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**Editorial: A fusion of evidence.**

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**Editorial: A fusion of evidence**

The need to demonstrate clinical effectiveness and value in orthopaedic spinal practice is unprecedented. Previously in this journal, Haddad has led a call to arms to enter more patients into prospective randomised studies, warning that orthopaedics ‘*undoubtedly lags behind other specialities in this area*’.1 Not only will data from such trials allow the risk of benefit and harm following an intervention to be quantified and variations of each within subgroups to be explored,2 it will also provide much-needed evidence on the clinical and cost-effectiveness for inclusion in national and international guidance, such as the National Institute for Health and Care Excellence (NICE), used to inform commissioning decisions and standardise service delivery. The strength of the randomised controlled trial (RCT) lies in its ability to minimise selection bias and generate groups in which confounding factors, both known and unknown, are equally distributed.3 Of course, not every published RCT is reflective of level 1 evidence, due to errors in design and methodology, as well as in interpretations of data4 and rarely considers the important non-specific treatment effects, so highly prized by patients as they rate their experiences. There are also inherent difficulties associated with developing a credible evidence-base in conditions that are rare, have multiple variables, or an unpredictable course.5 Furthermore, some elements of trauma and orthopaedic practice, such as total hip replacement and the surgical drainage of intra-articular infection,5 are underpinned by generations of experience and have withstood the test of time without ever formally being tested in a scientific way.2

Case series are often used in orthopaedics as evidence of clinical effectiveness, reporting the outcomes from an individual surgeon or team, and may involve comparing outcomes from different procedures. These non-randomised series are however subject to bias, thereby negating any findings of superior efficacy. Case series are not included as evidence for guidelines because of the methodological limitations and it is unclear why surgeons persist in undertaking two small case series and claiming efficacy, with missed opportunities to produce level 1 evidence? This practice is hindering orthopaedics in reaching its academic potential and should stop, especially when such comparisons readily lend themselves to a randomised trial, providing a higher level of evidence that will contribute directly to guidelines and meta-analyses.

To evidence this, we reviewed the abstracts from four major spinal conferences in 2015-16 to identify the prevalence of case series compared to level 1 evidence (randomised controlled trials, systematic reviews and meta-analyses) *Table 1*.

**Table 1: Levels of evidence in abstracts from 4 orthopaedic spinal meetings 2015-16.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **Level of evidence** | | | | | | |
|  | **Abstracts** | **1a** | **2** | **3** | **4b** | | **5** | **Otherc** |
| Britspine 2016 | 144 | 8 (4) | 3 | 6 | 108 (75%) | 3 | 0 | 16 |
| Eurospine speciality meeting 2016 | 24 | 2 (0) | 0 | 1 | 16 (67%) | 4 | 1 | 0 |
| Eurospine 2015 | 308 | 24 (21) | 0 | 27 | 223 (72%) | 1 | 0 | 33 |
| North American Spine Society 2015 | 378 | 27 (21) | 1 | 22 | 257 (68%) | 0 | 0 | 71 |
| **Total** | **854** | **61 (46)** | **4** | **56** | **604 (71%)** | **8** | **1** | **120** |

aThe number in brackets denotes randomised controlled trials included in this total.

bThe first figure in the level 4 column denotes case series, the second is case reports.

c*Other* includes: protocols; cadaveric, animal and basic science; biomechanical; qualitative studies; clinical tests; development of outcome measures; modelling, health economic and cost-utility analyses.

From the 854 abstracts reviewed, the overall prevalence of case studies presented was 71% (n=604), ranging from 67% to 75%. Oftentimes, case series were erroneously described as prospective or retrospective cohort, case-control, or cross-sectional studies. The errors in stated study design highlight the ongoing need to enhance evaluative and research methods in orthopaedic educational curricula.

The problem of missed opportunities to provide level 1 evidence is further compounded by the increased use of registries: Whilst they are to be commended on their attempts to link observational data with patient-reported outcome measures,6 it is important to remember that a registry is still a case series – and even though it can be vast, its size does not move it up the hierarchy of evidence. Registries clearly have a place in clinical practice and may indeed be helpful in identifying subgroups of patients who would benefit most from an intervention, as a precursor to randomised trials. It is beyond question that any resultant trials, if sufficiently powered for subgroup analyses, are much needed in the current healthcare climate.

Having completed a piece of research, there is a professional and moral duty to disseminate findings appropriately, not only at conferences but also in peer-reviewed publications. The quality of presentations at medical conferences is of major importance and the publication rate following congress presentations has been cited as an indicator of the extent and quality of a scientific society’s activity.7 In a review of 839 abstracts of podium and poster presentations at the Spine Society of Europe Congresses held between 2000-2003, only 37.8% were published in peer-reviewed journals within 5 years, with podium presentations having a significantly higher publication rate than posters (OR 2.062; 95%CI, 1.547-2.749, p<0.001).7 Furthermore, Schulte et al. warn of the danger that the conference review process is based on the limited abstracts submitted, where data may be incomplete, and not on the full-text manuscript received for journal publication, questioning whether it is acceptable to implement these findings in practice.7 A key question therefore, for clinicians to ask is: ‘*Should I change my practice based on what I’ve just heard / read?*’

As Griffin said ‘*It is our duty to be part of the proper development, conduct, review and application of high-quality research in order to lead our field*.’2 This is particularly pertinent for any surgeons seeking academic recognition for their clinical academic career, as case series are poorly viewed in the academic arena. Support is available for surgeons to engage in research to provide level 1 evidence, for example the Research Design Services in the UK, funded by the National Institute for Health Research, who provide free design and methodological support to develop grant and fellowship applications. They can also assist in building a team with qualitative, methodological and health economic expertise to maximise the quality and impact of a trial.see 8Whilst such support may not be available in every country, it is important for clinicians to investigate what research infrastructure and support exists locally and nationally (which may involve thinking laterally, for example the toolkits, training and resources offered by the US Department of Veterans Affairs), to help build a strong evidence-base in orthopaedic spinal practice.

The public are encouraged to believe that suitable evidence exists to underpin all medical and surgical interventions,5 and the current draft NICE guidelines for low back pain only serve to highlight how far removed this is from reality: In the 2016 draft for consultation, spinal fusion is not supported, with the statement: ‘*Do not offer spinal fusion for people with non-specific low back pain unless as part of a randomised controlled trial*’.9 This should be a warning to all of the urgent need to contribute to the evidence base with level 1 evidence and stop the practice of small-scale, comparative case series that do little to advance the field.

The gauntlet has now been thrown: Can every surgeon and health care professional working in orthopaedics rise to the challenge of contributing at least one piece of level 1 or 2 evidence AND disseminate their work in a peer-reviewed, academic journalduring their career, to help protect the future of spinal orthopaedic practice and ensure it gains the recognitions it deserves?

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