DEM Journal Club

Article Appraisal

Article: Does a single dose of intravenous dexamethasone reduce Symptoms in Emergency department patients with low Back pain and RAdiculopathy (SEBRA)? A double-blind randomised controlled trial

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Background and Study Objective(s):

Low back pain is a common presenting diagnosis. It is the 5th most common presenting complaint at all physician visits, and low back pain with radiculopathy represents 1% of all ED visits. The idea is that systemic glucocorticoids may decrease edema at the nerve root and act as an anti-inflammatory, resulting in pain reduction and increased mobility. The hypothesis was that a single dose of IV dexamethasone would lead to a greater reduction in the primary outcome (pain at 24 hours) as well as pain scores at 6 weeks, functional scores at 24 hours and 6 weeks, ED length of stay (LOS) and straight leg raise (SLR) angle.

Study Design:

This was a double blind, randomized controlled trial conducted at 2 public hospitals in Australia between November 2011 and November 2012. One hospital is a 570 bed major metropolitan teaching hospital and the other is a 200 bed urban hospital. Based on their own local audit of similar patients, they determined that "usual care" (analgesics, education and physiotherapy) resulted in a 1.5 point reduction on the VAS (visual analogue scale) (from 7.5 to 6). They deemed an additional 1.5 point reduction (from 7.5 to 4.5) would be considered clinically significant. Statistically, they required 44 patients to power this, so aimed to have 70-100 patients to account for loss to follow-up.

Results:

They identified 566 patients with low back pain, of which only 69 were "eligible" for enrolment. Of those, 48 completed the 24 hour questionnaire. For the primary outcome (pain at 24 hours), they found a statistically significant 1.86 point greater reduction in pain scores (from roughly 8 to 5.5). Secondary outcomes included a statistically significantly shorter ED LOS (3.5h vs 18.8h) and a roughly 15 degree greater improvement in SLR from presentation to discharge (despite a non-significant difference in pain from presentation to discharge). The secondary outcomes investigated at 6 weeks (return to normal activities and functional scores) were underpowered due to further loss to follow-up and were not statistically significant.

Validity of Results:

There are several concerns with this trial. The first is that the two groups had different baseline characteristics. The group receiving dexamethasone had a higher VAS score to start (8 vs 7). This difference was attributed to chance,

given the small number enrolled and the appropriate randomisation. However, when a regression analysis was applied to control for this difference, it reduced the treatment effect by 28% (dropping the total point difference from 1.86 to 1.33). As mentioned initially, the authors had chosen a 1.5 point difference as their "clinically significant" value, so this potentially invalidates their findings. The second major concern is differences in analgesic requirements. They did not record differences in all analgesic requirements, including usage of acetaminophen/codeine and ibuprofen. They did record differences between oxycodone use; there was not a difference between groups at 24 hours, but there was at 6 weeks. Interestingly, the authors failed to expand on the dramatic difference in LOS (or include confidence intervals for this measure). This would seem to imply outliers played a significant role in these results, otherwise this would be a potentially powerful outcome.

Generalizability of Results:

There is no reason to expect that these results (if valid) could not be applied to our patient population. We see a relatively large number of patients with low back pain, of which patients with radiculopathy are a subset. This was an Australian study, but there is no compelling reason to believe that the results would not apply to Canadian patients.

The Bottom Line:

Unfortunately, this small trial is not compelling enough evidence to advocate the usage of IV dexamethasone in patients with low back pain with radiculopathy, due to the questionable validity addressed previously. However, neither does this study definitively close the door on the question of systemic corticosteroids in low back pain with radiculopathy. The impression was that the physiology makes sense that this could be an effective treatment, and ED physicians are in need of more effective tools for treating this difficult condition. Unfortunately, at this time, further research is needed before this can be a widely applied practice.