Editorial

Spinal orthoses in osteoporotic vertebral fractures of the elderly

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Background

Osteoporosis is a chronic progressive disease estimated to afflict 23.1% of women and 11.7% of men worldwide (1). The prevalence of this global healthcare burden has increased and reflects the burgeoning elderly population (2,3). A pathological reduction of bone mass in combination with architectural deterioration leads to weakened bone and thus an increased risk of fragility fractures. Indeed, it is these low energy trauma osteoporotic vertebral fractures (OVFs) which are the hallmark of osteoporosis. Despite the significant mortality and morbidity associated with these increasingly common injuries, there remains a paucity of high-quality evidence to guide their management perhaps because only one-third are symptomatic (4,5).

The management of OVFs takes into consideration mechanical stability as implied by ability to sustain physiological loads, neurological status, degree of pain and overall medical health (6). Treatment may range from simple analgesia with physiotherapy, use of a rigid or semirigid orthosis or in certain circumstances surgical interventions such as percutaneous vertebroplasty or surgical stabilization. However, the role of spinal orthoses has remained controversial despite being investigated by a multitude of authors previously (7-9). Bracing has remained a non-operative option especially given the frailty of elderly patients which may preclude operative intervention (10-12).

On one hand, some argue that braces facilitate appropriate alignment and stabilization (13). On the other hand, others contend that braces provide no proven quantifiable benefit in protecting against post-traumatic kyphosis, analgesia or quality of life and simply result in deconditioning and decreased muscle strength whilst also carrying the risk of inflicting pressure sores (14). Genev *et al.* found that 60% of patients who were prescribed an orthosis complained of inadequate advice and 43% reported that it interfered with their activities of living (13). In contrast, Mulcahy *et al.* reported a more balanced approach finding equivalent functional and radiological outcomes (14). The data from trials investigating the role of orthoses in traumatic thoracolumbar burst fractures is interesting and relevant. For example, Linhares *et al.* argued that there was no difference in kyphosis progression with an orthosis and there may even be adverse effects from bracing such as muscle deconditioning (15). By extension, Alcalá-Cerra *et al.* supported this and found there was a doubtful impact on maintaining alignment or improving disability and pain with their assertions being similar to Giele *et al.* (16,17). These were based upon a randomized controlled study by Bailey *et al.*, but whilst this data applicable to thoracolumbar burst fractures sustained as a consequence of high energy trauma is useful, it does not apply to the low energy traumatic osteoporotic fractures (18).

Article review

We congratulate Squires *et al.* on their publications which

seeks to clarify some of the controversy regarding the effect of nonoperative management with soft and rigid bracing for acute thoracic and lumbar compression fractures when compared to using no brace (19). Their hypothesis was that clinical and radiological outcomes with or without brace usage were equivalent. This was investigated by performing a systematic review and meta-analysis of randomized trials published prior to October 2021. The following inclusion criteria was applied: prospective randomized controlled trials comparing the treatment of thoracolumbar compression fractures in neurologically intact adult patients with or without an orthosis, a minimum duration of follow-up of 3 months and evaluation of clinical and radiological outcomes following conservative treatment. Comparative studies, studies comparing surgical and nonsurgical treatments, studies on thoracolumbar burst fractures and animal studies were excluded. Three studies met the inclusion criteria and were included in the meta-analysis. These had a total of 447 patients (96% female). Fifty-four patients were managed without a brace, and 393 with a brace (195 rigid, 198 soft).

They extracted from included studies study identifiers (authors, publication year, title), study characteristics (design, region, sample sizes, sex, age, smoking status, level of injury), clinical outcomes ShortForm-36 Physical component and Mental Component (SF-36 PCS, SF-36 MCS), pain, satisfaction, Oswestry Disability Index (ODI), Limitations of Daily Living (LDL), Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOABPEQ), well-being, EuroQol-5 Dimension-3 Level (EQ-5D-3L), opioid use; and radiographic outcomes (body compression ratio, regional kyphosis angle). Orthosis patient groups (soft or rigid) were determined by existing groups within the included studies. When not specified, the author considered rigid braces those that inhibit spinal motion, and soft braces those that provide support but allow motion.

At 3 to 6 months postinjury, rigid bracing resulted in significantly less pain compared to no brace [standardized mean difference (SMD) =−1.32; 95% confidence interval (CI): −1.89 to −0.76; P<0.05; I^2=41%], though this diminished at long-term follow-up of 48 weeks. Subgroup analysis including both rigid and soft bracing groups similarly showed significantly less pain favoring the brace group (SMD =−1.27; 95% CI: −1.84 to −0.70; P<0.05; I^2=70%). This effect was not reproduced for soft bracing group vs no brace. Relative Visual Analogue Scale (VAS) reduction at 3 and 6 months for both soft and rigid bracing where greater than minimal clinically important difference (MCID) of 1.2 in the studies although this was not statistically significant. Radiographic kyphosis, opioid use, function, or quality of life were not significantly different at any timepoint.

The strengths of this study were the acceptance of only prospective randomized controlled trials and the strict inclusion criteria applied. However, this limited the number of eligibly studies with only three being deemed suitable for analysis. There was significant heterogeneity regarding treatment paradigm such as type of braces used and duration of use. Furthermore, this study population consisted of mainly female patients over the age of 50 which further limits the generalizability to other populations. Overall, the authors should be commended for a well-designed systematic review which improves our understanding of spinal orthosis use in osteoporotic vertebral body fractures.

Discussion

The word ‘orthosis’ has origins in Greek and means ‘to make straight’. Galen (c.131 to c.201 AD) was believed to be the first physician to use spinal orthoses (20). Further development of spinal orthoses in the premodern era was driven by the need to correct spinal deformity and to immobilize unstable fractures. Spinal orthosis work by reducing load applied on the anterior column and vertebral body by limiting forwarding flexion. Despite the lack of studies comparing spinal orthoses, most spinal orthoses regardless of make, rigid or soft, use a three-point pressure system (21). Early evidence for spinal orthosis use in OVFs was extrapolated from studies with non-osteoporotic fractures. The limited generalizability, insufficient data regarding types of orthoses, indications for orthosis use and duration of use resulted in weak recommendations for orthosis use in OVFs.

The first objective data on spinal orthosis use in OVFs came in 2004 where Pfeifer *et al.* performed a prospective, randomized and controlled crossover study to investigate the efficacy of a newly developed orthosis (Spinomed) in patients with OVFs (22). Sixty-two patients age more than 60 with OVFs were enrolled. All patients received standard medical treatment for osteoporosis. Half were required to wear the orthosis for approximately 2 hours/day for 6 months. It was determined that wearing the orthosis for 6 months was associated with 73% increase in back extensor strength, a 58% increase in abdominal flexor strength, 11% decrease in kyphotic angle, 38% decrease in average pain and 15% increase in well-being.

Overall, brace tolerability was good as evidenced by the low drop-out rate of 3%. These authors concluded that use of orthosis may represent an effective nonsurgical treatment modality for OVFs. However, it is notable that the study was funded by Spinomed and carries risk of moderate bias given the vested interest. However, this benefit was reproduced by Liaw *et al.* where they found the use of a Knight Taylor spinal brace in patients with OVF is associated with better static and dynamic motor balance with reduced fall frequency (23).

Contrary to that, Hoshino *et al.* published a report on the impact of bracing in patients with OVFs in 2013 (24). In this multi-center prospective cohort study, 362 patients with OVF over 65 years of age were enrolled (24). Patients received treatment based on physicians' preferences. Three hundred and twenty-seven patients received braces and 35 did not (24). After 6 months, groups showed no difference in pain or independence when measured using the VAS or SF-36. Other studies cautioned against the use of spinal orthosis in this population due to the risk of reduced strength of back extensors (25).

Other systematic reviews have reached differing conclusions regarding the utility of spinal orthoses. Undeniably, all have been in agreement that there is low quality evidence available to guide treatment recommendations. Goodwin *et al.* conducted a systematic review in 2016 to investigate the role of taping as well as orthotics in the management of vertebral fractures in the osteoporotic elderly (26). This represented a comprehensive search of all the major literature databases and yet only nine studies were included with two randomised controlled trials (26). There were 6 different orthotic devices evaluated with a heterogeneous range of outcome measure assessing activities (26). In light of this, these authors concluded the mixed quality evidence meant that there could be no conclusive evidence to support the use of bracing in osteoporotic fractures (26).

Extending their work, Hofler *et al.* in 2020 performed an updated review including 16 studies with 5 randomised controlled trials (27). It is striking that despite the number of studies included in their review the discussion centres around a single trial by Kim *et al.* which found that non-operative management without a brace is non-inferior to management with a brace (28). Murata *et al.* also found that fracture union was 88% at 6 months and the inherent natural history is for fracture healing in conjunction with medical management of low bone mineral density (29). Unfortunately, Hofler *et al.* seem to have interpreted the absence of high quality evidence for spinal orthoses as evidence of absence of benefit and therefore their conclusion was that bracing should not routinely be recommended (27). Our review disagrees with this conclusion given, as Hofler *et al.* themselves later admit, each patient is individualised and there should not be a generalised rule for all osteoporotic fractures (7). Indeed, a minor single endplate deformity fracture with completely preserved posterior wall involvement in a patient with minimal mechanical pain would indeed be reasonably managed without a brace. However, a comorbid patient not medially fit for stabilization surgery who finds relief in the acute phase from mobilising with a semi-rigid brace with a low risk of pressure ulcers with adequate care should not be actively denied a spinal orthosis on the basis of non-inferiority evidence alone (7).

Finally, Jin *et al.* also performed an independent systematic review and low-quality evidence meta-analysis in 2016 on the role of braces and arrived at a more balanced conclusion than Hofler *et al.* with the theory that Spinomed orthoses in certain fracture subgroups may be of benefit (9,27). In particular, Jin *et al.* did find there was very low-quality evidence that indicated there may be an improved quality of life with bracing (9). However, whilst some rigid brace could act as an anti-flexion device and limit kyphosis there was no clear translation into functional benefit in this cohort of patients (9).

The current study by Squires *et al.* attempts to build upon this and limited their systematic review to just randomized controlled trials. Their findings that a use of a rigid brace in patients with OVF may decrease pain up to 6 months post-injury adds further evidence towards the use of spinal orthosis for acute OVFs. Importantly, this particular review found that there was no difference in radiographic parameters, opioid use, function, or quality of life at short or long term follow up.

To better answer the question on bracing in OVFs, more randomized-controlled trials with longer duration of follow up are necessary. An ongoing trial by Weber *et al.* is investigating the effectiveness and cost effectiveness of dynamic bracing in addition to standard care for improving quality of life in post-menopausal women suffering from an osteoporotic vertebral compression fracture (OVCF) (30). Outcome assessment of up to 12 months would add valuable long-term outcome data on this subject. The use of temperature sensors would also allow an objective measure for compliance apart from patient self-reporting. In addition to clinical and functional outcomes, this trial also

aims to elucidate the economic viability of dynamic bracing in addition to standard care. The results from this emerging trial may add valuable insight into the current debate.

Conclusions

Contemporary guidelines for management of OVFs are limited in quantity and quality. Based on the evidence currently available, we believe there is a role for spinal orthosis in the management of OVFs and utilizing this useful adjunct does result in reduced pain and improved functional outcomes, postural stability and reduced kyphotic deformity. What remains unclear, given the low-quality evidence available, is whether this is significantly superior to the outcomes which would have been achieved without bracing. Further international multi-centre randomized trials are required to elucidate this.

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