Research into scorpion stings

Lack of funding and global investment are denying patients evidence based interventions

EPHOTOCORP/ALAMY

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With the growth of global health schools and programmes at most universities in developed counties and the interest in neglected tropical diseases, it should follow that common medical conditions in developing settings are being researched.[1] However, this is not so for scorpion stings, snake bites, and other animal envenomations. In the linked randomised clinical trial, Bawaskar and Bawaskar compare the effectiveness of scorpion antivenom plus or minus prazosin for the treatment of scorpion stings.[2] The trial is a reminder that global health researchers often neglect conditions that matter to large impoverished communities.

Of around 1500 species of scorpions worldwide, around 30 are potentially dangerous to humans.[3] About 1.2 million scorpion stings occur worldwide each year, of which roughly 3250 are fatal. The incidence and severity vary geographically, with reported incidence among the general population varying from 5 per 100 000 population in France to 6803 per 100 000 in Venezuela.[4] Incidences of more than 1000 per 100 000 have been reported in Algeria, Israel, Tunisia, Mexico, Chile, and Saudi Arabia. However, global data on scorpion stings tend to be scarce and unreliable because of the lack of robust community surveys. Mortality is underreported because deaths as a result of scorpion stings often occur outside hospital.

This lack of reliable data on diseases that predominantly affect poor populations is a recipe for neglect. People who are stung by scorpions and other venomous creatures tend to live in poor rural areas so lack a strong political voice. This allows them to be overlooked by politicians and health planners, who are poorly informed about major public health matters that affect rural areas.

In early 2007, the World Health Organization held the first ever meeting to define responses to the critical shortage of therapeutic antisera for the treatment of venomous snakebites and scorpion stings.[5] Several manufacturers in developed countries have abandoned antisera production because they don't make money. The future of the few manufacturers that remain is fragile because of uncertainties about market demand and the safety of production as a result of limited regulatory frameworks. An estimated 10 million vials of high quality potent antisera are needed annually to respond effectively to snakebites and scorpion stings, but the current worldwide production capacity is well below this, and antisera for one region may not be applicable to another.[5]

Lack of clinical evidence has also played its part, mostly as a result of lack of research funding and attention compared with more high profile diseases in the developed world.[6] Consequently, the management of snakebites and scorpion stings is not evidence based, but rigidly adheres to traditional ideas. Antiserum was first used to treat envenomings more than a century ago without formal trials,[7] and the results of the few small trials reported to date have been contradictory.[8 9]

Bawasker and Bawasker's trial found that patients given antivenom plus prazosin for the treatment of the Indian red scorpion sting recovered more quickly than those given prazosin alone. Although the conclusiveness of the study is debatable, the way the study was conducted (by practising doctors without staffing or funding) is perhaps more telling. The trial was pre-planned by the doctors, and patients were randomised in an open manner to each treatment while the doctor monitored outcomes from the bedside. Research funding for the treatment of scorpion stings is rare, if not impossible, so the authors funded their own study.

The millions of people who are stung or bitten by venomous creatures each year should receive treatment that is safe, effective, and affordable. Global stewardship from medical researchers and funders is needed to promote and undertake reliable research, build research capacity, provide the funding for it, and boost the production of effective treatments. Progress has recently been made with the launch of the Global Snakebite initiative in 2008 and the addition of snakebite to WHO's list of neglected tropical diseases in 2009.[10] Although progress in the neglected area of snakebites is welcomed, scorpion stings are in danger of falling off the agenda.

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Cardiovascular safety of NSAIDs

The cardiovascular risks should prompt evaluation of a broader range of alternatives

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Millions of patients with chronic musculoskeletal symptoms are long term users of non-steroidal anti-inflammatory drugs (NSAIDs). Unfortunately, these drugs have common and potentially severe adverse effects, including renal impairment, gastrointestinal complications, and as has been shown for selective cyclo-oxygenase-2 inhibitors, cardiotoxicity. The last effect is particularly worrying because many patients have both cardiovascular disease and musculoskeletal disease. Given that both mechanistic and clinical data suggest that individual NSAIDS may have different cardiovascular risk profiles, a natural question is: which NSAID is safest for patients with high cardiovascular risk? In the linked study, Trelle and colleagues investigate this question by using network meta-analysis to assess the cardiovascular safety of individual NSAIDS.[1]

All cyclo-oxygenase-2 inhibitors studied in large placebo controlled trials have been found to confer an increased risk of serious cardiovascular disease.[2-4] Furthermore, rofecoxib increases risk more than naproxen.[5] This suggests that patients with a high risk of cardiovascular disease should avoid cyclo-oxygenase-2 inhibitors. Although some trials suggest that celecoxib is safer in lower doses,[6] the possibility of dose escalation to improve pain control and the heterogeneity in patient response to a given dose all favour caution.

Several epidemiological investigations have studied the cardiovascular safety of NSAIDs.[7] These have confirmed the cardiotoxicity of rofecoxib and suggest that diclofenac has a similar cardiovascular risk.[7] Observational studies also indicate that naproxen has the best cardiovascular safety profile, consistent with the more limited data available from clinical trials.[8] A large cohort study of the cardiovascular effects of NSAIDs in patients recently admitted to hospital for serious coronary heart disease found that the cardiovascular safety of naproxen was superior to that of ibuprofen, diclofenac, celecoxib, and rofecoxib.[9]

What does Trelle and colleagues' study add to this knowledge?[1] The authors performed a meta-analysis of randomised trials of NSAIDs with at least 100 person years of follow-up in the studied arms. They used a potentially powerful technique known as network meta-analysis,[10] which, when certain assumptions are met, can extract more information from the available data than traditional methods. For example, the analysis was able to compare etoricoxib versus placebo despite there being no large placebo controlled trials. This is because etoricoxib has been compared with diclofenac, which in turn has been compared with both rofecoxib and celecoxib, which themselves have been compared with placebo. From this chain of direct comparisons, the effect of etoricoxib relative to placebo is estimated through an indirect comparison.

This example illustrates both the strengths and weaknesses of network meta-analysis. It uses all of the data, but certain assumptions about homogeneity are necessary for valid estimates of indirect comparisons. Although in theory these assumptions can be checked and uncertainty incorporated into the estimates, this may be difficult in practice with a limited number of comparisons. The usefulness of this technique is limited for NSAIDs because too few adequately powered clinical trials exist. For this reason, the estimates from the meta-analysis that primarily rely on indirect comparisons—such as those for the comparison of etoricoxib with placebo—should be interpreted with caution.

What does this all mean when prescribing NSAIDs for patients at high risk of cardiovascular disease? Current data suggest that selective cyclo-oxygenase-2 inhibitors, particularly in higher doses, should be avoided. With regard to traditional NSAIDs, the most extensive data are available for diclofenac, ibuprofen, and naproxen. Meta-analyses of clinical trials and observational studies have found greater cardiovascular risk for diclofenac,[7 8] which suggests that it should be avoided in high risk patients. Ibuprofen may attenuate the antiplatelet effects of aspirin, an important consideration in patients with a high risk of cardiovascular disease.[11] In contrast, currently available evidence indicates that naproxen has the best cardiovascular safety. Although the ongoing PRECISION (Prospective Randomised Evaluation of Celecoxib Integrated Safety versus Ibuprofen Or Naproxen) trial will eventually provide more information on the relative cardiovascular safety of naproxen, celecoxib, and ibuprofen, until these results become available, naproxen seems to be the best choice with regard to cardiovascular safety. As with any traditional NSAID, it is important to consider coprescription of gastroprotective drugs.[12]

The controversy and confusion about the cardiovascular safety of drugs to relieve chronic musculoskeletal symptoms provides an important lesson. Drugs for symptomatic relief must be evaluated with regard to the target symptoms as well as less frequent yet serious adverse effects. NSAIDs are not an ideal treatment with respect to efficacy or safety. Perhaps it is time for a larger more systematic evaluation of a broader range of alternatives. In clinical practice, patients with musculoskeletal symptoms receive both paracetamol and low dose opioid analgesics, and new drugs such as tanezumab, are being evaluated. Clearly, each of these has limitations. However, in the absence of large scale comparative trials that consider safety as well as efficacy, we cannot determine which best serves patients.

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Access to clinical trial data

Results and protocols go hand in hand

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The high frequency and negative impact of selective reporting of data from clinical trials are well documented.[1] The widespread occurrence of data suppression means that healthcare practitioners and policy makers largely make decisions on the basis of an incomplete and biased subset of trial results. Selective reporting can often be identified by reviewing trial protocols and publications; it can be mitigated by defining standard core outcome sets for trials, and by ensuring access to all unpublished and published data.[2 3]

However, two linked articles highlight major difficulties in obtaining access to protocols and unpublished data for both industry and non-industry trials and provide new insight into trialists' reasons for suppressing data.[4 5] These types of challenges have been described before,[6 7] and they reinforce the core principle that full knowledge of both the methods and results for all trials, independent of publication status, are essential for a complete and unbiased evaluation of an intervention.

Sources of information that should be consulted when appraising an intervention include trial protocols, registry records, regulatory agency documents, trial datasets, and journal publications. Smyth and colleagues also show the potential value of communicating with trialists and sponsors, although the yield was suboptimal.[5] The public availability, reliability, and completeness of these information sources vary, but they provide complementary information across the stages from trial inception to dissemination. Unfortunately, the two most reliable sources—the raw dataset and the protocol approved by the research ethics committee—are usually not publicly available.

To improve this lack of transparency, Jefferson and colleagues propose that journals should require submission of the most detailed anonymised dataset along with manuscripts.[4] This policy would be a positive initial step, but several factors need to be considered. Firstly, the criteria defining what constitutes an adequately detailed trial dataset need to be clearly established to ensure that data are submitted in an appropriate format.[8] Secondly, journal editors and peer reviewers may not be in the best position to reanalyse a raw dataset. Most have limited time, funds, and statistical expertise.

Thirdly, access to the raw dataset is of little use without access to the full protocol. Protocols and their amendments provide key methodological information that places trial results in their proper context and enables critical appraisal of whether a given dataset is complete, unbiased, and applicable to a given patient population.[3] The trial protocol is the most reliable source of methodological information because it is written before the study is started and cannot be influenced by the trial data. However, empirical evidence has shown that protocols are often incomplete.[3] For example, primary outcomes were defined in only half of protocols in the cohort reviewed by Smyth and colleagues.[5] This lack of prespecification is rarely acknowledged in trial reports and often leads to major discrepancies between protocols and publications.[2 5] The ongoing SPIRIT Initiative (Standard Protocol Items for Randomized Trials) aims to improve the completeness and quality of protocols by providing guidance on the key areas needed in the protocol.[9]

Finally, the difficulties encountered by both sets of authors[4 5] in obtaining information voluntarily from sponsors and trialists support the need for incentives to encourage adherence to policies that aim to increase transparency. Better adherence to trial registration and disclosure of summary results in recent years has been largely driven by policies enforced by journal editors and legislation.[10] In contrast, public access to trial protocols and raw datasets is lagging behind.

If the policy proposed by Jefferson and colleagues was broadened and extended, these challenges could be tackled. Journal editors and other stakeholders with the ability to enforce change—including funding agencies, research ethics committees, regulatory bodies, and legislators—could adopt and enforce a data sharing policy where, as a condition of approval, trialists commit to making both the protocol and anonymised raw dataset available to interested parties. Some journals have taken the first step of publishing protocols prospectively or requiring that they be submitted in confidence with manuscripts, but public access to protocols has yet to be made mandatory. Logical venues to house full protocols for public access would be the trial registries that record

basic protocol information and post summary results, such as ClinicalTrials.gov.

Calls for submission and publication of raw data are not new,[11] and guidelines for data sharing have been proposed.[8 12] Some journals and funders have adopted data sharing requirements, but promoting adherence is a challenge once the study has been published or funded. One solution is for journals to require posting of the anonymised raw dataset on their website or other internet repository at the time of study publication. Other considerations for implementation of data sharing policies include ensuring patient privacy, obtaining patient consent or waivers, and providing for restricted data access in limited circumstances.[8 12]

Public access to the full trial protocol and raw dataset is essential for the value or harm of an intervention to be adequately appraised. Stakeholders have a responsibility to try to prevent the consequences of data suppression. Failure to act will perpetuate the status quo of partially informed decision making and will compromise patient care.

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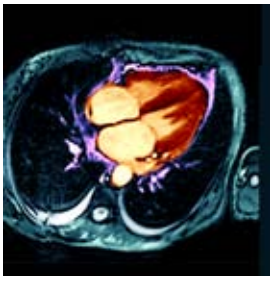
Surgery for degenerative mitral valve disease

Rates of repair are improving, but there is still wide variation



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Mitral valve prolapse is the most common cause of mitral regurgitation requiring surgical correction in Western Europe and the United States.[1] This condition is characterised by the accumulation of glycosaminoglycans in leaflet tissue and the appearance of billowing thickened leaflets on echocardiography.[2] Although mitral valve prolapse (also called floppy mitral valve or Barlow's syndrome) occurs in 4-6% of the population, only a small proportion of these people develop severe mitral valve regurgitation requiring intervention. People at risk include those over 50 years and patients with severe valvular regurgitation, atrial fibrillation, and greater thickening of leaflets.[2] Without treatment severe mitral regurgitation leads to deterioration of left ventricular function, pulmonary hypertension, and premature death.[1]

The aim of surgery is to restore left sided atrio-ventricular valvular competence. This can be achieved by resection of the native valve and implantation of a prosthetic valve—a mechanical valve in younger patients and a biological one (an inverted porcine aortic valve) in elderly patients.

The advantage of mitral valve replacement is that it is technically straightforward and within the ability of most cardiac surgeons. Since the early 1990s, Carpentier in France and others have promoted the repair of degenerative mitral valves.[3] Recently published survival studies of patients from large surgical databases (>2000 patients) indicate that repair has a survival advantage of 5-10% after five years in different age groups compared with replacement.[4] In addition, long term morbidity including thromboembolism is less after mitral valve repair (risk of an embolic event after 15 years 8%, 95% confidence interval 5% to 13%) when compared with replacement (after 12 years 32%, 26% to 38%).[5 6] Because of the known advantages of preserving the native valve for left ventricular function,[7] European and American Cardiology Associations recommend repair for patients with severe mitral regurgitation in their guidelines.[8]

Although there are no randomised controlled trials comparing repair with replacement, the strong data favouring repair make it unethical to conduct such a trial today. The main disadvantage of mitral valve repair is that not all cardiac surgeons can perform what is often technically demanding surgery. Despite this, the proportion of valves that are now repaired rather then replaced has, over a 10 year period, increased in the United Kingdom,[4] Europe, and the US.[9] In 2009, the Society for Cardiothoracic Surgery of Great Britain and Ireland published repair rates for patients with degenerative mitral valve disease in all the cardiac surgical centres in the UK.[4] The UK figures showed a wide variation, from 0% to 98%, with a national mean of 66.6%. Accurate diagnosis and characterisation of leaking degenerative mitral valves is possible with two dimensional and more recently three dimensional transoesophageal echocardiography.[10] Valves can be classified as requiring a simple (posterior leaflet) or complex (anterior, commissural, or bileaflet) repair.[11] Cardiologists who act as gatekeepers should ensure that such characterisation occurs and that patients are referred to a surgeon who has a repair rate of degenerative valves (proportion of total that are successfully repaired) of more than 70% and who carries out a sufficient number of mitral valve repairs (at least 25 a year per surgeon, 50 a year per institution[12]).

The implication of such a change in practice is that surgeons who carry out mitral repairs would be unable to perform many other cardiac procedures and this might herald the creation of "super specialist" consultant cardiac surgeons who carry out a single procedure. This could create problems associated with emergency on-call arrangements.

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Planning a consultant delivered NHS

Patient care is at risk unless workforce planning accounts for policy and financial limitations

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A crisis in the global healthcare workforce is currently looming.[1] In Europe, the problem is so great that the Belgian European Union presidency made "investing in Europe's health workforce of tomorrow" the subject of their ministerial conference recently held in Brussels. That conference, following on from an EU green paper,[2] showed that EU countries have very different perspectives on the needs of their workforces, but they all face similar problems—an ageing population; increasing public expectations; an increasing proportion of women (who are more likely to work part time) in the workforce; increasing worker mobility; and, most importantly, limited finances. The history of workforce planning in the NHS shows how difficult planning can be for an individual country and that seemingly well made plans can soon become inadequate with changes in policy and finances.[3]

The NHS has traditionally relied on junior doctors to deliver most acute services, and, until recently, many of these doctors had been trained abroad. Between 1992 and 2003, 42% of doctors entering the NHS workforce came from overseas, with most being international medical graduates.[4] In the late 1990s, the number of places at medical school increased so that the UK could become self sufficient with respect to its workforce. To create space for the additional "homegrown" doctors, in 2006 legislation was changed to limit the number of international medical graduates working in the United Kingdom.[5] This change, together with the painful rationalisation of training places (Medical Training Application Service; MTAS) that occurred around the same time,[6] meant that many international medical graduates subsequently left the UK. The exact numbers and pattern of migration were not monitored and the loss was seen most acutely in hospitals in less popular parts of the country. Such hospitals have struggled the most to recruit doctors ever since.

The available medical workforce is, obviously, a product of the number of doctors and the hours that they can work, and changes to working time regulation have substantially reduced working hours over the past decade. The "new deal" for junior doctors came into full force in 2003, and, although it allowed doctors to work up to 56 hours a week, it imposed severe financial disincentives for trusts where doctors worked for longer than 48 hours. The full implementation of the European Working Time Directive in 2009, and more importantly the SiMAP (Sindicato de Medicos de Asistencia Publica—a Spanish primary healthcare organisation) and Jaeger rulings,[7] then removed much of the remaining flexibility hospitals had in the way their doctors worked (box). Although the current UK government has declared an interest in revisiting the European Working Time Directive legislation, any changes will take years to get through the EU legislative process.

Thus, despite more junior doctors being produced by the UK since 2000, the availability of doctors for hospital

SiMAP and Jaeger rulings

- SiMAP ruling: any time that a doctor is on call counts as working time if the doctor is expected to be available immediately
- Jaeger ruling: any doctor who is resident on call is working even if asleep or otherwise resting and any compensatory rest needs to be taken before the next shift starts


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patient care has not increased, and out of hours care continues to be delivered largely by junior doctors. In 2001, the average junior doctor had 67 patients under his or her care at night, and by 2009 this figure was still 63.[8] Furthermore, the pressure on hospitals is worsening, with hospital admissions having increased by 19% during the past five years, and the UK continues to have fewer doctors per head of the population than most other EU countries.

The NHS is only too aware of the need for better workforce planning. The Centre for Workforce Intelligence was established in July 2010 to facilitate this and has already produced a set of recommendations for specialty training numbers in England.[9] These predictions use data from the NHS Information Centre on current doctor numbers and use weighted capitation to look at the distribution of specialists across different regions. They show that by increasing the number of consultants to mirror the output of specialist trainees the slow transition towards a consultant delivered service, which is undoubtedly better for patient care and training of doctors,[10] can continue.

This is a large and uncertain proviso. The number of hospital consultants has expanded at 4-5% each year during the past 15 years and would need to continue to expand at around 6% a year to ensure that all specialist trainees will be employed in the NHS as consultants. Even in a helpful financial climate this seems unlikely, and the financial winter that the NHS faces will mean that job numbers will be frozen by many trusts. This illustrates the major problem with workforce planning in the UK—no matter how good national planning is, adequate local finances are essential to delivering it.

The prospects for employment for trainees in the larger medical specialties are therefore unclear. Although an oversupply will be good news for regions of the country that struggle to recruit staff, it remains to be seen whether fully trained doctors will migrate around the UK or move abroad. Increased tightening of accreditation criteria for trainees during the past few years has removed the flexibility for doctors to move between specialties, which had been relatively common 15-20 years ago when a particular specialty became oversupplied. Some cynics say that oversupply of trained doctors in the UK was always intended and will open the door to a subconsultant grade. The King's Fund has included such a workforce in its predictions of the future NHS workforce,[3] and such posts are already present in some hospitals.

The UK needs to move away from a trainee delivered service, but this will take many years to achieve. In the interim, reversing the SiMAP and Jaeger rulings, renegotiating the new deal, relaxing immigration rules, and enhancing mobility between specialties will all give the NHS more flexibility to cope with its ever increasing demands. However, the healthcare crisis is global, and the NHS must be mindful of the impact of such changes on other healthcare economies.

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