MANAGEMENT OF TENNIS ELBOW

Don't forget orthoses and acupuncture

That Orchard and Kountouris's article was a clinical review[1] might suggest a comprehensive approach to the management of tennis elbow, but they did not mention the role of orthotic devices or acupuncture. The authors might find these four references useful.[2-5]

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Competing interests: None declared.

1 Orchard J, Kountouris A. The management of tennis elbow. *BMJ* 2011;342:d2687. (27 May.)
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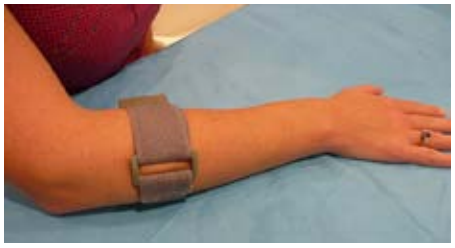
Tennis elbow myths

Orchard and Kountouris present a good summary of the evidence on so called tennis elbow, which is essentially that it's a painful self-limiting condition that gets better spontaneously and is not helped (at least on the basis of proper research) by medical intervention.[1]

Conventional treatments—and indeed some of the rapid responders to their article[2]—vividly express the "need to do something" motive of doctors confronted with this condition. It's just a pity that Orchard and Kountouris compound the mystique around this condition by repeatedly referring to a tendon. There is no tendon at the site of the condition, as anyone who has explored the area will know. Rather, it is a musculoligamentous insertion. Hence there is no gliding problem and no tendinopathy as usually understood. Can we please put this myth to bed once and for all?



Tennis elbow brace

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Competing interests: None declared.

1 Orchard J, Kountouris A. The management of tennis elbow. *BMJ* 2011;342:d2687. (27 May.)
2 Rapid responses. The management of tennis elbow. bmj.com 2011. www.bmj.com/content/342/bmj.d2687.full#responses.

Cite this as: *BMJ* 2011;342:d3837

Authors' reply

Barry mentions some relevant treatment options.[1] We think that all tennis elbow braces (figure), wrist splints, and acupuncture have low level evidence suggesting mild benefits,[2] but they can definitely be offered as they are all comparatively cheap treatments with low risk of harm.

Orthotic devices should probably be tried before prescription or purchase as patients can usually decide within minutes whether the device is more helpful than annoying. Acupuncture is at one end of a range of needle treatments, which includes tendon dry needling and platelet rich plasma, glucose, and other non-cortisone injections. We reiterate that the onus is on the advocates of the more expensive or invasive or specific of these to show superiority over the cheaper and less specific alternatives. Generic physiotherapy (eccentric exercises and electrotherapy) is probably comparable in efficacy to these other basic treatments.[3-5] Although it is harder to subject to randomised controlled trial, we believe that structured rehabilitation is the most successful. In other words, offer the patient supportive treatment alone until he or she is compliant with reducing overload, then add exercises to restrengthen only after any ongoing overload has been removed, encouraging a gradual return to normal loading.

Mahaffey highlights a valuable teaching point—that there is no tendon sheath at the common extensor origin and hence no tenosynovitis.[6] This may mean, for example, that tenosynovitis in other areas may differ in its response to, say, cortisone injections. However, a tendon exists at the common extensor origin and hence both a spring effect and hypertrophy in response to graduated loading. A ligament connects bone to bone whereas a tendon connects muscle to bone. Some authors prefer the term enthesopathy rather than insertional tendinopathy. It encompasses conditions such as plantar fasciitis, which has some features in common with tendinopathies, even though the plantar fascia is not a tendon.

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Cite this as: *BMJ* 2011;342:d3843

FRONT LINE CARE FOR BACK PAIN

Front line musculoskeletal care

Having trained as an osteopath and then as a doctor, I agree that training in medical school for the management of back pain is poor[1] and that physiotherapists, osteopaths, and chiropractors could provide a useful service to the NHS because they spend much longer studying musculoskeletal pain syndromes.

However, these clinicians are trained mostly in the private sector, and, although things are slowly changing, a solid environment of evidence based medicine is lacking. There can still be an emphasis on medicalising back pain, with intricate biomechanical diagnoses that require long treatment programmes, and limited evidence to back them up.

For instance, it would be unusual for an osteopath or chiropractor to tell patients that their back is strong and they have a simple sprain that will probably improve on its own if they keep mobile, and that hands-on manual treatment is not needed. Most of these professions work in the private sector, and the pressures are different from those in the NHS. This can make it difficult to challenge entrenched beliefs—for example, most patients attending chiropractors expect manipulation,

and chiropractors will have invested considerable time and money in training in manipulation, making it difficult for them to challenge this approach. Complex biomechanical diagnoses and manipulative treatments can risk making patients feel over-reliant on manual treatments.

Any inclusion of these professions must be accompanied by adequate training in critical thinking and incorporation of evidence based medicine. On this basis, I support their integration into front line musculoskeletal management.

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Competing interests: NJS is a qualified osteopath and a GP specialist trainee; he is currently working in emergency medicine.

1 Hartvigsen J, Foster NE, Croft PR. We need to rethink front line care for back pain. *BMJ* 2011;342:d3260. (25 May.)

Cite this as: *BMJ* 2011;342:d3683

Physiotherapists supporting GPs

GPs are the most appropriate gatekeepers for managing low back pain in the community.[1]

Many GPs across the UK currently have rapid access to triage services run by NHS physiotherapists, who are able to assess patients in a timely fashion. These physiotherapists undergo specialist training, and many have direct access to advanced imaging if needed. It is a system that works well, especially as GPs are often able to sift out patients they know are motivated enough to self manage.

Snelling makes a valid point that physiotherapists, osteopaths, and chiropractors often over-medicalise because of their enthusiasm to use non-evidence based treatments.[2] This may be a common feature in the private sector, but NHS physiotherapists are increasingly abandoning guru taught treatment techniques in favour of evidence based combined physical exercise and cognitive behavioural remedies.

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Competing interests: None declared.

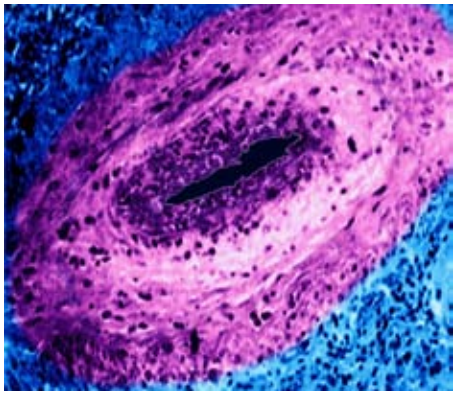
1 Hartvigsen J, Foster NE, Croft PR. We need to rethink front line care for back pain. *BMJ* 2011;342:d3260. (25 May.)
2 Snelling NJ. Front line musculoskeletal care. *BMJ* 2011;342:d3683.

Cite this as: *BMJ* 2011;342:d3684

GIANT CELL ARTERITIS

Test for inflammatory markers

Barraclough and colleagues suggest that 4% of patients present with a normal erythrocyte sedimentation rate (ESR) and C reactive protein (CRP) concentration.[1] This is incorrect—4% of patients may have "ESR negative" disease, but only one case report has demonstrated "CRP negative" disease.[2]



JAMES CAVALLINI/SPL

The economic burden of patients referred to secondary care for a temporal artery biopsy without having had their inflammatory markers determined (who therefore have low disease probability) is immense. CRP and ESR should always be determined in primary care before considering referral. This would also prevent the additional diagnostic dilemma in secondary care of a falsely normal ESR or CRP (or both) as a result of the initiation of steroids in primary care.

The theoretical existence of marker negative disease should not serve as an excuse for not doing these simple tests.

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Competing interests: None declared.

1 Hassan N, Dasgupta B, Barraclough K. Giant cell arteritis. *BMJ* 2011;342:d3019. (23 May.)
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Cite this as: *BMJ* 2011;342:d3685

Don't forget amaurosis fugax

The most feared complication of giant cell arteritis is permanent visual loss. Amaurosis fugax (transient uniocular visual loss) was not specifically mentioned in Hassan and colleagues' article,[1] but it often precedes permanent visual loss[2] and may be the key to early diagnosis and prevention in many cases.

Raised platelet count was also not mentioned,[1] although it is positively associated with biopsy confirmed giant cell arteritis and normalises with steroid treatment.[3] The largest population based study of the disease to date, which looked at 3001 patients who had undergone temporal artery biopsy, identified raised platelet count and raised C reactive protein (CRP) concentration as better than raised erythrocyte sedimentation rate in predicting a positive biopsy result.[4] Thrombocytosis also predicts permanent visual loss in giant cell arteritis.[5]

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Competing interests: None declared.

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Cite this as: *BMJ* 2011;342:d3686

KEEP GPs IN THE DRIVING SEAT

Collective commissioning is better

Hawkes argues against commissioning becoming a multidisciplinary cooperative enterprise.[1] But what does excellent commissioning, best commissioning policies, and robust decision making for consortium populations and individual patients mean?

A well defined process should be at the heart of commissioning to identify the most important disease areas and risk factors associated with mortality and morbidity in the population, as well as any socioeconomic and geographical inequalities. Once population groups have been identified, we need to develop and prioritise solutions for improving their health outcomes. This will require a search for the relevant and best quality evidence base, focusing on the distribution of disease; its causes; predispositions; and efficacious treatments, together with their relative clinical and cost effectiveness and research needs. The relevant outcomes that improve prognosis and quality of life will also need clarification, as will the service standards and models of care that will deliver the desired outcomes.

Such an epidemiological needs assessment will be done independently at the outset, then be validated by discussions with specialists to assess local service compliance and ascertain service gaps. Patient groups must also be consulted. Information thus collated will inform the development of commissioning requirements and an optimal service specification.

Only then can contracting options be considered. Their formulation should incorporate further clinical governance criteria based on current and future health workforce education and training needs, service sustainability, essential service interdependencies, research infrastructure, critical clinical activity volumes including complex case mix, arrangements for emergency/urgent 24 hour care, and critical care requirements. Investment decisions should guard against minimum service volumes, service duplication, and cross-subsidisation between private and NHS providers.

All the above stages will require close working,

collaboration, and links with specialist clinicians and public health consultants across the commissioning and patient pathway. Clinical links between GP commissioners, secondary and tertiary clinicians, and healthcare public health specialists will be required for corporate, planning, operational, and day to day work. The increasing specialisation of medicine and public health makes this mandatory. Not to do so would jeopardise the maximisation of limited healthcare resources and the optimisation of patient care and safety.

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Competing interests: None declared.

1 Hawkes N. Keep GPs in the driving seat. *BMJ* 2011;342:d3382. (1 June.)

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OPENING UP DATA AT THE EMA

EMA urgently needs a cure

The *BMJ* has dared to report that the European Medicines Agency (EMA) seems more interested in protecting the secrets of Big Pharma than in protecting the health of the European people.[1 2]

For too long the EMA has deliberately and cynically impeded access to information. *Prescrire*, the famous independent drug bulletin, was first refused access to the scientific analysis of rimonabant by the EMA. After a second request and a long delay the EMA eventually sent a document, but only two of the 68 pages were readable.[3]

Moreover, the European Parliament has just produced a damning report on the EMA's budget management and its handling of conflicts of interest.[4] Six hundred and twenty six of the 700 members of the European Parliament voted to postpone the closure of the EMA's 2009 accounts until an audit of the agency is produced. The EMA has been given until the end of June 2011 to produce the information requested.

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Competing interests: None declared.

1 Gøtzsche PC, Jørgensen AW. Opening up data at the European Medicines Agency. BMJ 2011;342:d2686. (10 May.)
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Cite this as: *BMJ* 2011;342:d3832

Still waiting for functional EU Clinical Trials Register

Gøtzsche and Jørgensen's comprehensive account of their efforts to obtain clinical trial data from the European Medicines Agency (EMA) highlights the problems researchers still face in healthcare evaluation.[1] In its response, the EMA refers to the steps it has undertaken to improve transparency, including the long awaited launch of the EU Clinical Trials Register (EU-CTR).[2]

The major goal of trial registration and results registration is to enable the unbiased assessment of an intervention. However, the simple disclosure of data in registries does not solve the problem because treatment decisions based on the extraction and evaluation of individual datasets or individual trials will inevitably run a high risk of bias. Therefore, the primary target group of registries should be authors of systematic reviews. Consequently, certain technical preconditions must be fulfilled—to use registry data in reviews, the trials and datasets must be adequately searchable and processable.

The current search functions of EU-CTR are limited, because neither a proper keyword search nor a search for synonyms seems to have been implemented. The search results depend heavily on how the registered trials were named, and the retrieved study pool is highly likely to be incomplete. In addition, an export function is not yet available.

EMA has announced that the functionality of the registry will be improved.[3] However, in view of previous delays, explained partly by technical difficulties,[3] it is unclear how and when this will be implemented.

Thus Europe still lags behind the US, where ClinicalTrials.gov has been in operation for several years and is an increasingly important source of evidence. Hopefully, current discussions on increasing transparency in clinical research in Europe will also accelerate the development of EU-CTR.

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Competing interests: All authors require full access to clinical trial data for the production of unbiased reports and support mandatory trial registration and results disclosure.

1 Gøtzsche PC, Jørgensen AW. Opening up data at the European Medicines Agency. *BMJ* 2011;342:d2686. (10 May.)
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3 European Medicines Agency. EU Clinical Trials Register. Frequently asked questions. 2011. https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf.

Cite this as: *BMJ* 2011;342:d3834

Proactive transparency?

Formindep (www.formindep.org) is an independent self funded association of health professionals and citizens that advocates for transparency in medical information and education and freedom from interests other than those of patients. Our experience of the European Medicines Agency's (EMA) implementation of its transparency policy agrees with Gøtzsche and Jørgensen's findings.[1]

Directive 1049/2001/EC,[2] which governs access to public data, has been in force for a decade, but the agency still ignores its main requirements. Pott says "there will be a move towards proactive publication of more . . . documents over the next few years."[3] This means the EMA will roll out, sometime in the indefinite future, the public register of documents demanded by article 11 of the regulation. This is hardly proactive transparency.

EMA European experts' nominations and "public" declarations of interest remain undisclosed, although these are key to the agency's mission to provide independent scientific opinion. In contrast to national counterparts, such as the French AFSSAPS,[4] the EMA has constantly refused to publish these documents online. Unsurprisingly, the European Parliament "finds it unacceptable that the agency does not apply the relevant rules effectively, resulting in the fact that there is no guarantee that the evaluation of human medicines is performed by independent experts." The European ombudsman concluded in several cases that EMA's repeated refusals to disclose public documents constituted acts of "maladministration."

The EMA is not even transparent on transparency—Formindep had to complain to the European ombudsman about the agency's refusal to disclose its audit on access to documents.

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Competing interests: AC is a member of the management board and PF is president of Formindep.

1 Gøtzsche PC, Jørgensen AW. Opening up data at the European Medicines Agency. BMJ 2011;342:d2686. (10 May.)
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EMA's response to articles

Two recent *BMJ* articles have given the European Medicines Agency (EMA) useful feedback from the academic community on its provision of information on the scientific review of medicines.[1 2] The agency is grateful for and open to suggestions on how this can be improved.

The authors of both articles ignore recent steps that the agency has taken to improve the transparency and presentation of this information.

The agency's new policy on access to documents,[3] which became effective in November 2010, has pushed transparency further forward than in most other drug regulatory authorities. It grants wider access than ever before to documents originated, received, or held by the agency, including clinical trial reports submitted as part of marketing-authorisation applications. There will be a move towards proactive publication of more of these documents over the next few years.

The presentation of information in the European Public Assessment Report (EPAR) has also been improved. The EPAR summarises the scientific conclusions reached at the end of the centralised evaluation process, and it allows researchers to identify which published and unpublished studies were evaluated in the authorisation process. Full clinical trial reports of these studies can be released on request, in line with the agency's new access to documents policy.

At the end of 2010, the agency responded to requests from its stakeholders by introducing a new tabular format for the presentation of relevant results from clinical studies (including number of randomised patients per treatment arm, results per intention to treat and per protocol, number of patients analysed for primary outcomes, efficacy results, and size) assessed in the support of new marketing-authorisation applications.

Further improvement of the EPAR, specifically information on the assessment of the benefit-risk balance, is one of the key priorities in the agency's *Road map to 2015*.[4]

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Competing interests: None declared.

1 Gøtzsche PC, Jørgensen AW. Opening up data at the European Medicines Agency. *BMJ* 2011;342:d2686. (10 May.)
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Cite this as: *BMJ* 2011;342:d3838

RESPONSE

World Health Organization responds to Fiona Godlee and Ray Moynihan

In her editor's choice in the print issue of 14 May Godlee asks: "Who should define disease?"[1] This question was answered by international treaty in 1948, when the World Health Organization was founded as a specialised agency of the United Nations. The WHO has unique authority to establish global health standards and secure international agreement on defining diseases. Among the core functions in its constitution are responsibility for international definitions and nomenclatures of disease, and standardising diagnostic procedures.[2] The WHO's 193 member states have agreed to use the *International Classification of Diseases* (ICD) as a basis for reporting health information that is usable and comparable across countries. The World Health Assembly—comprising the health ministers of all member states—has directed the WHO to revise ICD-10, a process expected to lead to the completion of ICD-11 in 2014.

The classification of mental and behavioural disorders is particularly sensitive in terms of creating and defining disease categories,[1] so the WHO has implemented a systematic process for evaluating and using evidence as part of the ICD-11 development process, including formative and evaluative field testing. Existing categories and definitions of mental disorders should be changed through a transparent, international, multidisciplinary, and multilingual process that entails the direct participation of a broad range of stakeholders and is as free as possible from conflicts of interest. As Moynihan argues,[3] a truly multilateral process of disease definition cannot be legitimately managed by a single professional organisation representing a single health discipline in a single country with a substantial commercial investment in its products.

The WHO is concerned about the proliferation of diagnoses of mental disorders. The use of classification systems by professional societies to mark out professional turf may lead to redundancy and clinically unimportant distinctions in disease definitions—which is less likely in the context of a global public health agency. Even so, issues of threshold are complex because the pathophysiology underlying mental disorders cannot be assessed directly and many symptoms of psychopathology are continuous with normal phenomena. Appropriate use of the ICD would discourage reification of questionable entities because it contains specific provisions for identifying phenomena that are important to treatment and clinical management but are not in themselves disorders.

Identifying a phenomenon as an important topic for research does not automatically mean that it should be defined as a disease. Evidence on validity and clinical importance is required, as well as consideration of the public health justification for inclusion. Disease classifications have not proved to be the best organising framework for research on basic mechanisms,[4] but a classification's usefulness for research should not be confused with its validity for other purposes. Evidence evaluation for disease definitions should focus on their different purposes and target users, using a broader range of methods appropriate to evaluating clinical utility and public health outcomes.

The argument for definition of new conditions is often implicitly based on the goal of obtaining reimbursement to treat them, if not to expand markets for pharmaceutical products. However, healthcare financing and reimbursement policy are separate issues from disease definition.[5] To conflate them is not helpful in reducing the global burden of disease. To include a condition in a disease classification does not automatically mean that treatment should be provided or that governments or private insurance should pay for it. Failure to separate diagnosis from health policy contributes to over-treatment but also to under-treatment of serious mental disorders and misdirection of mental health care resources.

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Competing interests: None declared.

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