BMJ

Osteoarthritis of the knee in primary care

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BMJ 2008;336;105-106; originally published online 4 Dec 2007;
doi:10.1136/bmj.39412.592477.80

Osteoarthritis of the knee in primary care

Topical NSAIDs are as effective as oral NSAIDs, and patients prefer them

RESEARCH, pp 138 , 142

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Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

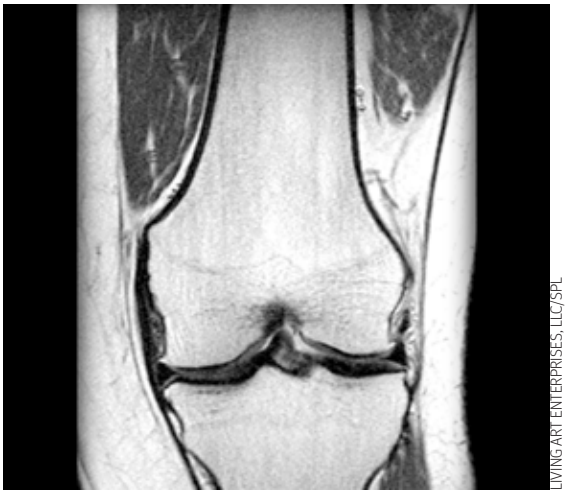
BMJ 2008;336:105-6
doi: 10.1136/bmj.39412.592477.80

Many older people have pain in one or both knees from time to time, and the most likely cause is osteoarthritis. In some people the symptoms are severe or intrusive enough to consider an intervention.

The National Institute for Health and Clinical Excellence (NICE) has just published its draft guideline on the management of osteoarthritis.[1] It lists five interventions regarded as "core treatments" for osteoarthritis of the knee—paracetamol; education and information; exercises; weight loss (if the patient is overweight); and topical non-steroidal anti-inflammatory drugs (NSAIDs). The guideline lists another 14 interventions, ranging from those that are safe (such as alterations to footwear or local heat and cold), to those that are potentially harmful (such as oral NSAIDs, opioids, and surgery). The first sentence of the draft guideline says, "Treatment and care should take into account the patients' needs and preferences." So what choices are available and how should people decide?

Two accompanying papers compare the value of a topical NSAID (ibuprofen gel) with oral use of the same drug for osteoarthritis of the knee.[2 3] The first study by Underwood and colleagues describes two trials—a randomised controlled trial that compares advice to use topical ibuprofen with advice to use oral ibuprofen, and a preference trial offering the same options. The second paper by Carnes and colleagues is a nested qualitative study that explores the reasons for patients' preferences. The randomised controlled trial was powered for equivalence, and it found no significant difference in the WOMAC osteoarthritis index or major and minor adverse effects at one year between people who used the topical preparation or the oral drug. Cynics might conclude that both interventions are useless, but other data indicate that topical and oral ibuprofen perform slightly better than placebo, at least in the short term.[4 5]

The results from the preference data are fascinating. Firstly, more people chose the preference study than the randomised controlled trial, and nearly three times more of them opted for the topical preparation (n=224) than the oral preparation (n=79). Quantitative analyses showed that women and people with a lower socioeconomic status were more likely to choose the preference study. Another intriguing finding was that adverse events after oral ibuprofen occurred less often in participants who chose tablets than in those who were randomised to them. The qualitative data indicated that the choice between the topical or oral preparation depended on the severity of the pain, whether or not participants had pain at other sites, and their perceptions of likely adverse effects. So participants with more constant or severe pain and other painful sites (or both), and those who were more concerned about toxicity, opted for the topical gel. These choices seem reasonable.



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So what does this mean? Firstly, it shows that, given options, patients will make sensible rational choices about how they want to be treated, and that their ability to choose may improve efficacy and reduce toxicity. Secondly, the data indicate that topical NSAIDs are a viable safe alternative to oral NSAIDs for the treatment of osteoarthritis of the knee. A systematic review of a different topical NSAID found similar results,[6] and the NICE guideline suggests that topical agents are cost effective.[1] In view of the current distrust of oral NSAIDs among patients and professionals—because of problems with drugs like Vioxx and Prexige—this is important.

But will this change our practice, and will we switch our patients from oral drugs to topical ones? A variety of topical agents are available for osteoarthritis, ranging from old fashioned ointments, linaments, and balms that have been used for centuries,[7] to topical NSAIDs, capsaicin,[8] local anaesthetics, patches containing opioids or other analgesics, and topical preparations of seemingly ineffective agents such as glucosamine.[9]

The over the counter market for these preparations is huge. Why? Is it because of the efficacy of the drugs within them, or is it more about the age old practice of "rubbing it better?" In my view, placebo or context effects explain most of the value of topical agents in osteoarthritis.[10] But for me to recommend a placebo it must be safe and be something that I believe in (so that I can prescribe it without damaging the trust between

me and my patients). In addition, it is more likely to work if the patient believes in it.[11] Evidence based medicine and randomised controlled trials have sadly taken away the option of prescribing placebos even if, like topical NSAIDs for osteoarthritis, they are safe and useful. Perhaps it is just as well that the trials reported here did not include a placebo arm.

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Maximising research opportunities of new NHS information systems

Don't ignore the potential of health services research

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FEATURE, p 120

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Competing interests: None declared.
Provenance and peer review: Commissioned; externally peer reviewed.

BMJ 2008;336:106-7
doi: 10.1136/bmj.39364.586146.80

Amid all the controversy and debate around the introduction of a new national information technology programme for the English National Health Service (NHS), the needs of researchers for information have been largely ignored while—perhaps understandably—the immediate needs of clinicians, administrators, managers, and policymakers have been prioritised.

Reluctance to consider the needs of researchers may also reflect managers' fears of a loss of control of the data and the public's and politicians' concerns about breaches of confidentiality. Whatever the reason, researchers and research funders are increasingly concerned that the people responsible for designing the new system lack awareness of the potential research uses of routinely collected healthcare data. This is despite at least three recent documents showing the benefits of such data to the NHS and public health,[1-3] and examples of successful relationships between health systems and researchers, such as is seen in the United States[4] and Canada.[5]

A further attempt to demonstrate the value of routine data for research has recently been made by the UK Clinical Research Collaboration (a partnership of all major funders of clinical research) through a joint initiative with Connecting for Health (the NHS agency responsible for instituting the new IT programme). The first product of a jointly convened advisory group appeared in June.[6]

Their report is based on simulations of four approaches to using routine NHS data for research—surveillance (to detect rare and long term adverse effects of healthcare interventions), support for clinical trials (to establish the effectiveness of interventions), longitudinal cohorts (to discover the causes of disease), and observational epidemiology (to determine the distribution and trends in the occurrence of disease in the population). Some common lessons from these simulations led to six recommendations for maximising the research potential of NHS data in the short term: mandatory use of patients' NHS numbers; greater recognition by IT managers of the importance of routine information for research; high level support for facilitating the linking of different databases (creating what they call a federation); improvements in completeness and quality of data; removal of unnecessary data governance obstacles, while retaining necessary safeguards; and persuasion of clinicians regarding the benefits of research. Such proposals are likely to find widespread support, except from those adamantly opposed to any collective use of personal data.

While five of these six recommendations are neither novel nor contentious, the creation of a federation of existing databases is a welcome break with the past. Since the introduction of mainframe computers into the NHS several decades ago, government and NHS policy has been dominated by a command and control approach. Despite rapid evolution in hardware and software, this has remained an absolute and driving principle even for the current IT programme, although recent political signals have indicated that some central control might be relinquished.

To date, devolution and diversification of the collection and storage of data in the NHS has at best been ignored and at worst been actively discouraged. Despite this, groups of dedicated clinicians, sometimes allied with epidemiologists and statisticians, have established specialised databases[7] that can complement the limited potential of routine administrative databases. Groups that have attracted adequate resources have often produced high quality databases that allow adequate adjustment of case mix for evaluative research to be carried out and for meaningful audit of outcomes.[8]

Unfortunately, despite the best endeavours of their

creators, other databases have proved less successful. The recommendation to encourage a federation of databases should therefore be accompanied by greater support for the many specialised databases that exist and encouragement of others to emulate these successes. This could be aided by creating one or more clinical database support units along the lines of support units for clinical trials. In addition, the eHealth Research Board being established by the new committee that will coordinate publicly funded health research in the United Kingdom—the Office for Strategic Coordination of Health Research—will hopefully contribute to improving specialised databases.

Although the report[6] makes a convincing case as to why research uses should be considered in the design and implementation of new IT systems in the NHS, the case could have been stronger. While the use of databases to support clinical research and public health research is well represented, the contribution of health services research is limited to its activities in evaluating clinical interventions (or health technology assessment). The potential contribution of the other principal activities of health services research—studying how services are organised and delivered and research to inform policy and evaluate policy—are ignored. This is particularly pertinent given that many of the questions in these areas can only be answered using databases.

Consider, for example, just three studies that illustrate the valuable contribution that health services research has made. One showed that discharging patients from adult intensive care units at night is dangerous,[9] another showed that the quality of care for some conditions improved when payment for performance for general practitioners was introduced,[10] and yet another established that the outcome of some surgical operations improves when a surgeon or hospital carries out the procedure more often.[11]

If the contribution of such research is valued by clinicians, managers, and policymakers, it is essential that the needs of health services and healthcare policy research are taken into account alongside those of clinical and public health research. Research at the organisational and system levels has much to contribute and strengthens the case for the recommendations put forward in this recent report. The three complementary areas of health research—clinical, health services, public health—all stand to gain from a wider recognition of the need for access to good quality routine data from the NHS.

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Follow-up after breast cancer

Should be evidence based, flexible, and tailored to patients' lifelong needs

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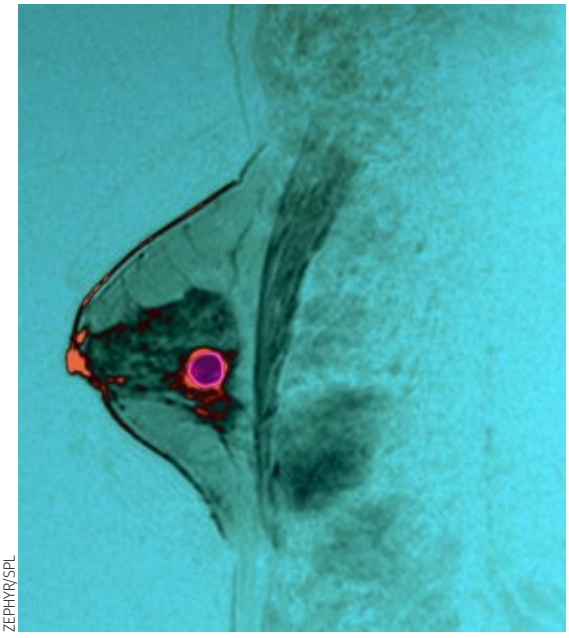
Competing interests: None declared.
Provenance and peer review: Not commissioned; externally peer reviewed.
BMJ 2008;336:107-8
doi: 10.1136/bmj.39421.440799.BE

More than 1.2 million women and men worldwide are diagnosed with breast cancer each year. In 2007, the 20 year survival rate for breast cancer will be greater than the five year survival rate 30 years ago.[1] Breast cancer is now recognised as a chronic disease that can recur even after 20-30 years. Follow-up protocols vary widely—both within and between countries—and are not always evidence based. The challenge is to develop follow-up programmes that reflect current knowledge and meet the ongoing needs of this growing number of people.

Guidelines from the National Institute for Health and Clinical Excellence (NICE) in England and Wales state that the aims of breast cancer follow-up are to detect and treat local recurrence, to deal with adverse effects of treatment, and to provide psychological support.[2] Routine surveillance for metastatic disease is not recommended because data from randomised studies have shown no improvement in outcomes for patients who undergo intensive programmes to detect and treat asymptomatic metastatic disease. The guidelines suggest that the aims can be met by two to three years of follow-up, and they conclude that routine long term follow-up is ineffective and unwarranted. The guidelines provide no specific recommendations for mammography; they claim that the yield from mammography is low, and that networks should derive their own evidence based policy on how often mammography should be conducted.

The incidence of metastatic disease peaks around two to three years after diagnosis and stays at 2% annually for up to five years before decreasing, but the pattern is different for treatable locoregional recurrences and contralateral breast cancer. Although true local recurrence after breast conserving surgery falls with time, the development of new cancers in the treated breast increases, so the overall incidence of ipsilateral breast events is constant—at 0.5-1% each year for at least the first 10 years and probably for the rest of the patient's life. Patients with cancer in one breast have increased risk of contralateral breast cancer—the incidence is 0.3-0.4% each year. If "recurrences" in the treated breast and axilla are combined with new



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MRI scan of 56 year old woman with breast cancer

cancers in the other breast, the annual incidence of treatable locoregional disease is constant at 1-1.5% for at least the first 10 years, and 70% of such events occur after the first three years. If NICE is to achieve its aim of detecting and treating local recurrence it clearly cannot be achieved with a three year follow-up.

The value of regular clinical examination to detect treatable recurrences is questionable. In a recent audit of patients treated by breast conservation in our unit, only 15 of 110 treatable locoregional recurrences were detected by clinical examination. In contrast, 56 events were detected by mammography, 37 were detected by the patients themselves, and two were diagnosed incidentally during breast reshaping.[3] Importantly, patients with recurrence in the ipsilateral breast that was symptomatic or detected by mammography had a significantly better survival than patients with a clinically detected recurrence (P=0.0002). In an unpublished audit carried out by our unit, annual mammography detected 5.37 ipsilateral and contralateral breast cancers per 1000 mammograms. This compares favourably with the prevalent detection rate in the National Health Service Breast Screening Programme (where women have a mammogram at three yearly intervals) of 4.7 per 1000 women screened in 2003.[4] In contrast to NICE's suggestion, mammography is a very effective way to detect treatable local disease, and fully funded mammographic surveillance programmes specifically for patients with breast cancer are urgently needed.

Psychological concerns after treatment for breast cancer often become apparent during follow-up, although clinic visits are not always helpful in detecting or treating such problems.[5 6] Nurses detect more psychological problems than clinicians doing routine follow-up clinics.[7] Side effects of drug treatment and unrelated medical problems are other common concerns reported by patients, but these are often underestimated and unrecognised by clinicians.[8 9] One solution is to provide patients with self completed quality of life questionnaires, which are reliable and effective at identifying such difficulties. Continued clinical input will be needed for some patients, including those who request revisional or reconstructive surgery, those with serious side effects from treatment, people with signs and symptoms that suggest recurrence, and those suitable for switching to aromatase inhibitors agents after two or five years of tamoxifen. Long term complications of treatment and bone health are other areas where specialist medical management is increasingly required.

The NICE guidelines need urgent revision as they do not meet their stated aims. Clinical examination should be annual for two years. Any unit performing more regular clinical assessments should consider amending their protocols now. Psychological support should be available and focused when patients' needs are greatest—not only at diagnosis and during treatment but after treatment ends.

Discharging patients from breast units to breast screening programmes after two years is unlikely to meet their specific needs. Follow-up care and the health professionals involved will vary in different settings. One model that meets the aims set out by NICE is annual clinical examination for two years and surveillance by mammography thereafter. Our audit data support annual mammograms. Assessment before these annual visits by note review and postal questionnaires should identify those patients who need medical or nursing input when they attend for mammography. In between visits for mammograms, patients should have direct access to a named breast care nurse, specialist nurse, or doctor and access to prosthesis advice and fitting. Timely investigation of symptoms and communication of test results to patients and primary care doctors will help reduce anxiety and improve ongoing care. Patients' needs vary, so follow-up programmes for patients with breast cancer need to be evidence based, flexible, and tailored to their lifelong needs.

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