treatment however one would proceed with caution, particularly as it relates to the use of compression stockings and the increased risk of microvascular compression and arterial compromise in these patients when using stockings.

With regards to [Mrs A's] suitability for the procedures taken, it is now recommended that patients with CEAP 2, symptomatic disease, be offered treatment with a combination of Endovenous Laser Ablation and Ultrasound Guided Foam Sclerotherapy (NICE, European Venous Forum guidelines).

2. It appears from the documentation available that [Dr B] provided adequate pre procedural information, particularly regarding possible complications. I understand that he has made amendments to his information document and consent form to further highlight the devastating effects of intra arterial injections and this should be commended. Intra-arterial Injections are still considered a rare complication but it is important to document what measures are taken to mitigate the risks of this happening in the information document and consent form. One of the ways to reduce the risk is to use Duplex Ultrasound Examination during the sclerotherapy procedure. It is important that this is discussed with the patient at the initial consultation.

The patient was given adequate time (approximately a month) to read through the information, discuss any concerns or seek an alternative opinion. Following this, the patient made an appointment for her treatment. This appears to be an appropriate standard of care.

3. It is difficult to make an assessment as to whether the sclerosant procedure was performed appropriately. With his own admission, [Dr B] stated that he inadvertently injected the Dorsalis Pedis artery. Generally speaking, this would be an extremely difficult thing to do and would require deeper penetration of the needle in the anterior aspect of the ankle. Great care is recommended when injecting veins in the ankle and foot region. According to the Fibrovein Product Guidelines, "Sclerosants must never be injected into an artery as this can cause extended tissue necrosis and may result in loss of the extremity. Injection under duplex ultrasound is recommended in order to avoid extravasations and arterial injection".¹ To the point of "extravasations", it is theoretically possible to cause inadvertent arterial spasm if there is extravasation into the perivascular space.² It is difficult to determine whether this was the case in this instance but it nevertheless highlights the importance of using Ultrasound Guidance to inject veins in high risk

areas and avoid extravasation. Most cases have involved the posterior tibial artery above the medial malleolus.

To mitigate the risks of direct intra arterial injections there are several things expected of a Phlebologist:

- a) **Thorough anatomical knowledge** of the lower limb arterial and venous system and an awareness in real time, where nerves and arteries are located during the sclerotherapy and Endovenous Ablation procedure. Arteries appear different to veins on duplex ultrasound. Arteries have thicker walls, are rigid and virtually non-compressible and smaller than their venous counterparts. It would be virtually impossible to mistake a major below knee artery for a vein when using ultrasound guidance, for the experienced and learned Phlebologist. Arteries are either inter or intramuscular and therefore out of reach of the Phlebologist's "working zone".
- b) **Direct Vision Sclerotherapy in** high risk areas, such as the medial and anterior ankle, popliteal area and groin, should be carried out with **great care**. Direct cannulation of the abnormal vein and withdrawal of blood into the hub of the syringe are two ways to confirm direct cannulation of the vein and not the artery. This should be followed by very careful, slow and gentle plunger pressure. It is often not practical to use a Duplex Ultrasound to inject veins in the lower leg particularly in the anterior ankle region or foot. In these cases, careful, superficial injection must be carried out. Historically, the medial malleolar region was the most common site for intra-arterial injection, but the anterior foot and ankle region has also been flagged as a high risk area.^{3,4} This may relate to direct vision sclerotherapy in these regions targeting the posterior artery and dorsalis pedis artery respectively, in a relatively superficial position, rendering them more susceptible to inadvertent injection. It appears that this was the mechanism of injury in this case.
- c) **Meticulous use of a Duplex Ultrasound machine** is highly recommended when injecting subdermal and subcutaneous veins, particularly in areas prone to intra-arterial injections, including the medial and anterior ankle, the popliteal area and the groin. It would be virtually impossible to inject an artery if the offending vein is accurately targeted by ultrasound and the needle is carefully and accurately directed into the vein all the way. The two below-knee arteries which are relatively close to the surface (and therefore palpable) are the Dorsalis Pedis and Posterior Tibial Arteries.

4. and 5.

As stated earlier, intra-arterial injections during sclerotherapy are an extremely rare event.² The most serious adverse events include Deep Vein Thrombosis and Pulmonary Embolus, Stroke and Intra-Arterial Injection leading to critical ischaemia. The most recent publication reviewing the literature revealed that critical ischaemia requiring amputation occurred in 52.5% of cases, despite varying levels of intervention.³ There

are many approaches to managing this and as has been illustrated in the literature, there is no guarantee that it will not lead to critical ischaemia and limb amputation. The goal is to institute early therapeutic management, aiming to relieve the patient's symptoms and re-establish macro and micro vascular perfusion of the affected tissues.

It appears that [Dr B] took several reasonable steps to manage what is considered a rare complication, by

- a. immediately stopping the injection procedure
- b. prescribing anticoagulation
- c. performing an arterial examination and duplex assessment

On point C, it has been noted that even if the Dorsalis Pedis pulses (bilaterally) were palpable and patent on ultrasound, this does not rule out microvascular disease distal to the Dorsalis Pedis and therefore one cannot assume that there had not been a significant arterial event. One of the signs of distal microvascular spasm is pallor, often followed by a dusky purply-red colour indicating reperfusion. This was observed by [Dr B] and documented in his notes. [Dr B] states that he saw some foam within the dorsalis pedis artery and reports pallor of the toes, indicating a possible arterial event affecting the distal microvasculature. Having already prescribed anticoagulation, it may not have been advisable to place the patient into compression stockings, which may have had the potential to further compress the distal arteries. (Please refer to section 1 and discussion on Peripheral Arterial Disease.)

The patient's extensive cardiovascular history and acknowledgement of possible direct injection of the Dorsalis Pedis and physical changes indicating an arterial event, were strong indications to consider immediate referral to a Tertiary Hospital Emergency Facility for immediate assessment and management. A multidisciplinary approach involving the Vascular Unit within the first few hours may have altered the course of this catastrophic event.

It is important to add that any acute, post sclerotherapy event such as an anaphylactic reaction, pulmonary event or stroke would be handled the same way and that is, immediate initiation of emergency protocols and referral to the Emergency Department.

According to the Aethoxysklerol Product Information available to all doctors, the following has been recommended: "Aethoxysklerol must never be injected intra-arterially because this can cause severe necrosis that may necessitate amputation. **A vascular surgeon must be called in immediately if any such incidents occur.** In order to avoid undue adverse reactions when performing sclerotherapy in the ankle area, only a small quantity of a low concentration of Aethoxysklerol should be used. The risk of inadvertent intra-arterial injection in the foot and ankle region should also be taken into consideration."⁵

The “watch and wait” management plan adopted by [Dr B] is generally accepted by my peers for dermal arteriolar injections or veno-arteriolar spasm events resulting in localised (minor) dermal necrosis.⁶ In these instances, prescribing an anticoagulant, prednisolone and topical or oral vasodilators is considered a standard care of practice. The patient can be managed as an outpatient and does not require immediate referral to an Emergency Department. Hyperbaric Oxygen has also been used in cases to help with arterial reperfusion. If there is evidence of a major arterial injection involving the dermis, that could result in major skin loss, then management under a Vascular or Plastic/Reconstructive Unit may be required.

It is important to once again emphasize that it is difficult to predict the outcome of an intra-arterial event, even with immediate referral but transfer of care following a major arterial injection seems to be the most appropriate action to take, considering the potential for critical limb ischaemia and potential amputation.³

Moving forward, the Australasian College of Phlebology and the Royal Australasian College of Surgeons will need to adopt an emergency protocol for direct intra-arterial injections, which will involve institution of immediate anticoagulation (oral or intravenous) and referral to a hospital with an Emergency Department and Vascular Unit equipped to adequately deal with this medical emergency.

Summary: As stated earlier, intra-arterial injections of major arteries, during sclerotherapy are an extremely rare event.³ The single most important modality used to avoid or at the very least greatly mitigate the chances of an intra-arterial event is the use of Duplex Ultrasound during sclerotherapy. Ultrasound visualisation allows the treating doctor to accurately direct the treatment needle into the offending vein, thereby avoiding inadvertent arterial cannulation or perivascular infiltration. Great care must be adopted in patients with possible peripheral vascular disease, with adequate pre procedural assessment to assess severity before embarking on Varicose Vein Treatment. Post Graduate credentialing in Ultrasound Examination of the lower limb may be a necessary requirement for doctors performing Ultrasound Guided Sclerotherapy to enhance their ultrasound skills. Recognition of a major intra-arterial injection is critical as it allows the treating doctor to initiate emergency treatment. There is no clear consensus on how to approach such a complication, but it is generally considered appropriate to seek emergency care under a Vascular Unit.

With Regards

Dr Peter Paraskevas

References:

1. **Fibrovein 3% Solution for Injection** Summary of Product Characteristics Updated 06-Sep-2018 | STD Pharmaceutical Products Ltd
2. Tran D, Parsi K, Veno-arteriolar reflex vasospasm of small saphenous artery complicating sclerotherapy of the small saphenous vein Aust NZ J Phleb. 2007;10:29–32

3. Hafner F, Froehlich H, Gary T, et al. Intra-arterial injection, a rare but serious complication of sclerotherapy. *Phlebology* 2013; 2013: 64–73.
4. Fegan, W, Pegum, J. Accidental intra-arterial injection during sclerotherapy of varicose veins. *Br J Surg* 1974; 61: 124–126.
5. Aethoxysklerol (Lauromacrogol 400) Product Information, Date of most recent Amendment 12/1/18
6. Cavezzi A and Parsi K. Complications of foam sclerotherapy. *Phlebology* 2012; 27(Suppl 1): 46–51.

Addendum: 10/04/2021

With regards to four questions posed in an email to me on the 9th of April 2021 (8.52 am) these are the following responses:

1. A basic arterial examination of the lower limbs in a patient who presents for assessment of their peripheral venous system is usually carried out if there are obvious symptoms on history or signs on physical examination that are suggestive of peripheral arterial disease of the lower leg. In the absence of any obvious signs of arterial disease, omitting a detailed arterial examination would generally not be considered a significant departure from standard practice. However, if for example the patient complained of intermittent claudication or there were obvious pallor/skin changes in the feet suggestive of arterial disease, then in this case, an arterial examination would be mandatory. There is no way of knowing this as it was not indicated in the clinical notes.
2. As you have indicated, [Dr B] has clarified that the injections were Ultrasound Guided. I would have great concerns if this were the case, as it is extremely difficult, if not impossible to inject a major artery, during Ultrasound Guided Sclerotherapy, without piercing the fascial layer. To clarify this further, it is important to recognise the anatomy of the lower leg. Superficial veins lie in the superficial compartment, either on the dermis, sub-dermal, subcutaneous or within the saphenous compartment. When performing ultrasound guided sclerotherapy to subdermal and subcutaneous veins, the needle is directed into these superficial veins before injection of the sclerosant foam. Major arteries do not lie in the superficial compartment. They are deep to the fascial layer and can be either inter- or intramuscular. As shown in Figure 1, an artery like the Dorsalis Pedis Artery, lies deep to the superficial compartment behind several tendons of the ankle/foot (the extensor tendons). One must traverse the fascial layer and deep to the tendons to directly inject the Dorsalis Pedis Artery. Figure 1 With meticulous technique this is just not possible. There is no way to confirm that this is what happened on the day of treatment and I cannot directly comment on [Dr B's] technique without observing it. Having said that, arterial injections should not occur with meticulous ultrasound guidance.
3. In my opinion, the patient should have been referred immediately to an emergency facility upon recognition of an arterial event of such significance. Not doing so, may

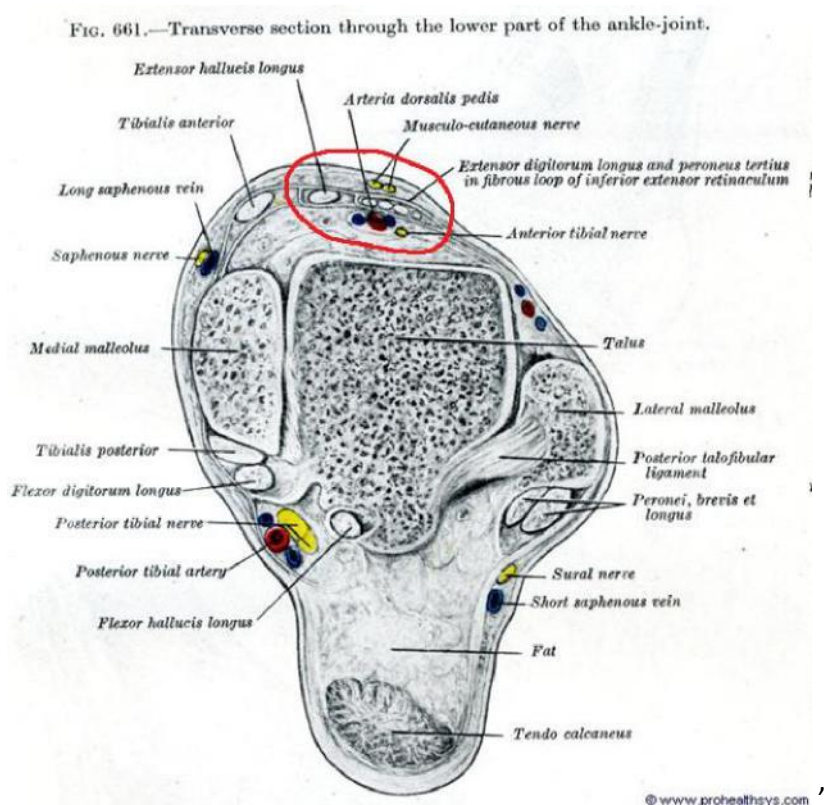
be considered a significant departure from standard practice. A major arterial injection is considered one of the most devastating complications of ultrasound guided sclerotherapy and as such, is a clinical emergency that requires immediate attention.

4. If there was a recognised arterial event or suspicion of an arterial event, compression stockings could have potentially aggravated the situation by further compromising peripheral arterial microcirculatory flow. Peripheral arterial injections are such a rare event that there is no documented, agreed upon consensus, regarding immediate management. However, it is well documented that compression stockings are contraindicated in moderate to severe Peripheral Arterial Disease (ABI < 0.5)⁷. It is in this context that upon recognition of an arterial injection, where there has been intimal damage and microthrombus obstruction to the peripheral circulation of the foot, stockings would be highly contraindicated; and as such to apply compression stockings would be considered a departure from accepted practice amongst Phlebologists.

References:

7. Stucker et al, Safety of a compression stocking for patients with Chronic Venous Insufficiency (CVI) and Peripheral Arterial Disease (PAD). Journal of the German Society of Dermatology 2019; 18(3): 207–213

Figure 1



The following further advice was received from Dr Paraskevas:

“I have read through [Dr B’s] response.

1. There are no other matters in this case that require further comment. My initial Expert response was pertinent and addressed my concerns regarding this case.
2. It appears that [Dr B] has taken all practical measures, within his power to make improvements to his Practice.

Regards

Dr Peter Paraskevas”

Appendix B: Medical Council of New Zealand statement on maintenance and retention of patient records, August 2008



MEDICAL COUNCIL OF NEW ZEALAND

AUGUST 2008

www.mcnz.org.nz

The maintenance and retention of patient records

Introduction

Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any future dispute or investigation.

01 Maintaining patient recordsⁱ

(a) You must keep clear and accurate patient records that report:

- relevant clinical findings
- decisions made
- information given to patients
- any drugs or other treatment prescribed.

(b) Make these records at the same time as the events you are recording or as soon as possible afterwards.

02 Practice systems

(a) Council recommends that every practitioner has access to systems for recall of patients who need regular checks or treatment.

(b) Doctors should have systems in place to ensure that test results are acted upon in a timely manner, including notification of patients as appropriate.

03 Fees and patient records

(a) Section 22F of the Health Act 1956 states that transfer of patient records cannot be refused because of money owing or conflicting commercial interests.

(b) A patient or representative of the patient cannot be charged for copies of his or her records unless they have previously requested the information within the past year. Video recordings, x-rays and CAT scans are exceptions to this rule.ⁱⁱ

(c) Patients have a right of access to information in their records because the information belongs to the patient, whereas the record belongs to the doctor.ⁱⁱⁱ

(d) When sending information to patients it is advisable to ask the patient what method is preferred because message services, facsimiles and e-mails are not always secure.

04 Transferring patient records

(a) It is advisable to transfer patient records using some form of registered mail so that tracing the records is possible if they go missing in the mail.

(b) The Medical Protection Society strongly recommends that medical practitioners retain a copy or summary of any patient records that are transferred, for subsequent reference, particularly if there may be disciplinary action to follow.

ⁱ Refer to *Good medical practice*. Cole's Medical Practice in New Zealand contains further guidance on record management.

ⁱⁱ Part III (6) Health Information Privacy Code 1994

ⁱⁱⁱ There may be situations where a doctor feels it is unwise to provide access to all the information. Rule 11 of the Health Information Privacy Code 1994 provides situations where a doctor may not have to disclose all health information about the patient.

05 Retaining patient records

How long should PHOs, private hospitals and doctors in private practice keep patient records?

- (a) The Health (Retention of Health Information) Regulations (*the Regulations*) outline the legal requirements for the retention of patient records by PHOs, private hospitals and doctors in private practice. The regulations state that all records must be retained for a minimum of 10 years from the day following the last date of the patient consultation.
- (b) Retention of records for longer than the minimum 10 years is recommended for children with significant problems or patients with conditions in paediatrics, psychiatry, obstetrics and gynaecology, orthopaedics or other problems likely to persist in the long-term.
- (c) The Regulations state that health information does not have to be retained in any particular form. If the material on which the health information is contained will deteriorate before the minimum 10-year retention period, it is sufficient compliance for an accurate summary, or interpretation of that information to be made and retained.

How long should DHBs keep patient records?

- (d) Under the Public Records Act 2005 most records held by government agencies (including patient records held by DHBs) are public records and may not be disposed of (whether by transfer, destruction, alteration, sale or discharge) without the authorisation of the Chief Archivist. DHBs should contact Archives New Zealand for information regarding authorisation for disposal of records and, in any case, once they reach 25 years of age.

Planning for retirement

- (e) Meeting all the requirements for the retention of patient records can be difficult, especially for sole practitioners, who form a large section of the medical workforce. Before retiring doctors should:
 - make prior arrangement for another practitioner to accept responsibility for them (through power of attorney); and/or
 - arrange for patients to pick up their own records.

The important thing is to make some arrangement well before retirement.

- (f) The Regulations states that when a patient dies a doctor may transfer the record to the representative of the deceased.
- (g) In the situation where arrangements have not been made for the retention of patient records and the doctor dies, the Executor of the estate or Power of Attorney should endeavour to return records to the patient (the patient's family if the patient is dead), or another doctor.

06 Storage requirements

- (a) The Health Information Privacy Code 1994 outlines the requirements for storage of patient records.
- (b) Patient records should be filed securely and away from public areas but also be easily accessible in case a request is received for a copy. They should only be visible and accessible to appropriate members of staff. Computer files must be protected by password and have backups in case of technical difficulties.

07 Destruction of patient records

- (a) Destruction of a patient record must be done in such a manner as to preserve the privacy of the patient. Burning or shredding the documents is acceptable and there are security companies that destroy documents.

Notes:

Contact the Privacy Commission for any information about the storage, transfer and privacy of patient records: 0800 803 909. *On the Record* is a useful guide about privacy of health information and is available from the Commission.

Relevant legislation

- Health Act 1956
- Health (Retention of Health Information) Regulations 1996
- Health Information Privacy Code 1994
- Code of Health and Disability Services Consumers' Rights

August 2001

Amended October 2005 and August 2008

This statement is scheduled for review by August 2013. Legislative changes may make this statement obsolete before this review date.