Recent NICE guidance of interest to surgeons

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Interventional procedures

Cyanoacrylate glue occlusion for varicose veins (IPG526)

This is a novel way of treating varicose veins under local anaesthesia and ultrasonography guidance. It adds to the variety of treatments already available, in particular endothermal ablation (using radiofrequency or laser), ultrasonography guided foam sclerotherapy and surgery, all of which are now the subject of a NICE clinical guideline (CG168),¹ a NICE quality standard (QS67)² and commentary in a past issue of the *Annals*.³ Using cyanoacrylate glue offers the potential to occlude truncal veins (great or small saphenous veins) without the need for the tumescent local anaesthesia required during endothermal ablation, which patients may find quite uncomfortable.

The evidence on safety and efficacy of using cyanoacrylate glue was quite limited, consisting of a randomised controlled trial (RCT) of 222 patients and some case series. These showed generally good occlusion rates (with a follow-up period of up to two years for some patients) and no major adverse events. The Interventional Procedures Advisory Committee decided on a 'special arrangements' recommendation, not least because it considered that rare or uncommon adverse events might not yet be apparent, based on the limited numbers of patients included in the RCT and case series.

Conflicts of interest

I am guessing that the committee may have been mindful of its experience in producing guidance for ultrasonography guided foam sclerotherapy; there turned out to be rare occurrences of very serious side effects. The reason that I am guessing is that I was not present for any of the discussion. This is because I had a conflict of interest (as a vascular specialist who had undertaken varicose vein procedures in the private sector in the previous year) and I therefore took no part in developing the guidance on the procedure. The same would apply if I had received financial support of any kind from a manufacturer of the glue used for this procedure or from any manufacturer of any other kind of technology that could be used to treat varicose veins, as an alternative to this procedure.

NICE is very strict in its exclusion of committee chairs on the basis of any financial conflict.⁴ In addition, there may be circumstances in which a chair might be excluded from any involvement in producing guidance if he or she has expressed a strong opinion about a particular topic.

The approach to conflicts of interest of committee members is more flexible.⁴ NICE recognises that many committee members will have legitimate interactions with industry, in further to having private medical practices, so it does not regard these as necessarily precluding people from membership of advisory committees. Interests must always be declared but depending on their nature, members may be permitted to participate in the committee's discussion about a topic (at the discretion of the committee chair). However, they may be asked to leave the room when making of decisions about NICE recommendations.

Specialist committee members often have conflicts, through the nature of their clinical and/or research work, but it is important to have them present for informed discussion on account of their knowledge and expertise. Many of the specialist advisers who provide advice for NICE (either by correspondence or by joining various specific committee meetings to respond to questions) have conflicts; these simply need to be declared so that the committee members are aware of them when taking their advice into account.

Checking guidance relevant to you during public consultation

NICE IPG526 on cyanoacrylate glue occlusion for varicose veins provides a valuable lesson for all specialists about reading draft interventional procedures guidance carefully during its one-month public consultation period. That is the time to comment on it and to get discrepancies (large or small) changed. The specialist societies involved, specialist advisers and anyone else who has expressed an interest in the topic automatically receives notice of the start of public consultation.

A short time after this guidance was published, in its final version, I received a somewhat emotional email from a group of senior vascular surgeons who were concerned that one descriptive sentence about treatment of varicose veins was incorrect and out of tune with other NICE recommendations on varicose veins. I agreed with them but enquired why nobody among the leaders of my own specialty had spotted this during public consultation. Advisedly, I had remained distant from any kind of involvement in the production of this guidance, for the reasons explained above.

It may be that the descriptive text that has caused concern will be altered but it is much better to 'get it right first time' using NICE's careful processes. Interventional procedures guidance documents are not lengthy; I urge specialists

and (especially) representatives of their specialist societies to read draft guidance that is relevant to them, and to comment on it if they spot any discrepancies.

Electrotherapy for the treatment of haemorrhoids (IPG525)

Electrotherapy (also called electrocoagulation) aims to offer an option for treating all grades of haemorrhoids. It can be used in an outpatient setting, or (generally when using a higher current) under general or spinal anaesthesia. The published evidence on efficacy included four RCTs: 50 patients randomised against injection sclerotherapy (electrotherapy better); 100 patients randomised against rubber band ligation (no significant difference in efficacy); 100 patients treated by monopolar or bipolar electrocoagulation (recurrence rates around 50% at one year for both); and 272 patients treated by different electrotherapy currents versus haemorrhoidectomy. In addition, in a case series of 931 patients, over 90% were back at work within 2 days.

With regard to safety, no major adverse events were reported. A proportion of patients found the procedure painful and it seemed that higher current levels (which may be more effective) are better used under general or spinal anaesthesia. Treatment using low currents may need to be repeated.

Dilemmas in decision making

This amount of efficacy evidence (especially in the form of RCTs) was substantially greater than the norm for 'new' procedures. It was in stark contrast to the tone of the advice received from six specialist advisers, all of whom regarded the procedure as novel. Only two had performed

it (NICE had to seek them out) and overall, their level of enthusiasm for the procedure seemed quite low. This contrast between the published evidence and the specialist advice gave the Interventional Procedures Advisory Committee a dilemma.

An additional dilemma was that the mechanism of action of electrotherapy, as described by manufacturers and proponents, was considered by committee members to be dubious and implausible. Doubt about the concept or mechanism of any procedure naturally tends to sway any judgement against it but (as always for this committee) I advised the committee members that their focus should be on the evidence of clinical benefit or harm of the procedure, regardless of any scepticism they might have about the claims for its mechanism of action.

Having debated all the issues, the committee drafted a 'normal arrangements' recommendation, recognising that specialists might find this surprising for a procedure that has clearly not yet gained any particular popularity in the UK. The views of specialists generally have a powerful influence on the committee's decision making but a large volume of good published evidence is the crux to supportive decisions, throughout the work of NICE.

References

1. National Institute for Health and Care Excellence. *Varicose Veins in the Legs: The Diagnosis and Management of Varicose Veins*. London: NICE; 2013.
2. National Institute for Health and Care Excellence. *Varicose Veins in the Legs*. London: NICE; 2014.
3. Campbell B. Recent NICE guidance of interest to surgeons. *Ann R Coll Surg Engl* 2014; **96**: 159–160.
4. National Institute for Health and Care Excellence. *Policy on Conflicts of Interest*. London: NICE; 2014.