**Synopsis**


**Question:** Does the instillation of normal saline before suctioning reduce the incidence of ventilator-associated pneumonia in intubated and ventilated adults? **Design:** Randomised, controlled trial with blinded outcome assessment. **Setting:** The medical/surgical intensive care unit of a tertiary oncology hospital in Brazil. **Participants:** Adults expected to require at least 72 hours of mechanical ventilation via an endotracheal or tracheostomy tube. **Interventions:** Participants were randomly assigned to the intervention group (n = 130) or control group (n = 132). Suctioning was performed at the discretion of the respiratory therapist in the control group. In the intervention group, therapists instilled 8 mL of normal saline prior to suctioning as part of a standardised procedure that included preoxygenation. This protocol was maintained by the physiotherapy interventions received beyond suctioning: enhancement of peak inspiratory pressures, decreased tidal volumes, and increased secretion clearance. **Outcome measures:** The primary outcome was the incidence of ventilator-associated pneumonia (VAP). Secondary outcome measures included time to VAP, duration of mechanical ventilation, length of stay in the intensive care unit, and mortality in the control group (31/132), relative risk reduction 0.54 (95% CI 0.18 to 0.74). This indicates that one patient will avoid developing VAP for every 8 patients in which saline instillation is used. **Conclusion:** Instillation of normal saline before tracheal suctioning decreases the incidence of VAP in mechanically ventilated adults.

**Commentary**

Normal saline instillation (NSI) prior to endotracheal suctioning has been practised widely for over two decades in intensive care units. High quality, clinical evidence about the effects of NSI is limited. *In vitro* evidence that NSI dislodges bacteria from endotracheal tubes suggests that it would increase contamination of the lower respiratory tract (Hagler and Traver 1994). On this basis, some have recommended that its routine use be discontinued (Thompson 2000). The study by Caruso and colleagues (2009), however, demonstrates that NSI reduces the incidence of VAP in intubated patients. The authors suggest possible mechanisms for this reduction: enhancement of sputum clearance by cough stimulation, dilution and loosening of sputum thus aiding secretion clearance, and a reduction in the endotracheal tube biofilm ‘VAP reservoir’ by frequent rinsing with NSI. As none of these was measured specifically during this study, the mechanism(s) for the reduction in VAP remains undetermined. Additional studies could clarify the relative impact of these proposed mechanisms.

Wide variation in the administration of NSI is known to occur between intensive care units. Published studies of NSI frequently do not specify the patient’s position during NSI, the length of time from NSI to suction, or individual and cumulative NSI dosages. These details would help guide those clinicians continuing to implement NSI. Whilst the meta-analysis may not fully address the debate, it provides the first high quality, clinical evidence of benefit which must certainly reopen the debate.

**References**


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Multidisciplinary assessment of elderly people with a history of multiple falls reduces the risk of further falls

Synopsis


**Question:** Does assessment by a multidisciplinary team, or assessment by a community nurse with the ability to refer to other professionals, reduce further falls in recurrent fallers?  
**Design:** Cluster-randomised, controlled trial.  
**Setting:** 18 general practices in the UK.  
**Participants:** Adults aged at least 65 years, living in the community, who had experienced 2 or more falls in the past year, and who did not present to an emergency department for their most recent fall. Inability to participate for one year, abbreviated mental test score less than 7, and nursing home placement were exclusion criteria.  
**Interventions:** Participants allocated to secondary care attended a multidisciplinary clinic (comprising a doctor, nurse, physiotherapist, and occupational therapist) with referral for investigations, interventions (including Homecheck), and follow-up if necessary. Participants allocated to primary care were assessed by a community nurse who identified risk factors for falls and could refer to other professionals. Participants in the usual care group were assessed by their usual primary care physicians, who provided management at their own discretion.  
**Outcome measures:** The primary outcome was the proportion of participants in each group who had at least one fall during the follow-up period of 12 months. Other outcomes were death, move to institutional care, change in Barthel score, change in the timed Get Up and Go score, fall-related fractures, and hospitalisations. Participants lost to follow-up were assumed to have had an adverse outcome.  
**Results:** 466 participants contributed data to the primary outcome, with an adverse outcome assumed for a further 39 participants on falls and other dichotomous outcomes. At 12 months, 75% of the secondary care group, 87% of the primary care group, and 84% of the usual care group had fallen. Secondary care prevented significantly more falls than usual care (adjusted odds ratio 0.52, 95% CI 0.35 to 0.79). The secondary care group also had a significantly more positive Barthel index than the usual care group. The groups did not significantly differ on the other outcomes. The data were also analysed without imputing adverse outcomes for participants who were lost to follow-up. Compared to the usual care group, the secondary care group had significantly fewer falls, fractures, hospitalisations, and deaths.  
**Conclusion:** Multidisciplinary assessment of elderly, recurrent fallers reduces the risk of further falls compared to usual care. Assessment of risk factors for falls by a community nurse with the potential to refer to other professionals did not have the same benefit.

Commentary

The Winchester Falls Project concludes that a multidisciplinary intervention in secondary care is effective in reducing falls in community dwelling older people who have suffered recurrent falls in the previous year.

The design and analysis of cluster-randomised, controlled trials is notoriously difficult. Such designs are particularly vulnerable to selection bias, which occurs where individuals are recruited after the unit of randomisation (in this case the general practice) is aware of their allocation (Farrin et al 2005). Those practices allocated to the intervention arms are often highly motivated to recruit, whereas those allocated to the control arm are not. This can result in imbalances in the fraction of eligible participants being recruited, and also in the general demographic profile of the samples within each trial arm. Unfortunately, the authors of the Winchester Falls Project fail to provide a sufficiently accurate account of the population base in each of the trial arms to determine the extent of this problem. Complex statistical models have been built to deal with the imbalances, which favour the multidisciplinary intervention arm as it contains fewer women and people of younger age. These shortcomings notwithstanding, the conclusion that falls can be prevented in recurrent fallers is merited. Comments relating to other outcomes and secondary analyses are much less robust and readers are advised to be circumspect. It is disappointing that the authors have not provided a better description of the intervention tested to enable both researchers and clinicians to gain more from their work.

The reference list for the paper is now quite dated. An updated systematic review and meta-analysis of multi-factorial fall prevention programs was published recently and concluded that multi-factorial fall prevention programs may not be as effective as originally estimated, with the fall reduction being approximately 9%, and no evidence of fracture reduction (Gates et al 2008). The findings of the Winchester Falls Project are remarkably similar. Future research must determine whether these relatively small gains are cost effective, and assess the broader impact on health-related quality of life.

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References

Do lumbar stabilising exercises reduce pain and disability in patients with recurrent low back pain?

Synopsis


Question: Does a graded exercise program emphasising lumbar stabilising exercises reduce pain and disability at 12 months, compared with a walking program, for patients with recurrent low back pain? Design: Randomised controlled trial. Setting: A single private physiotherapy clinic in Sweden. Participants: 71 patients with recurrent mechanical low back pain (> 8 weeks duration, with at least 1 pain-free period during the past year) and without leg pain were allocated to one of two groups, using a concealed allocation process. The groups were comparable at baseline with respect to age, sex, proportion of participants who had sought care for back pain, and pain duration (approximately 10 years). Interventions: The graded exercise program and the walking program were both 8 weeks’ duration. The exercise program was individually supervised by a physiotherapist weekly for 45 minutes. In the walking program, patients met with a physiotherapist for 45 minutes in week 1 and again in week 8. The exercise program consisted primarily of stabilising exercises for the lumbar spine, commencing with re-learning activation of the transversus abdominis and multifidus muscles, with assistance of a pressure biofeedback cuff. Exercises were progressed according to clinical judgement, pain levels, and movement control and quality. Progression entailed incorporation of muscle activation in upright positions and during functional activities. Continued implementation of the exercises in daily life was encouraged. The reference group were instructed to walk for 30 minutes daily at the fastest pace that did not aggravate pain. Walking compliance was monitored with a self-completed daily diary. Outcomes: The primary outcomes were perceived pain and disability at 12 months, measured by self-completed questionnaires returned by post. Disability was measured with the Oswestry Disability Questionnaire (scale 0–100, where 100 = maximum disability). Pain was measured with 100-mm visual analogue scale (where 100 = worst pain imaginable). Results: At 12 months 86% of patients were followed up. At this time there was no clinically-important difference between the groups with respect to median (IQR) change in pain: exercise group –12 (–34 to –3); walking group –12 (–22 to 0). For disability at 12 months, the between-group difference in median scores was 8 on the Oswestry score: exercise group –10 (–20 to –2); walking group –2 (–12 to 2). Conclusion: Lumbar stabilising exercises appear to have a similar effect on pain and disability for patients with recurrent low back pain as a daily walking program.

Commentary

This is a methodologically sound, randomised, controlled trial investigating the efficacy of stabilising exercises for back pain. The study showed a higher percentage of patients with a clinically important reduction of disability, but not pain, at 12-month follow-up. However, several issues need to be taken into account.

First, the differences regarding pain and disability were no longer clinically relevant at 36 months follow-up.

Second, it can be debated whether walking is a valid control treatment as it has been proven ineffective for chronic patients (Torstensen et al 1998). At best it can be regarded a minimal intervention. As such the results are in agreement with a recent meta-analysis showing that stabilising exercises are more effective than minimal interventions (Macedo et al 2009). It would have been more interesting to compare stabilising exercises to another active form of exercise, or home exercises focussing on patient-relevant activities (as walking might have minimal or no limitation). Based on the abovementioned meta-analysis it is hypothesised that the differences would have been negligible. One can also argue that the control treatment might be less appealing to the patients who were randomised to this treatment. Although the authors state that the level of expectation was equal for both treatments, this was measured before and not after randomisation.

Third, the baseline levels of pain and disability were rather low and patients were all working. Unfortunately the authors don’t provide a full explanation of why they included only working patients. This limits generalisation to primary care physiotherapy practices.

Fourth, although the stabilising treatment aims to alter motor control of the transversus abdominis and multifidus muscles, neither motor control changes nor their association with outcome were assessed.

The positive results of the stabilising exercises are probably caused by general effects of exercise, such as improved self-efficacy (which indeed did occur) or reduced catastrophising (Smeets et al 2006).

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References

Arthroscopic surgery provides no additional benefit over physiotherapy and medication for the treatment of knee osteoarthritis

Synopsis


Question: What is the effect of the addition of arthroscopy to physiotherapy and medication in patients with osteoarthritis (OA) of the knee? Design: Randomised, controlled trial with blinded outcome assessment and intention-to-treat analysis. Setting: A university sports medicine clinic in Ontario, Canada. Participants: Adults with idiopathic or secondary moderate-to-severe OA of the knee (Grade 2, 3, or 4 radiographic severity on the modified Kellgren-Lawrence classification). Key exclusion criteria were large meniscal tears, inflammatory arthritis, previous arthroscopic treatment for knee OA and more than 5 degrees of lateral deformity. Randomisation of 188 participants allotted 94 to an intervention group and 94 to a control group. Interventions: The intervention group underwent arthroscopy within 6 weeks after randomisation and a standard physiotherapy and medication regimen was initiated within 7 days after surgery. The control group initiated the same physiotherapy and medication regimen at an equivalent time. Physiotherapy was provided for 1 hour once a week for 12 weeks. It included range-of-motion and strengthening exercises to be performed at home twice daily, information about activities of daily living, instruction in the use of heat and cold, and an educational video. Exercises were individualised according to the severity of OA and age. After the 12-week period, participants were advised to continue the exercise program. Medications (potentially including paracetamol, non-steroidal anti-inflammatory drugs, hyaluronic acid, and glucosamine) were prescribed according to standard guidelines. Outcome measures: The primary outcome was the WOMAC score at 2 years follow up. The WOMAC is scored from 0 (worst) to 2400, with subscales for pain, stiffness, and physical function. Secondary outcomes included the Physical Component Summary Score of the Short Form-36 (0 to 100); the McMaster Toronto Arthritis patient preference (MCTAR) questionnaire (0 to 500); and the Arthritis Self-Efficacy Scale (ASES) (10 to 100). Results: 168 participants completed the study. After 2 years, the mean (SD) WOMAC scores were 874 (624) in the intervention group and 897 (583) in the control group, mean difference 23 (95% CI –208 to 161). The groups differed on the SF-36 by only 0.2 (95% CI –3.2 to 3.6), on the MACTAR questionnaire by only 6 (95% CI –37 to 49), and on each of the ASES subscales by less than 6 (all non-significant). Conclusion: The addition of arthroscopy to a regimen of physiotherapy and medication does not improve physical function, pain, or health-related quality of life in patients with moderate-to-severe OA of the knee.

Commentary

Currently, evidence-based treatment of knee OA is based on updated guidelines, which recommend medical management and exercise therapy (Walsh et al 2009, Fransen et al 2008). Evidence in support of arthroscopic surgery has been lacking although the procedure remains in wide use. Randomised controlled trials (RCTs) of arthroscopic surgery are therefore needed to determine both its effect on clinical outcomes and its cost-effectiveness. This RCT (Kirkley et al 2008) is well performed and therefore provides important knowledge to physiotherapists, orthopaedic surgeons, other health care practitioners, and patients regarding the clinical effects of arthroscopy. Unfortunately, cost was not examined, but the authors were able to improve upon several methodological limitations in the previous RCT of arthroscopy by Moseley et al (2002).

Patients with substantial malalignment were not included. The conclusion of the study should therefore have specified that the results apply to individuals with mild-to-moderate knee OA, not to knee OA in general. It is also worth noting that patients with Kellgren-Lawrence Grades 3 and 4 demonstrated a significant benefit from arthroscopy after 3 months compared with those receiving exercise therapy only. However, the groups did not differ significantly thereafter. The sham effect of surgery must be considered (Zhang et al 2008). Furthermore, a statement regarding whether the study was intended as a non-inferiority trial should have been included (Piaggio et al 2006). Hypotheses are, however, not included in the article, and therefore it is not obvious if the authors intended this as a superiority or non-inferiority trial. Non-inferiority trials require different sample size calculations.

It is also worth noting that this RCT started in 1999 and was therefore based on current guidelines at that time. New guidelines have been published during recent years, improving exercise therapy (Walsh et al 2009, Fransen et al 2008) and commentaries on the recommendations for medical treatment for individuals with knee OA used in the study have been published (Brandt 2001).

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References
