

Dear Mr Wood,

Please find comments from BASS, representing spinal surgeons from neurosurgical and orthopaedic backgrounds.

Overall we are in agreement with conclusions but it is important to state that whilst Operative Placebo Local Anaesthesia (OPLA)

–may alleviate pain, as part of the optimal pain management described in point 1.1 of the appraisal committee's preliminary recommendations, in the short term, but will not treat any progressive vertebral collapse.

There are quite a few critique papers published on the RCTs analysed. Their analysis highlights the two issues below as well as controversy about optimal timing.

The major problem is that the dose of cement is not stated in one study, and is inconsistent in the other. No drug trial (eg hypertension, chemotherapy, antibiotics etc) would be accepted for publication with this fairly major flaw. It is also compounded by the fact that the placebo OPLA was not standardised for exact anatomical location. This was highlighted by one of your health economists in a personal communication with one of the senior authors.

Higher quality studies with these problems addressed are needed. We still have a lot to learn about this technique.

Also the technology is evolving in terms of cement viscosity and delivery systems. For NICE there is a moving target!

I also include the comments from one of my orthopaedic colleagues:

I think it is not appropriate to mention specific manufacturers in NICE guidance - 3.2 and 3.4 and 3.5.

There are also many other techniques evolving which vary in nuances - e.g. osseofix, Dfine etc..

I assume this is for this document only and not for the final guidance.

CPC - CPC is by no means to be considered a standard alternative. Biomechanics are sketchy as are clinical results.

Probably only suitable when MRI verifies no endplate lesion.

Adverse reactions: when balloons rupture contrast is set free - this can theoretically be of concern in patients with hyperthyroidism.

The Buchbinder and Kallmes trials are simply invalid - although this seems a ridiculous claim to make, it is based in fact as the cement volume was not recored in the Kallmes trial and is documented to be insufficient in the Buchbinder trial - see Boszczyk Volume matters ESJ 2010 - attached

Simple vertebroplasty can be done for under £500 per level using standard Jamshidi needles and a pack of confidence. This may not be the technically most advanced way of doing this but it places the dedicated systems into perspective.

What does make sense is the radiation reducing systems such as DFine which reduce patients and operator radiation.

Yours Sincerely

[Redacted signature]



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