RESEARCH

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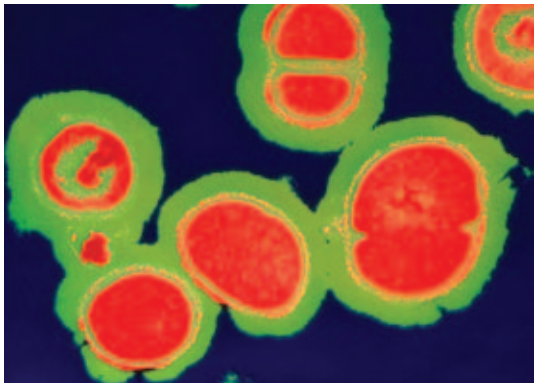

Recently published

Decline of meticillin resistant *Staphylococcus aureus* in Oxfordshire hospitals is strain-specific and preceded infection-control intensification http://bmjopen.bmj.com/content/1/1/e000160.full

Clostridium difficile infection: diagnosis and treatment http://bit.ly/MT8rIi

Can Twitter predict disease outbreaks? http://www.bmj.com/content/344/bmj.e2353

RESEARCH ONLINE: For this and other new research articles see www.bmj.com/research

Potential impact on estimated treatment effects of information lost to follow-up in randomised controlled trials (LOST-IT)

Up to a third of trials published in five top general medical journals and reporting significant results for binary primary outcomes lose significance if one makes plausible assumptions about their loss to follow-up. Such assumptions could change the interpretation of the trial results, say the authors of this systematic review.

Comparisons of established risk prediction models for cardiovascular disease: systematic review

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EDITORIAL
by Collins and Moons

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STUDY QUESTION

What is the relative performance of validated cardiovascular risk prediction models?

SUMMARY ANSWER

Current studies comparing predictive models often have limitations or missing information and lack standardised reporting, which makes it difficult to reach robust conclusions about the relative performance of the models.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Several risk prediction models for cardiovascular disease have been proposed for clinical use, most of which have been developed and validated in different populations with unknown comparative prognostic performance.
Our systematic evaluation showed that studies on the comparative performance of such models lack standardised methods of evaluation and reporting.

Selection criteria for studies

We carried out a systematic review of studies examining the relative prognostic performance of at least two major risk models for cardiovascular disease in general populations. Eligible articles were identified through Medline and screening citations and references. We extracted information on study design, risk models assessed, and outcomes.

Primary outcomes

We included studies that assessed coronary heart disease or cardiovascular disease morbidity or mortality.

Main results and the role of chance

Twenty articles including 56 pairwise comparisons of eight models (two variants of the Framingham risk score, the assessing cardiovascular risk to Scottish Intercollegiate Guidelines Network to assign preventative treatment (ASSIGN) score, systematic coronary risk evaluation (SCORE) score, Prospective Cardiovascular Münster (PROCAM) score, QRESEARCH cardiovascular risk (QRISK1 and QRISK2) algorithms, Reynolds risk score) were eligible. Only 10 of 56 comparisons exceeded a 5% relative difference in the area under the receiver operating characteristic curve. Among the 50 comparisons that included variants of the Framingham risk score, in 37 the area under the receiver operating characteristic curve estimate was higher for the comparator model. Use of other discrimination, calibration, and reclassification statistics was less consistent. In 32 comparisons, an outcome was used that had been used in the original development of only one of the compared models, and in 25 of these comparisons (78%) the outcome-congruent model had better areas under the receiver operating characteristic curve. Moreover, authors always reported better area under the receiver operating characteristic curve for models that they themselves developed (in five articles on newly introduced models and in three articles on subsequent evaluations).

Bias, confounding, and other reasons for caution

Most of the analysed studies and models pertained to populations of European descent. Risk models may, however, perform differently in populations of different racial or ethnic backgrounds. Also, more formal statistical testing would have required access to individual level data to account for the fact that models were evaluated in the same population in each comparison using the pairwise individual level correlation in the calculations.

Study funding/potential competing interests

This study received no additional funding. We have no competing interests.

Suggestions for studies comparing risk prediction models

- Comparative studies should be carried out in independent samples from those where each model was originally developed, and ideally by investigators other than those who originally proposed these models
- The study setting, country, and type of population should be described; it should also be recognised whether these characteristics are expected to offer any clear advantage to one of the compared models
- The main outcome of the study should be clearly defined and clinically relevant; it should be recognised that models originally developed to predict other outcomes may exhibit inferior predictive performance
- Models should be calculated using the same exact predictors and coefficients as when they were originally developed and validated
- The follow-up time should correspond to the same follow-up time as when the models were developed (for example, 10 year risk); deviations should be clarified and an explanation about choice given
- The discrimination of each model should be given with point estimates and confidence intervals; differences between the discrimination of compared models should be formally tested, reporting the magnitude of the difference and the accompanying uncertainty
- The calibration of each model may be assessed with statistical tests, but there is no good formal test for comparing calibration performance; it is useful also to show graphically the expected versus predicted risk for different levels of risk or levels of predictors
- Examination of reclassification performance of examined risk scores is meaningful when there are well established clinically relevant risk thresholds; it is useful to provide information on the number of correct and incorrect classifications; avoid using the net reclassification improvement for non-nested models
- The extent of missing information for outcomes and predictors should be described, also explaining how missing information was handled

Effectiveness of dementia follow-up care by memory clinics or general practitioners: randomised controlled trial

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STUDY QUESTION

What is the effectiveness of post-diagnosis treatment and coordination of care for patients with dementia and their caregivers by memory clinics compared with care provided by general practitioners?

SUMMARY ANSWER

Memory clinics are no more effective than general practitioners with regard to post-diagnosis treatment and coordination of care for patients with dementia.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Memory clinics have been shown to be effective as diagnostic facilities. No evidence was found of a difference in effectiveness between memory clinics and general practitioners in treating and coordinating care for patients with dementia.

Design

This was a multicentre pragmatic randomised controlled trial. Web based randomisation took place after baseline measurements were made. Participants (patient-caregiver pairs) were assigned for post-diagnosis dementia care to either the memory clinic or the general practitioner. The interventions in this study consisted of usual care by either the memory clinic or the general practitioner.

Participants and setting

Participants (n=175) were recruited by nine Dutch memory clinics after diagnostic investigation. Patients had to be newly diagnosed as having dementia meeting the criteria of the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV), with a clinical dementia rating of 0.5, 1, or 2. Each patient had an informal caregiver.

Primary outcome(s)

The primary outcomes were quality of life of the patient as rated by the caregiver, assessed with the quality of life in Alzheimer's disease instrument, and self perceived caregiving burden of the informal caregiver, measured by the sense of competence questionnaire at 12 months' follow-up.

Main results and the role of chance

The patients in the memory clinic group scored 0.5 (95% confidence interval −0.7 to 1.6) point higher on the quality of life in Alzheimer's disease instrument than did those in the general practitioner group. Caregivers in the memory clinic group scored 2.4 (−5.8 to 1.0) points lower on the sense of competence questionnaire. None of the differences was statistically significant.

Harms

No incidents occurred as a result of our study. The only interventions were usual care by either the memory clinic or the general practitioner.

Bias, confounding, and other reasons for caution

Dementia is a disease that progresses over years, so an extended follow-up lasting several years would be preferable to the relatively short 12 month period we used.

Generalisability to other populations

Participation of nine different memory clinics enhanced the generalisability of the study. However, we recruited participants only from memory clinics and not from general practices, which means that the results may not be representative for all patients with mild to moderate dementia in the general population. Also differences in healthcare systems between countries make generalisability more difficult.

Study funding/potential competing interests

This work was supported by ZonMw (Netherlands Organization for Health Research and Development) and by the Radboud University Nijmegen Medical Centre.

Trial registration number

Clinical trials NCT00554047.

Analysis of covariance for difference between memory clinic (MC) and general practitioner (GP) in primary outcome measures at 12 months' follow-up

Outcome	Difference (95% CI) between MC and GP	P value	No
QoL-AD patient, as rated by caregiver*	0.49 (−0.66 to 1.63)	0.40	153
Caregiver's sense of competence questionnaire†	−2.43 (−5.82 to 0.96)	0.16	153

*Quality of life in Alzheimer's disease: range 13-52; higher score indicates better quality of life.
†Range 27-135; higher score reflects greater sense of competence.

Effects of circuit training as alternative to usual physiotherapy after stroke: randomised controlled trial

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STUDY QUESTION

What is the effect of task oriented circuit training compared with usual physiotherapy in terms of self reported walking competency for patients with stroke discharged from a rehabilitation centre to their own home?

SUMMARY ANSWER

Task oriented circuit training started in the first six months is as effective as individually tailored physiotherapy for patients with moderate to mild stroke and allows patients to exercise more intensively with a lower ratio of staff to patients.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

In patients with stroke, group circuit training is safe and has good results in terms of walking distance and walking speed. Previous trials, however, have been conducted in patients with chronic stroke, were small, and failed to follow up adequately. Though significant treatment effects favouring task specific circuit training were found for walking distance, walking speed, and stair walking, the differences between groups were small and the sustainability of effects was limited.

Design

Multicentre randomised single blinded controlled trial with follow-up to 24 weeks. After stratification by rehabilitation centre, patients were randomly allocated to circuit training or usual outpatient physiotherapy with an online randomisation procedure. Patients in the intervention group received circuit training in 90 minute sessions twice a week for 12 weeks. The training included eight different workstations and was intended to improve gait and gait related activities.

Participants and setting

250 patients with stroke who were able to walk a minimum of 10 m without physical assistance and were discharged from inpatient rehabilitation to an outpatient rehabilitation clinic were eligible. Patients were included in nine rehabilitation centres in the Netherlands.

Primary outcome

The primary outcome was the mobility domain of the stroke impact scale (version 3.0) and was determined at baseline and 6, 12, 18, and 24 weeks.

Effect of class circuit training on mobility domain of stroke impact scale 3.0

	Circuit training		Usual physiotherapy	
	No of patients	Mean (SD) score	No of patients	Mean (SD) score
Baseline	126	80.9 (13.0)	124	77.8 (15.0)
12 weeks	125	87.3 (12.4)	117	83.7 (13.3)
24 weeks	125	86.6 (13.2)	117	84.4 (14.5)

Main results and the role of chance

In total 126 patients were included in the circuit training group and 124 in the usual care group (control), with data from 125 and 117, respectively, available for analysis. There were no significant differences between groups for the change in the mobility domain of the stroke impact scale (β=0.049 (SE 0.682), P=0.47) between baseline and 12 weeks.

Harms

Circuit training was a safe intervention, and no serious adverse events were reported.

Bias, confounding, and other reasons for caution

Patients recruited for the present study were aware of type of intervention they received, and the combination of workstations used in this trial was an arbitrary selection on the basis of safety, clinical relevance in terms of activities, simplicity of execution, and feasibility without additional costs to the physiotherapy department.

Generalisability to other populations

We were able to recruit only a quarter of all patients who were discharged from one of the participating rehabilitation centres in the Netherlands. Only patients with a mild to moderate stroke were selected for the trial.

Study funding/potential competing interests

This study was funded by the Netherlands Organisation for Health Research and Development (ZonMw), No 80-82310-98-08303.

Trial registration number

Dutch Trial Register (NTR1534)

Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial

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STUDY QUESTION

Is a single ultrasound guided corticosteroid injection an effective treatment for plantar fasciitis?

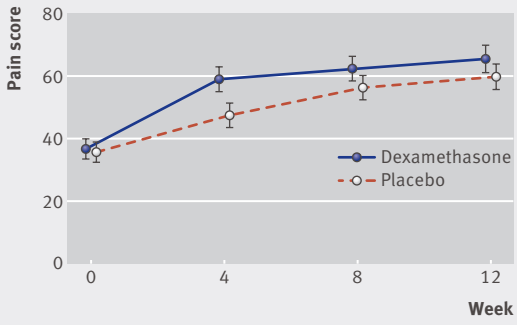
SUMMARY ANSWER

A single ultrasound guided dexamethasone injection is a safe and effective short term treatment for plantar fasciitis, providing better pain relief than placebo at four weeks. The treatment also reduces abnormal swelling of the plantar fascia soon after treatment, and continuously for several months.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Plantar fasciitis is the most common cause of inferior heel pain. This trial shows that an ultrasound guided dexamethasone injection can provide short term pain relief.

Mean (SD) scores* for pain on foot health status questionnaire (0-100 points) according to treatment



* High values represent better pain, low values represent worse pain

Design

This was a randomised, investigator and participant blinded, placebo controlled trial. Participants were randomly allocated to ultrasound guided injection of the plantar fascia with either 1 mL of 4 mg/mL dexamethasone sodium phosphate or 1 mL of normal saline (placebo).

Participants and setting

82 people with clinical and ultrasound diagnosis of plantar fasciitis unrelated to systemic disease and seen at a university clinic in Melbourne, Australia.

Primary outcomes

Primary outcomes were pain measured by the foot health status questionnaire (0-100 point scale) and plantar fascia thickness measured by ultrasound at 4, 8, and 12 weeks.

Main results and the role of chance

Reduction in pain at four weeks favoured the dexamethasone group by 10.9 points (95% confidence interval 1.4 to 20.4, P=0.03). Between group differences for pain scores at eight and 12 weeks were not statistically significant. Plantar fascia thickness measured at four weeks favoured the dexamethasone group by −0.35 mm (95% confidence interval −0.67 to −0.03, P=0.03). At eight and 12 weeks, between group differences for plantar fascia thickness also favoured dexamethasone, at −0.39 mm (−0.73 to −0.05, P=0.02) and −0.43 mm (−0.85 to −0.01, P=0.04), respectively. The number needed to treat with dexamethasone for one successful outcome for pain at four weeks was 2.93 (95% confidence interval 2.76 to 3.12).

Harms

No adverse events associated with the trial intervention were reported: in particular, post-injection flare, soft tissue infection, or rupture of the plantar fascia.

Bias, confounding, and other reasons for caution

Clinicians offering this treatment should note that significant pain relief did not continue beyond four weeks.

Generalisability to other populations

Factors limiting generalisability include the provision of regional anaesthesia, use of an ultrasound guided injection technique, selection of a corticosteroid (dexamethasone) infrequently used by clinicians treating musculoskeletal disorders, and injection of plain corticosteroid solution (without mixing with local anaesthetic). Points of difference between the procedure tested and the techniques used by clinicians should be considered when interpreting the trial findings, as variation in clinical techniques may lead to different patient outcomes.

Study funding/potential competing interests

This study was funded by the Australian Podiatry Education and Research Foundation. AMcM has received an Australian Postgraduate Award scholarship. HBM is a National Health and Medical Research Council senior research fellow (ID: 1020925).

Trial registration number

Australian New Zealand Clinical Trials Registry ACTRN12610000239066.

Association of onset to balloon and door to balloon time with long term clinical outcome in patients with ST elevation acute myocardial infarction having primary percutaneous coronary intervention: observational study

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STUDY QUESTION

Are the benefits of short onset to balloon time and short door to balloon time apparent in patients with ST segment elevation myocardial infarction (STEMI) having primary percutaneous coronary intervention in daily clinical practice?

SUMMARY ANSWER

Short onset to balloon time was associated with better three year clinical outcome in patients with STEMI having primary percutaneous coronary intervention, whereas the benefit of short door to balloon time was limited to patients who presented early.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Results from previous studies have been quite inconsistent regarding the relation between delay in intervention and clinical outcomes. A clear association has been shown between an onset to balloon time of less than three hours and better long term (three year) clinical outcomes; the benefit of short door to balloon time was limited to patients with early presentation.

Participants and setting

We included patients with STEMI who had primary percutaneous coronary intervention within 24 hours of symptom onset in 26 tertiary hospitals in Japan.

Design, size, and duration

We identified 3391 eligible patients among a large acute myocardial infarction cohort. We evaluated the relation between the onset to balloon time and door to balloon time and long term (three year) clinical outcome. The primary outcome measure was a composite of death and congestive heart failure.

Main results and the role of chance

Compared with an onset to balloon time greater than three hours, a time of less than three hours was associated with a lower incidence of a composite of death and congestive heart failure (13.5% (123/964) *v* 19.2% (429/2427), P<0.001; relative risk reduction 29.7%). After adjustment for confounders, a short onset to balloon time was independently associated with a lower risk for the composite endpoint (adjusted hazard ratio 0.70, 95% confidence interval 0.56 to 0.88; P=0.002). We found no significant difference in the incidence of a composite of death and congestive heart failure between the two groups of patients with short (≤90 minutes) and long (>90 minutes) door to balloon time (P=0.54). After adjustment for confounders, no significant difference existed in the risk of the composite endpoint between the two groups. A door to balloon time of less than 90 minutes was associated with a lower incidence of a composite of death and congestive heart failure in patients who presented within two hours of symptom onset (P=0.01) but not in those who presented later (P=0.44). Short door to balloon time was independently associated with a lower risk of the composite endpoint in patients with early presentation but not in those with delayed presentation. We found a significant interaction between door to balloon time and time to presentation (P=0.01).

Bias, confounding, and other reasons for caution

We could not exclude the influences of patients' recall bias for symptom onset, of survivor bias, or of variations in the time course of development of myocardial necrosis. The huge differences in baseline characteristics between patients with early reperfusion and those with delayed reperfusion might limit comparability, although we adjusted as extensively as possible to minimise the influence of unmeasured confounders.

Generalisability to other populations

The findings of this study were derived from a large cohort in Japan. The benefit and importance of reducing total ischaemic time, however, would be expected in all patients with STEMI having primary percutaneous coronary intervention.

Study funding/potential competing interests

This study was supported by the Pharmaceuticals and Medical Devices Agency in Japan.

Association of door to balloon (DBT) time with outcome in patients with early and delayed presentation

Patient group	Incidence of composite endpoint*		Relative risk reduction (%)	Adjusted hazard ratio (95% CI)	P value
	DTB time ≤90 minutes	DTB time >90 minutes			
Entire cohort	16.7% (270/1671)	18.4% (282/1720)	9.2	0.98 (0.78 to 1.24)	0.87
Presentation ≤2 hours after symptom onset	11.9% (74/883)	18.1% (147/655)	34.3	0.58 (0.38 to 0.87)	0.009
Presentation >2 hours after symptom onset	19.7% (196/788)	18.7% (135/1065)	−5.3	1.57 (1.12 to 2.18)	0.008

*Death plus congestive heart failure.