Diclofenac gel provides modest pain relief for people with osteoarthritis in one knee

Research question Does diclofenac gel work better than placebo for people with moderately painful osteoarthritis of one knee?

Answer Diclofenac gel (1.16%) relieves pain and stiffness somewhat better than a placebo, but it takes about a week to start working.

Why did the authors do the study? European and American guidelines recommend oral or topical non-steroidal anti-inflammatory drugs as second line treatment for osteoarthritis. The authors, supported by the drug manufacturer Novartis, wanted to evaluate the topical gel in a clinical trial with modern robust methods.

What did they do? 237 German patients with osteoarthritis of one knee took part in a double blind, placebo controlled trial. They had moderate pain and radiographic changes, including osteophytes. After a washout period, during which they could take only paracetamol (up to 2 g a day), participants used 4 g of diclofenac gel (1.16%) four times a day, or an identical placebo, for three weeks. They kept daily diaries of symptoms and use of paracetamol. The authors assessed participants' pain, stiffness, and physical function at the end of each week using a 100 mm visual analogue scale of pain intensity and the Western Ontario and McMaster osteoarthritis index questionnaire. At the end of three weeks, participants were asked to rate their treatment overall on a scale from 0 (poor) to 4 (excellent). The main measure of outcome was patient's daily record of pain on movement, averaged over the first 14 days.

What did they find? Patients using the diclofenac gel reported a slightly greater improvement in pain on movement than those using the placebo. Averaged over 14 days, their scores fell by 14 mm on the visual analogue scale compared with 10 mm for patients using the placebo (absolute difference 4 mm, $P = 0.02$). The difference increased a little during the study, averaging 6 mm in the second and third week ($P = 0.005$).

Patients using the diclofenac improved significantly more than controls in their scores on the osteoarthritis index. During weeks 2 and 3 they reported an extra 7-9 point improvement on the three 100 point scales measuring pain, stiffness, and physical function.

At the end of the study, 69% of patients using diclofenac and 58% of controls rated their treatment as good, very good, or excellent ($P = 0.03$). Few patients reported side effects. One patient in each group developed contact dermatitis.

What does it mean? Diclofenac gel worked better than placebo in this study, but the benefits were modest and took about a week to develop. The authors note that oral non-steroidal anti-inflammatory drugs work much faster but are associated with substantially more side effects. This is the first study to suggest that topical treatments can be effective beyond two weeks. But the results should not be extrapolated to patients with severe pain or extensive radiographic changes. Two thirds of the patients in this study were well enough not to need paracetamol during the washout period.

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Editor's choice

A time for courage

More than a decade ago, in an editorial entitled "Where now for the NHS reforms?" Chris Ham asked "what is the purpose of a national health service?" (*BMJ* 1994;309:351-2) This week Neville Goodman says it's a question that governments refuse to ask (p 363). Until it is answered, he says, "we will stagger from crisis to crisis, pressure groups forcing the government to give in on expensive but dubious therapies, while the government imagines that all it needs is the next big restructuring to get things right."

It all sounds depressingly familiar. A range of news and views in this week's *BMJ* paint a picture of continuing turmoil and unhappiness within the NHS. A meeting organised by the National Patient Safety Agency last week heard that waiting list targets had pushed safety down the agenda (news extra bmj.com). A UK parliamentary select committee heard that prescription charges could seriously undermine plans to reach people most in need (news extra bmj.com). A King's Fund report concludes that almost 90% of new investment in the NHS has gone on higher pay and other costs rather than on direct improvements to patient care (p 319). A general practitioner in Halifax thinks that while expectations are rising, the NHS is being downsized and fragmented (p 363). A director of public health despairs at the impossible task of dealing with growing financial deficits at her primary care trust (p 363).

There is more. Sam Ramaiah bemoans the organisational disruption that is driving public health doctors away from the NHS at a time when the government wants them to help implement its white paper (p 370); and Michael Goodman (p 371) says managers are interfering with referrals between hospital consultants, prioritising referrals from general practitioners in order to meet government targets. He urges doctors to defend their professional position or risk "handing over clinical decisions to lay managers, acting under the dictat of politicians." The unedifying herceptin story is just another example of political interference (p 320, p 368). Even Richard Lewis (p 315), who seems upbeat about the government's "much needed reforms," ends by saying that the financial and managerial climate is not encouraging. Success will depend, he thinks, on political will.

So back to Ham's original question, what is the purpose of a national health service? Neville Goodman is not optimistic. "The sort of courage needed to even ask, let alone answer, the question does not go with the need for re-election," he says.

On another front, it just can't be right, in fact it is obviously wrong, that the tobacco industry can influence national governments and opinion leaders to the extent described in this week's *BMJ* (p 321, p 353, p 355) And it is depressing to hear from Ernesto Sebríe and Stanton Glantz (p 313) that WHO has been silent about countries that fail to honour its framework convention on tobacco control. WHO took a brave stand a few years ago in facing up to its own tobacco links (*BMJ* 2000;321:314-5). Now is the time for WHO to speak out again.

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