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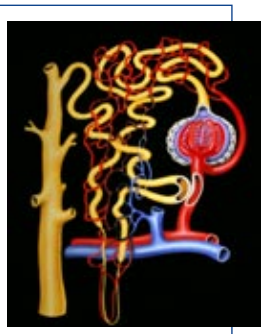
RESEARCH

THIS WEEK'S RESEARCH QUESTIONS



FRANCIS LEROY,BIOCOSMOS/SPL

300 In patients with active psoriasis and psoriatic arthritis, is etanercept 50 mg twice weekly more effective than 50 mg once weekly in clearing skin symptoms?

301 Does using a transparent collector bag to measure blood loss after vaginal delivery alert staff and thereby reduce severe postpartum haemorrhage?

302 What happened to cancer patients' access to hospital care and surgery in England after the NHS Cancer Plan was launched?

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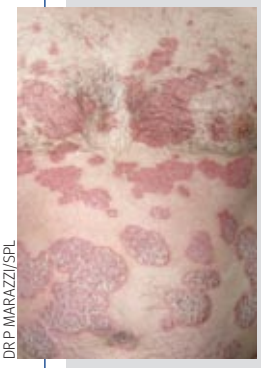
Treatment for severe psoriasis



DR P MARAZZI/SPL

This multinational double blind trial by Wolfram Sterry and colleagues aimed to find the most effective regimen for taking etanercept, or injectable tissue necrosis factor blocker, in moderate to severe plaque psoriasis with psoriatic arthritis (p 300). The drug has already been approved by NICE as a second line treatment. But how often should patients take it? For the primary outcome—clearance of psoriasis by at least 75% at three months—50 mg twice weekly was significantly more effective than the same dose weekly, although even the more frequent regimen achieved near or complete clearance for less than half the patients. By contrast, for both regimens arthritis improved significantly in about three quarters of patients, but this was a secondary outcome. This study is clearly at the specialist end of research and the *BMJ* doesn't have a tradition of publishing drug trials. But we're keen to publish head to head trials about the comparative effectiveness of treatments and regimens and, as long as industry sponsored trials are reported transparently and ask relevant questions that can improve doctors' decisions and patients' care, we're happy to consider them (see our policy at http://resources.bmj.com/bmj/authors/types-of-article/research). And, of course, psoriasis is a common and often disabling and distressing condition that's managed by generalists and specialists alike.

Access to NHS cancer care

Critics often say that access to cancer services is limited by a postcode lottery. Has the NHS Cancer Plan, published in 2000 to improve outcomes for patients and reduce health inequalities, made a difference? Rosalind Raine and colleagues looked at hospital episode statistics on more than half a million NHS patients in England between 1999 and 2006 (p 302). They wanted to see whether the type of hospital admission (emergency compared with elective) and surgical procedure for colorectal, breast, and lung cancer varied by socioeconomic circumstances, age, sex, and year of admission, and whether the picture changed over time. Despite many improvements in cancer care across the NHS, they found that social factors are still strongly associated with access to and the provision of care.

Measuring blood loss after vaginal delivery

Common sense might suggest that using a transparent bag to collect and measure postpartum blood loss could more accurately alert staff and reduce delays in treating severe postpartum haemorrhage. But this widely used, low tech tool hadn't been tested, so Wei-Hong Zhang and colleagues evaluated its use in a cluster randomised controlled trial across Europe (p 301). Severe postpartum haemorrhage occurred in 1.71% of vaginal deliveries in the intervention group compared with 2.06% in the control group, where staff simply estimated the volume of blood loss by looking . The difference was not significant, and the authors wonder whether this might reflect lack of compliance or a ceiling effect, with included centres already assessing the risk of postpartum haemorrhage accurately. Either way, the bag's effectiveness hasn't been proved.

RESEARCH ONLINE: For these and other new research articles see http://www.bmj.com/channels/research.dtl

Venlafaxine versus other antidepressant drugs: risk of sudden cardiac death or near death
In late 2004 safety concerns led the UK Medicines and Healthcare products Regulatory Agency (MHRA) to restrict prescribing of the selective serotonin receptor inhibitor venlafaxine to specialists and contraindicated its use in patients with heart disease, electrolyte imbalance, or hypertension. In May 2006 the MHRA again allowed prescribing by non-specialists and advised that only patients at very high risk of ventricular arrhythmia or with uncontrolled hypertension should not use venlafaxine, even though there were still limited data on its safety in clinical practice. Now, this population based cohort study adds reassuring real life data: in more than 200 000 patients treated for depression or anxiety there was no evidence that those using venlafaxine had a higher risk of acute ventricular tachyarrhythmia or sudden cardiac death in the community than those taking fluoxetine, citalopram, or dosulepin (doi:10.1136/bmj.c249).

Slideshow: How to get your research published
Three of the *BMJ*'s senior research editors give insiders' tips on how to focus your research question, write a great paper, and maximise your chances of getting it published (www.bmj.com/video/how-to-write.dtl)

Video: Why submit your research to the *BMJ*?
We've produced a short video to help you find out about getting research published in the *BMJ*. It includes interviews with published authors and clips from some of the short films we often commission to accompany important research articles. View it at bmj.com/video/research.dtl or on the *BMJ*'s YouTube channel, youtube.com/bmjmedia. We can also supply this video in DVD format if you would like to include it in a presentation but do not have a suitable internet connection—email jhayes@bmj.com.

Comparison of two etanercept regimens for treatment of psoriasis and psoriatic arthritis: PRESTA randomised double blind multicentre trial

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EDITORIAL by Gladman

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bmj.com archive
Clinical review. Managing comorbid disease in patients with psoriasis (2010;340:b5666)

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STUDY QUESTION In patients with active psoriasis and psoriatic arthritis, will etanercept 50 mg twice weekly be more effective than 50 mg once weekly in clearing skin symptoms?

SUMMARY ANSWER In patients with both psoriasis and psoriatic arthritis, initial treatment of the psoriasis with etanercept 50 mg twice weekly may allow for more rapid clearance of skin lesions than 50 mg once weekly.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Etanercept is approved for treatment of moderate to severe plaque psoriasis and active psoriatic arthritis on the basis of its efficacy in treating both skin and joint symptoms. Treatment with etanercept 50 mg twice weekly may be superior in treating the skin symptoms, but a regimen of 50 mg weekly seems to be appropriate for treatment of joint and tendon rheumatic symptoms of psoriatic arthritis.

Design

This was a randomised, double blind study. Although the second phase of the study was open label, investigators and participants remained blinded to the participant's regimen during the entire study.

Participants and setting

In 98 outpatient facilities in Europe, Latin America, and the Asia Pacific region, 752 patients with both psoriasis (evaluated by dermatologists) and psoriatic arthritis (evaluated by rheumatologists) were treated with either etanercept 50 mg twice weekly (n=379) or 50 mg once weekly (n=373) for 12 weeks by subcutaneous injection. All participants were then treated with open label etanercept 50 mg once weekly for 12 additional weeks. Ninety-two per cent (695/752) of participants completed the study.

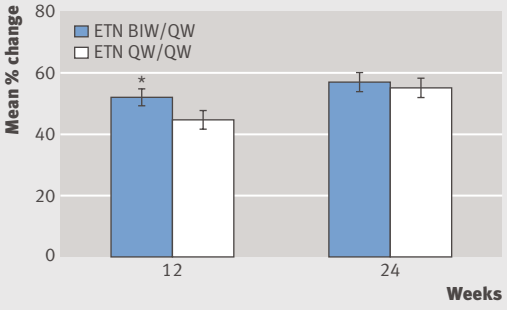
Primary outcome(s)

The primary efficacy end point was the proportion of participants who achieved "clear" or "almost clear" on the physician's global assessment of psoriasis at week 12.

Main results and the role of chance

At week 12, 46% (176/379) of participants receiving etanercept 50 mg twice weekly achieved a physician's global assessment of psoriasis of "clear" or "almost clear" compared with 32% (119/373) in the group treated with 50 mg weekly (P<0.001). An equally high percentage of participants in both groups achieved significant psoriatic arthritis response criteria (77% (284/371) in the twice weekly/once weekly group versus 76% (282/371) in the once weekly/once weekly group). Participants treated with 50 mg twice weekly/once weekly had greater mean reductions from baseline in the psoriasis area and severity index compared with those who received 50 once weekly/once weekly at week 12 (71% *v* 62%, P<0.001), with less of a difference at week 24 (78% *v* 74%, P=0.110). Joint and tendon disease manifestations improved from baseline to a similar extent in both groups; most of the improvement occurred by week 12.

PHYSICIAN'S GLOBAL ASSESSMENT OF PSORIASIS



Mean percentage improvement from baseline at 12 weeks (*P<0.001) and 24 weeks; BIW=twice weekly; QW=once weekly

Harms

No new safety signals were seen in either etanercept treatment group. A total of 26/752 (3%) participants reported serious adverse events, including infections (5/752, 0.7%). Four malignancies were reported: two skin carcinomas (one basal cell, one squamous cell) and one breast carcinoma in the twice weekly/once weekly group, and one skin carcinoma (basal cell) in the once weekly/once weekly group. No participant died during the study.

Study funding/potential competing interests

Wyeth Research, which was acquired by Pfizer in October 2009, sponsored this clinical trial and was responsible for the collection and analysis of data. WS, J-PO, BK, and OB have affiliations with several pharmaceutical companies (Abbott, Bristol-Myers Squibb, Centocor, Chugai, Galderma Laboratories, Janssen-Cilag, Laboratorios Pierre-Fabre, Leo Pharma, MedPharma, Merck-Serono, Roche, Schering-Plough, and Wyeth). DR, RDP, JE, CTM, and BF are all employees of Pfizer.

Trial registration number

Clinical trials NCT00245960.

Effect of a collector bag for measurement of postpartum blood loss after vaginal delivery: cluster randomised trial in 13 European countries

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EDITORIAL by Prata and Gerdts

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STUDY QUESTION How effective is the systematic use of a transparent collector bag to measure postpartum blood loss after vaginal delivery in reducing the incidence of severe postpartum haemorrhage?

SUMMARY ANSWER Severe postpartum haemorrhage was not reduced by use of a collector bag after vaginal delivery compared with visual estimation of postpartum blood loss.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS
A collector bag has been proposed as a useful tool to increase the accuracy of measurement of postpartum blood loss and reduce delays in the initial care of women, but has not been tested despite being used by many maternity units in Europe. The incidence of severe postpartum haemorrhage was not reduced by routine use of a collector bag to objectively measure blood loss after vaginal delivery, without specific guideline on threshold and action.

Design
The study was a cluster randomised controlled trial with the maternity unit as the unit of randomisation. The random allocation was produced centrally with stratification by country and size of maternity unit. The maternity units were randomly allocated to systematic use of a collector bag after vaginal delivery (intervention group) or no use of the bag (control group).

Participants and setting
We studied 78 maternity units in 13 European countries. Maternity units were eligible if they had more than 200 vaginal deliveries annually and no previous policy for routine use of collector bags. The 78 units agreed to take part before being allocated to intervention or control group. The trial was implemented between January 2006 and May 2007, depending on country.

Primary outcome(s)
The primary outcome was the incidence of severe postpartum haemorrhage after vaginal deliveries, defined as a composite of all women who experienced one or more of blood transfusion, intravenous plasma expansion, arterial embolisation, surgical procedure, admission to an intensive care unit, treatment with recombinant factor VII, and death. Each participating centre was asked to collect data for four months from all women who had a vaginal delivery: one month before randomisation (baseline period) and three months after randomisation (trial period).

Main results and the role of chance
Severe postpartum haemorrhage occurred in 189 of 11 037 vaginal deliveries (1.71%) in the intervention group compared with 295 of 14 344 in the control group (2.06%). The difference was not statistically significant. Sensitivity analyses were done to test the robustness of this result, excluding units that deviated from the protocol and by country and baseline rate of severe postpartum haemorrhage. The results of these analyses were similar.

Harms
No harms occurred during the study.

Bias, confounding, and other reasons for caution
A lack of compliance with the intervention is possible but is unlikely to explain the results because of the persistent absence of a difference between the groups when the analysis was restricted to those units that used the bag in a high proportion of deliveries. Participation in the study may indicate a particular interest in the management of postpartum haemorrhage so that existing management had little room for improvement.

Generalisability to other populations
The cluster randomised design, the large number of clusters, and their diversity provide good external validity to this trial, at least for high income countries.

Study funding/potential competing interests
The study was funded by the European Union under framework 5 (contract QLG4-CT-2001-01352). We have no competing interests.

Trial registration number
Current Controlled Trials ISRCTN66197422.

MAIN OUTCOMES IN WOMEN ALLOCATED TO COLLECTOR BAG OR NO COLLECTOR BAG (CONTROL GROUP) TO MEASURE BLOOD LOSS AFTER VAGINAL DELIVERY

Outcomes	Intervention (n=11 037)	Control (n=14 344)	Adjusted odds ratio (95% CI)*	P value
Severe postpartum haemorrhage†	189 (1.71)	295 (2.06)	0.82 (0.26 to 2.53)	0.7
Blood transfusion	86 (0.78)	135 (0.94)	0.80 (0.33 to 1.90)	0.6
Plasma expander	127 (1.15)	222 (1.55)	0.95 (0.62 to 1.46)	1.0
Surgical procedure or embolisation	50 (0.45)	76 (0.53)	0.78 (0.18 to 3.40)	0.7
Prostaglandins	501 (4.54)	766 (5.34)	0.85 (0.40 to 1.80)	0.7

*Adjusted for clustering (maternity unit), maternal age, prophylactic uterotonics used in third stage, mode of delivery, and birth weight.
†Primary outcome, defined by one of following: maternal death, transfusion, plasma expansion, surgery or embolisation, admission to intensive care unit, or treatment with recombinant factor VII.

Social variations in access to hospital care for patients with colorectal, breast, and lung cancer between 1999 and 2006: retrospective analysis of hospital episode statistics

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STUDY QUESTION Does type of hospital admission (emergency compared with elective) and surgical procedure for colorectal, breast, and lung cancer vary by socioeconomic circumstances, age, sex, and year of admission?

SUMMARY ANSWER Despite the implementation of the NHS Cancer Plan, social factors still strongly influence access to and the provision of care in England.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

The NHS Cancer Plan aimed to improve outcomes overall and to reduce health inequalities. In this study, living in deprived areas and being male were associated with lower likelihood of receiving preferred surgical procedures for cancers within the National Health Service (NHS); older people were more likely to receive the preferred surgical procedure for rectal cancer but less likely to receive breast conserving surgery and lung cancer resection.

Participants and setting

564 821 patients aged 50 and above admitted to NHS hospitals in England between 1 April 1999 and 31 March 2006 with a diagnosis of colorectal, lung, and breast cancer.

Design

Repeated cross sectional study with data on individual patients from the hospital episode statistics (HES) dataset.

Primary outcomes

Proportion of patients admitted as emergencies and receiving recommended surgical treatment.

Main results and the role of chance

Patients from deprived areas, older people, and women were more likely to be admitted as emergencies. For example, the adjusted odds ratio for patients with breast cancer in the least compared with most deprived fifth of deprivation was 0.63 (95% confidence interval 0.60 to 0.66) and that for patients with lung cancer aged 80-89 compared with those aged 50-59 was 3.13 (2.93 to 3.34). There were some improvements in disparities between age groups but not for deprived patients over time. Patients from deprived areas were less likely to receive preferred procedures for rectal, breast, and lung cancer. These findings did not improve with time. For example, over 67% of patients in the most deprived fifth of deprivation had anterior resection for rectal cancer compared with 76% of patients in the least deprived fifth (1.34, 1.22 to 1.47); and 54% of patients in the most deprived fifth had breast conserving surgery compared with 64% of patients in the least deprived fifth (1.21, 1.16 to 1.26). Men were less likely to undergo anterior resection and lung cancer resection and older people were less likely to receive breast conserving surgery and lung cancer resection. The adjusted odds ratio for patients with lung cancer aged 80-89 compared with those aged 50-59 was 0.52 (0.46 to 0.59).

EFFECT OF SOCIAL FACTORS AND ADMISSION PERIOD ON EMERGENCY ADMISSION FOR PATIENTS WITH COLORECTAL CANCER

Variable	Total	Odds ratio (95% CI)	P value
Men	102 772	1	<0.001
Women	84 205	1.15 (1.12 to 1.17)	
Fifth of index of multiple deprivation:			
1 (most deprived)	34 404	1	<0.001
2	36 470	0.83 (0.80 to 0.86)	
3	39 309	0.75 (0.72 to 0.77)	
4	39 753	0.68 (0.65 to 0.70)	
5 (least deprived)	37 041	0.66 (0.64 to 0.68)	
Age group (years):			
50-59	25 002	1	<0.001
60-69	47 149	1.05 (0.98 to 1.11)	
70-79	67 625	1.41 (1.33 to 1.49)	
80-89	41 299	2.53 (2.37 to 2.69)	
≥90	5902	5.85 (5.23 to 6.55)	
Admission period:			
Per year	—	1.00 (0.98 to 1.01)	0.595
Interaction between age group and admission period:			
50-59 x period	—	1	0.010
60-69 x period	—	1.00 (0.98 to 1.01)	
70-79 x period	—	0.98 (0.96 to 1.00)	
80-89 x period	—	0.98 (0.96 to 1.00)	
≥90 x period	—	0.99 (0.96 to 1.02)	

Bias, confounding, and other reasons for caution

Routinely collected data have limited completeness and accuracy of data coding but there is no reason to assume that these limitations should be correlated with deprivation, sex, or age of patients. We used the index of multiple deprivation (IMD), an established method of assigning socioeconomic characteristics based on area of residence that assumes individuals conform to the socioeconomic profile of their area. Data are unavailable on tumour stage, case mix, and preference of patients, which are potential confounders.

Generalisability to other populations

These findings apply to patients admitted to NHS hospitals in England with colorectal, breast, or lung cancer.

Study funding/potential competing interests

The research was funded in part by the Legal and General Group and the Institute of Actuaries. The authors' work was independent of the funders.

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Myocardial infarction and stroke associated with diuretic based two drug antihypertensive regimens: population based case-control study

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STUDY QUESTION What is the association of several commonly used two drug antihypertensive treatment regimens with myocardial infarction and stroke incidence?

SUMMARY ANSWER In relatively low risk patients with hypertension, the use of diuretics plus calcium channel blockers was associated with a higher risk of myocardial infarction than the use of diuretics plus β blockers or diuretics plus angiotensin converting enzyme inhibitors or angiotensin receptor blockers.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Current US guidelines recommend low dose diuretics as first line pharmacological treatment for uncomplicated hypertension; however, many patients with hypertension require a second medication to control blood pressure. In our study, the use of diuretics plus calcium channel blockers was associated with a higher risk of myocardial infarction than the other commonly used two drug combinations.

Participants and setting

Participants were identified from patients enrolled in the Group Health Cooperative, a large health maintenance organisation in Washington state. Cases were aged 30-79 years old, had pharmacologically treated hypertension, and were diagnosed with an incident myocardial infarction or stroke between 1989 and 2005. Controls were receiving pharmacological treatment for hypertension but had not experienced a myocardial infarction or stroke. Controls were frequency matched to myocardial infarction cases by age, sex, and calendar year of the cases' diagnoses at a ratio of between 2:1 and 3:1.

Design, size, and duration

We excluded individuals with heart failure or evidence of coronary heart disease, diabetes, or chronic kidney disease. We included only patients who were currently treated with one of the three common two drug combinations: diuretics plus β blockers; diuretics plus calcium channel blockers; and diuretics plus angiotensin converting enzyme inhibitors or angiotensin receptor blockers. The risk of myocardial infarction and stroke among these three groups was compared using multiple logistic regression models adjusted for the matching variables, smoking status, and total cholesterol levels.

Primary outcome(s), risks, and exposures

The primary outcomes were fatal and non fatal myocardial infarction and stroke.

Main results and the role of chance

We identified 1305 patients who used two drug antihypertensive treatment regimens: 211 patients who had a first myocardial infarction, 142 who had a first stroke, and 952 controls. Of these 1305 individuals, 629 were treated with diuretics plus β blockers, 273 with diuretics plus calcium channel blockers, and 403 with diuretics plus angiotensin converting enzyme inhibitors or angiotensin receptor blockers. Compared with treatment with diuretics plus β blockers, treatment with diuretics plus calcium channel blockers was associated with an increased risk of myocardial infarction (adjusted odds ratio (OR) 1.98, 95% confidence interval 1.37 to 2.87, but not stroke (OR 1.02, 95% CI 0.63 to 1.64). Treatment with diuretics plus angiotensin converting enzyme inhibitors or angiotensin receptor blockers might be associated with a lower risk of myocardial infarction and stroke than treatment with diuretics plus β blockers (myocardial infarction: OR 0.76, 95% CI 0.52 to 1.11; stroke: OR 0.71, 95% CI 0.46 to 1.10); however, these associations could well have been owing to chance.

Bias, confounding, and other reasons for caution

Patients were not assigned at random to receive the antihypertensive therapy options. The blood pressure measurements used were obtained as part of routine care and are subject to measurement error. There may have been residual confounding by indication owing to the presence of other comorbid conditions.

Generalisability to other populations

The participants in our study were almost 90% white, so our conclusions might be limited in their application to other populations.

Study funding/potential competing interests

This research was supported in part by grants from the National Heart, Lung, and Blood Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute or the National Institutes of Health.

RELATIVE RISK OF MYOCARDIAL INFARCTION AND STROKE IN PATIENTS USING VARIOUS TWO DRUG ANTIHYPERTENSIVE REGIMENS THAT INCLUDED A DIURETIC

	Myocardial infarction (OR (95% CI))	Stroke (OR (95% CI))
Diuretics and β blockers	Ref	Ref
Diuretics and calcium channel blockers	1.98 (1.37 to 2.87)	1.02 (0.63 to 1.64)
Diuretics and angiotensin converting enzyme inhibitors or angiotensin receptor blockers	0.76 (0.52 to 1.11)	0.71 (0.46 to 1.10)

Adjusted for age, sex, index year, smoking, and total cholesterol.