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Acupuncture treatment for pain: systematic review of randomised clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups

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EDITORIAL by White and Cummings

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ABSTRACT

Objectives To study the analgesic effect of acupuncture and placebo acupuncture and to explore whether the type of the placebo acupuncture is associated with the estimated effect of acupuncture.

Design Systematic review and meta-analysis of three armed randomised clinical trials.

Data sources Cochrane Library, Medline, Embase, Biological Abstracts, and PsycLIT.

Data extraction and analysis Standardised mean differences from each trial were used to estimate the effect of acupuncture and placebo acupuncture. The different types of placebo acupuncture were ranked from 1 to 5 according to assessment of the possibility of a physiological effect, and this ranking was meta-regressed with the effect of acupuncture.

Data synthesis Thirteen trials (3025 patients) involving a variety of pain conditions were eligible. The allocation of patients was adequately concealed in eight trials. The clinicians managing the acupuncture and placebo acupuncture treatments were not blinded in any of the trials. One clearly outlying trial (70 patients) was excluded. A small difference was found between acupuncture and placebo acupuncture: standardised mean difference −0.17 (95% confidence interval −0.26 to −0.08), corresponding to 4 mm (2 mm to 6 mm) on a 100 mm visual analogue scale. No statistically significant heterogeneity was present (P=0.10, I^2=36%). A moderate difference was found between placebo acupuncture and no acupuncture: standardised mean difference −0.42 (−0.60 to −0.23). However, considerable heterogeneity (P<0.001, I^2=66%) was also found, as large trials reported both small and large effects of placebo. No association was detected between the type of placebo acupuncture and the effect of acupuncture (P=0.60).

Conclusions A small analgesic effect of acupuncture was found, which seems to lack clinical relevance and cannot be clearly distinguished from bias. Whether needling at acupuncture points, or at any site, reduces pain independently of the psychological impact of the treatment ritual is unclear.

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INTRODUCTION

Acupuncture is commonly used for the treatment of pain. Studies indicate that penetration of a needle through the skin, whether at an acupuncture point or not, has physiological effects.[1-3] The "gate control theory" and the release of endogenous opioids have been suggested as explanations for the apparent analgesic effect of acupuncture.[4-6]

In 2005 two large, high quality trials in patients with headache found little difference between the effects of acupuncture and placebo acupuncture but a substantial difference between placebo acupuncture and no acupuncture.[w1 w2] This result differed from that of a large systematic review comparing all placebo interventions with no treatment that found only a small to moderate analgesic effect of placebo, which could not be clearly distinguished from reporting bias.[7-9] We systematically reviewed trials of acupuncture for pain that had two control groups consisting of placebo acupuncture and no acupuncture. Our objectives were to study the analgesic effect of acupuncture and placebo acupuncture and to explore whether the type of placebo acupuncture is associated with the estimated effect of acupuncture.

METHODS

Search strategy—The literature searches have been described elsewhere.[9] We searched the Cochrane Library, Medline, Embase, Biological Abstracts, and PsycLIT. The search included all trials published before 1 January 2008.

Inclusion criteria—We included all trials that labelled the intervention "acupuncture." We excluded trials that used transcutaneous electrical nerve stimulation and manual acupressure. We accepted the placebo interventions used in the trials, such as the use of non-penetrating needles. We excluded trials in which the no acupuncture group received an intended basic care that differed from that provided to the acupuncture and placebo acupuncture groups. We included trials if pain had been estimated by the patients on a visual analogue scale or ranking scale.

Assessment of risk of bias—We noted whether the allocation of patients in each trial was adequately concealed, whether patients had been blinded, and whether dropout was below 15%. We considered such trials to have low risk of bias.

Data analysis—For each trial, we calculated the standardised mean difference. We pooled the standardised mean differences from the trials by using meta-analysis, comparing the effect of acupuncture with that of placebo acupuncture and the effect of placebo acupuncture with that of no acupuncture. In a preplanned sensitivity analysis, we used the authors' primary outcome.[10 11] In unplanned sensitivity analyses, we studied the impact of the methodological quality of the trials and of the type of acupuncture. We assumed that trials in which experienced acupuncturists were allowed to use individually chosen acupuncture points could differ in effect from other trials. We studied whether the difference between acupuncture and placebo acupuncture was related to the type of placebo, by using meta-regression.

RESULTS

The search included 234 trials eligible for our Cochrane review of placebo interventions (in progress).[7-9] We identified 20 potentially eligible trials for this review. We excluded seven trials because they studied transcutaneous electrical nerve stimulation or manual acupressure. We included 13 trials of acupuncture for pain (3025 patients) (see bmj.com).[w1-w13]

The patients' type of painful conditions varied, and duration of treatment ranged from one day to 12 weeks. Eight trials had concealed the allocation of patients.[w1 w2 w7-w11 w13] No trials reported blinding of the clinicians, whereas blinding of the patients was reported in 10 trials.[w1-w3 w6-w12] In five trials the acupuncture treatment involved sessions with acupuncturists who could choose additional acupuncture points.[w1 w2 w4 w7 w11] In two trials the placebo procedures consisted of non-penetrative needling.[w4 w9] In 11 trials the placebo procedure penetrated the skin.

In all trials, all patients were provided with standard concomitant care, typically consisting of analgesics (n=13) and physiotherapy (n=5). The patients in the no acupuncture groups used more concomitant treatment than did the patients in the placebo acupuncture and acupuncture groups.

Acupuncture versus placebo acupuncture

Substantial heterogeneity was present in the comparison between acupuncture and placebo acupuncture (P<0.001, I^2=66%). A trial by Kotani et al was a clear outlier.[w13] After we excluded this trial, heterogeneity was substantially reduced (P=0.10, I^2=36%). We found a statistically significant difference between acupuncture and placebo acupuncture (P<0.001)—pooled standardised mean difference −0.17 (−0.26 to −0.08) (fig 1).

Placebo acupuncture versus no acupuncture

Substantial heterogeneity existed in the comparison between placebo acupuncture and no acupuncture (P<0.001, I^2=66%) (fig 2). We found a statistically significant difference between placebo acupuncture and no acupuncture (P<0.001)—pooled standardised mean difference −0.42 (−0.60 to −0.23).

Secondary analyses

In two trials,[w3 w4] we could not define the authors' primary outcome, so the sensitivity analysis included 10 trials. Substantial heterogeneity existed in the comparison between acupuncture and placebo acupuncture (P<0.001, I^2=73%). The pooled standardised mean difference was −0.26 (−0.46 to −0.07) (P< 0.001). For the comparison of placebo acupuncture with no acupuncture, substantial heterogeneity was also present (P<0.001, I^2=59%). The pooled standardised mean difference was −0.48 (−0.65 to −0.30) (P=0.009).

Trial	Acupuncture Mean	Acupuncture SD	Acupuncture No	Placebo acupuncture Mean	Placebo acupuncture SD	Placebo acupuncture No	Weight (%)	Standardised mean difference (95% CI)
Brinkhaus[w11]	34.5	28.5	140	43.7	29.8	70	9.3	-0.32 (-0.61 to -0.03)
Fanti[w5]	2.0	1.3	10	2.8	1.6	10	1.0	-0.53 (-1.42 to 0.37)
Foster[w9]	6.38	4.1	113	5.98	4.3	115	11.5	0.09 (-0.16 to 0.35)
Kotani[w13]	2.5	2.3	23	5.6	1.2	23	0	-1.66 (-2.34 to -0.98)
Leibing[w12]	-2.7	2.2	35	-2.1	2.2	40	3.7	-0.27 (-0.73 to 0.19)
Lin[w3]	30.6	23.5	50	34.5	23.5	25	3.4	-0.16 (-0.65 to 0.32)
Linde[w2]	3.7	2.0	138	3.6	2.1	78	10.0	0.05 (-0.23 to 0.33)
Melchart[w1]	2.9	1.6	119	3.1	1.7	58	7.9	-0.12 (-0.44 to 0.19)
Molsberger[w10]	26.0	21.0	58	36.0	19.0	58	5.7	-0.50 (-0.87 to -0.13)
Scharf[w8]	3.0	2.3	315	3.3	2.4	358	33.7	-0.13 (-0.28 to 0.02)
Sprott[w4]	6.9	5.6	10	7.9	5.7	10	1.0	-0.17 (-1.05 to 0.71)
Wang[w6]	44.5	24.5	50	48.0	22.0	25	3.4	-0.15 (-0.63 to 0.33)
Witt[w7]	24.4	16.9	145	33.2	17.1	73	9.5	-0.52 (-0.80 to -0.23)
Total (95% CI)			1206			943	100.0	-0.17 (-0.26 to -0.08)

Test for heterogeneity: χ^2=17.23, df=11, P=0.10, I^2=36%
Test for overall effect: z=3.80, P<0.001

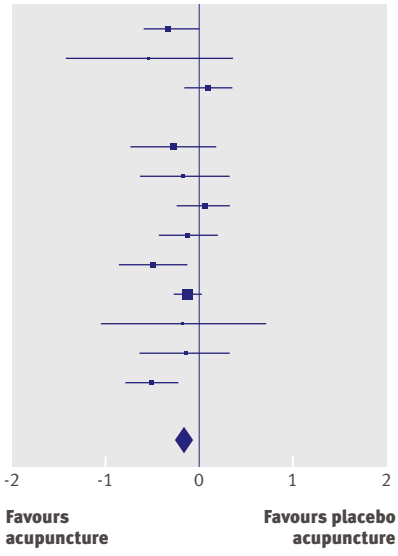

Fig 1 | Meta-analysis of acupuncture versus placebo acupuncture

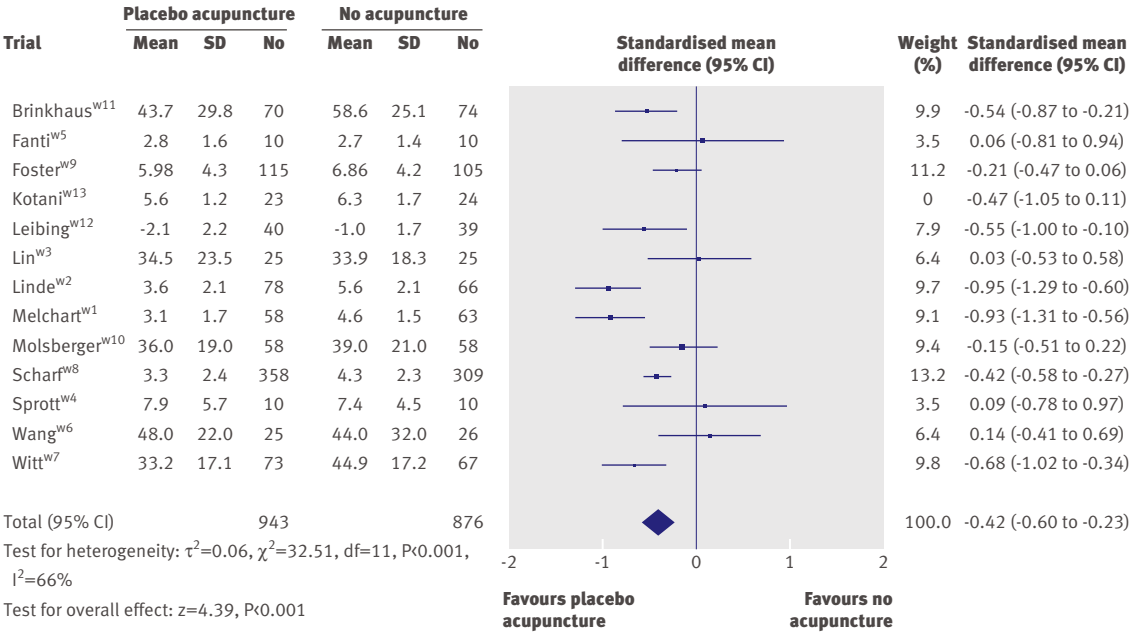

Fig 2 | Meta-analysis of placebo acupuncture versus no acupuncture

When we restricted the analysis to the seven trials with least risk of bias, substantial heterogeneity existed in the comparison between acupuncture and placebo acupuncture (P=0.01, I^2=63%). The pooled standardised mean difference was −0.19 (−0.35 to −0.02) (P=0.03). Heterogeneity was also present in the similar comparison between placebo acupuncture and no acupuncture (P=0.001, I^2=72%). The pooled standardised mean difference was −0.54 (−0.75 to −0.33) (P<0.001).

When we restricted the analysis to the five trials that involved acupuncture treatment with acupuncturists who could choose additional acupuncture points, we also found heterogeneity in the comparison between acupuncture and placebo acupuncture (P=0.07, I^2=53%). The pooled standardised mean difference was −0.23 (−0.45 to −0.01) (P=0.04). Heterogeneity also existed in the similar comparison between placebo acupuncture and no acupuncture (P=0.09, I^2=49%). The pooled standardised mean difference was −0.71 (−0.96 to −0.45) (P<0.001).

Type of placebo acupuncture

A meta-regression of the 12 trials found no statistically significant relation between the type of placebo intervention and the effect of acupuncture (P=0.60).

DISCUSSION

We found a small difference between acupuncture and placebo acupuncture and a moderate difference between placebo acupuncture and no acupuncture. The effect of placebo acupuncture varied considerably.

Strengths and weaknesses

The review is fairly large, includes several trials of high methodological quality, and covers a range of common painful conditions. Our main results were similar to those found in the subgroups of trials with low risk of bias, in trials using experienced acupuncturists choosing acupuncture points at their discretion, and when we analysed the primary outcomes of the trials.

All included trials provided additional standard care to the patients, and we excluded trials with different intended standard care for the no acupuncture group compared with the acupuncture and placebo acupuncture groups.[12-14] Thus, our findings are limited to the additive effect of acupuncture and placebo acupuncture. The standard care was unlikely to have resulted in a "ceiling effect," because we found an effect of placebo acupuncture beyond that of standard care.

Our meta-regression analysis found no association between type of placebo and effect of acupuncture. The analysis was based on a subjective ranking of the possibility of a physiological effect of placebo. However, our findings are similar to that of a randomised trial reporting no difference in analgesic effect between three types of placebo acupuncture.[15]

We found a tendency for an increase in the use of analgesic drugs in the no acupuncture groups compared with the placebo and acupuncture groups. This would tend to underestimate the effect of placebo acupuncture.

Other studies

Our finding of limited analgesic effects of acupuncture corresponds with the seven Cochrane reviews on acupuncture for various types of pain, which all concluded that no clear evidence existed of an analgesic effect of acupuncture.[16-22] Most stressed the methodological shortcomings of the included trials.

Our finding of a moderate difference between placebo acupuncture and no acupuncture agrees fairly well with our previous review of the effect of placebo in general.[7-9] We saw a tendency for larger effects when

WHAT IS ALREADY KNOWN ON THIS TOPIC

Acupuncture is commonly used for the treatment of pain

Acupuncture involves close patient-provider interaction with suggestive components

Blinding patients and especially treatment providers in acupuncture trials is a challenge

WHAT THIS STUDY ADDS

The analgesic effect of acupuncture is small and cannot be distinguished from bias resulting from incomplete blinding

The analgesic effect of placebo acupuncture is moderate but very variable as some large trials report substantial effects

The effect of acupuncture seems to be unrelated to the type of placebo acupuncture used as control

the placebo intervention was procedural and not merely a placebo tablet.

Meaning of our review

On the basis of the trials that used visual analogue scales, the effect of acupuncture corresponds to a reduction of 4 (2 to 6) mm on a 100 mm scale. The effect of placebo acupuncture corresponds to a reduction of 10 (6 to 15) mm. A consensus report characterised a 10 mm reduction on a 100 mm visual analogue scale as representing a "minimal" change.[23] Thus, the apparent analgesic effect of acupuncture seems to be below a clinically relevant improvement.

Considerable heterogeneity existed when we compared placebo acupuncture with no acupuncture but not when we compared acupuncture with placebo acupuncture. Lack of blinding is inherent in the no acupuncture groups.[24] Variations in reporting bias, in use of concomitant treatment, and in the patient-provider interaction could explain some of the observed variation in the effect of placebo. Insufficient blinding is also a problem for the comparison between acupuncture and placebo acupuncture. The incomplete blinding of the patients, and the interaction between the unblinded acupuncturist and the patients, could explain the observed small effect.

Unanswered questions and future research

Our findings question both the traditional foundation of acupuncture and the prevailing hypothesis that acupuncture has an effect on pain in general. Important heterogeneity in the effect of placebo acupuncture remains unexplained and calls for further studies on the underlying mechanisms of the effects of placebo acupuncture.

We suggest that future trials on acupuncture for pain focus on two strategies. Firstly, reducing bias by ensuring blinding when possible. Secondly, separating the effects involved: the physiological effect of needling at acupuncture sites and the psychological effect of the treatment ritual or patient-provider interaction.[25]

Conclusion

We found a small analgesic effect of acupuncture that seems to lack clinical relevance and cannot be clearly distinguished from bias. Whether needling at acupuncture points, or at any site, reduces pain independently of the psychological impact of the treatment ritual is unclear.

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Effectiveness of acute geriatric units on functional decline, living at home, and case fatality among older patients admitted to hospital for acute medical disorders: meta-analysis

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ABSTRACT

Objective To assess the effectiveness of acute geriatric units compared with conventional care units in adults aged 65 or more admitted to hospital for acute medical disorders.

Design Systematic review and meta-analysis.

Data sources Medline, Embase, and the Cochrane Library up to 31 August 2008, and references from published literature.

Review methods Randomised trials, non-randomised trials, and case-control studies were included. Exclusions were studies based on administrative databases, those that assessed care for a single disorder, those that evaluated acute and subacute care units, and those in which patients were admitted to the acute geriatric unit after three or more days of being admitted to hospital. Two investigators independently selected the studies and extracted the data.

Results 11 studies were included of which five were randomised trials, four non-randomised trials, and two case-control studies. The randomised trials showed that compared with older people admitted to conventional care units those admitted to acute geriatric units had a lower risk of functional decline at discharge (combined odds ratio 0.82, 95% confidence interval 0.68 to 0.99) and were more likely to live at home after discharge (1.30, 1.11 to 1.52), with no differences in case fatality (0.83, 0.60 to 1.14). The global analysis of all studies, including non-randomised trials, showed similar results.

Conclusions Care of people aged 65 or more with acute medical disorders in acute geriatric units produces a functional benefit compared with conventional hospital care, and increases the likelihood of living at home after discharge.

INTRODUCTION

Several interventions have been proposed to improve the effectiveness of hospital care for older people (≥65 years) with acute medical disorders. Assessment of patients by a multidisciplinary team has not, however, shown benefits for case fatality, functional decline, or living situation at discharge.[1 2] Hospital at home care for elderly medical patients reduces hospital stay but increases overall length of care.[3] Another type of intervention is that provided by multidisciplinary teams in acute geriatric units.[4]

We reviewed the effect of acute geriatric units compared with conventional hospital care on functional decline, living at home after discharge, case fatality, and hospital stay in older people with acute medical disorders.

METHODS

Our review included randomised trials, non-randomised trials, and case-control studies that compared outcome of care in acute geriatric units with that in conventional hospital units in patients aged 65 years or more with acute medical disorders. Acute geriatric units were defined as hospital units with their own location and structure and run by a multidisciplinary team with responsibility for the care of elderly people with acute medical disorders that do not require treatment in other specialised units.

The primary outcomes were functional decline, living at home, and case fatality at discharge and three months. We considered functional decline to be loss of independence in one or more basic activities of daily living compared with before admission,[4 5] using the Katz index and the Barthel index; activities were classified as independent or dependent according to the need for assistance.[5 w3 w6 w10] Secondary outcomes were hospital stay during the index admission and the cost of the index admission.

We searched Medline, Embase, and the Cochrane Library up to 31 August 2008 and reference lists of relevant articles. Authors were contacted for missing information. JJB and FS independently extracted and compared data. For randomised trials we extracted information on allocation concealment, the proportion of patients lost to follow-up, intention to treat analysis, and whether assessment of outcomes was done blinded to intervention. For non-randomised trials we recorded only losses to follow-up and outcome assessment.

We summarised the overall quality of randomised trials with the Jadad scale[6] and the quality of all studies with the Van Tulder scale.[7]

Data synthesis

For dichotomous outcomes we give the results as combined odds ratios with 95% confidence intervals and for quantitative outcomes as differences in means with standard errors. We used fixed effects methods to combine outcomes across studies, except when important heterogeneity was observed. Heterogeneity was quantified with the I^2 statistic, with I^2 more than 30%

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considered as important. We used random effects methods when results had to be combined.[8] Statistical analyses were carried out using RevMan 4.3 (Cochrane Collaboration).

When appropriate we approximated standard deviations from the standard error and 95% confidence intervals.[9] For two centres participating in one study,[w1] we considered them as independent for the analysis of hospital stay and its cost.

RESULTS

Twelve articles totalling 11 studies met the inclusion criteria (see bmj.com). Seven were from the United States, the remainder from Australia, Canada, Sweden, and Peru. Authors of five studies were contacted for data,[w3 w5 w6 w9 w10] but for only one[w6] was unpublished data on patients' living at home after discharge and at three months used.

Five studies were randomised trials,[w1-w6] four non-randomised trials,[w7-w10] and two retrospective case-control studies (see bmj.com).[w11 w12] The quality of the studies was heterogeneous, especially for non-randomised trials. Three of the randomised trials used sealed envelopes for allocation concealment.[w3 w5 w6] Only one did an intention to treat analysis at discharge, but not at follow-up.[w6] Of the four non-randomised trials, three used informal procedures for allocation based on bed availability.[w7 w9 w10]

Criteria for patient selection were age plus a medical condition not requiring admission to specialty units. Five studies included patients aged 70 or more,[w2 w7] three aged 65 or more,[w1 w10 w11] and one aged 75 or more.[w9] One study selected patients aged 75 or more with at least one geriatric condition.[w8] One study selected patients aged 65 or more admitted for heart failure, pneumonia, or urinary tract infection.[w12] Two studies excluded older people (≥70 years) living in nursing homes,[w2 w6] and one[w11] included only those living in nursing homes.

In four of the five randomised trials all the patients came from emergency services,[w2-w6] whereas in three non-randomised studies more than 62% came from emergency services.[w7 w9 w10] Three studies did not provide this information.[w8 w11 w12]

The intervention units functioned in similar ways, generally having four characteristics that distinguished them from conventional units: comprehensive assessment of patients, use of standardised instruments for measurements, weekly multidisciplinary meetings, and early planning of discharge. The composition of the basic multidisciplinary team typically included at least one geriatrician, nurses trained in geriatrics, a social worker, and therapists.

The follow-up period varied. All the randomised studies except one[w1] provided follow-up data at three months, at a minimum. Five studies reported on readmissions, two at three months[w3 w5] and three at one month.[w6 w9 w11]

Functional decline

Only three studies presented results on functional decline at discharge, two of which were randomised trials (see bmj.com). In these two studies, the patients in acute geriatric units showed a lower risk of functional decline than those in conventional units (combined odds ratio 0.82, 95% confidence interval 0.68 to 0.99). After the inclusion of a non-randomised study, results were similar (0.78, 0.65 to 0.94) but showed greater heterogeneity (I^2=55.7%) because of the large reduction in functional decline in the acute geriatric unit in that study (0.35, 0.17 to 0.76).[w10]

Only one study[w6] provided data on functional decline at three months after discharge, with no differences between the groups. Another three randomised studies provided data that could not be analysed but reported an absence of differences in functional decline at three months.[w2 w3 w5]

Living at home

In randomised studies, patients cared for in acute geriatric units were more likely to return home after discharge (1.30, 1.11 to 1.52), a benefit that was marginally maintained three months after discharge (see bmj.com). Results at discharge still held when analyses were repeated including non-randomised studies (1.28, 1.12 to 1.47).

Acute geriatric units and conventional care units showed no differences in frequency of admission to a nursing home at discharge (0.76, 0.51 to 1.28) or three months (0.90, 0.74 to 1.14).

Case fatality

No significant differences were found in case fatality between acute geriatric units and conventional care units either in hospital or three months after discharge (see bmj.com).

Length of hospital stay and cost of admission

All the included studies reported on length of hospital stay, but three did not report dispersion measures.[w1 w3 w11] The length of stay in the acute geriatric units was fewer than 12 days; fewer than nine in studies published from 1995. In nine of the 11 studies a trend was towards a reduced length of stay, of 6-39%,[w1 w3 w5 w6 w8-w12] but was heterogeneous among studies (I^2 was 49.4% in randomised studies, 74.1% in non-randomised studies).

Data on the cost of hospital stay were reported in four of the five randomised studies[w1 w3-w6] and in three of the six non-randomised studies.[w7 w8 w12] Although the data are difficult to interpret because they did not allow cost effectiveness ratios to be estimated, a slightly, yet significant, lower cost of hospital care was found in acute geriatric units (combined mean difference −0.31, 95% confidence interval −0.52 to −0.09; I^2=0%).

Sensitivity analysis

Results for separate analyses for the randomised studies and the other studies were similar, except that

WHAT IS ALREADY KNOWN ON THIS TOPIC

The effect of geriatric assessment has been evaluated in hospital and community settings

In older people admitted to hospital with acute disorders, the intervention of consultation teams has not shown clinical or administrative benefits

WHAT THIS STUDY ADDS

Care of older people with acute disorders in acute geriatric units reduces the risk of functional decline at discharge and increases the probability of returning home

This benefit is not accompanied by an increase in case fatality or hospital costs

the reduction in hospital stay was larger in the non-randomised studies. The analysis was repeated after excluding the oldest studies (published before 1995 and lacking a geriatrician), and after assuming adverse results in people lost to follow-up or lacking data on outcomes. No substantial changes were found.

DISCUSSION

The results of this meta-analysis suggest that care of older people (≥65 years) with acute medical disorders in acute geriatric units leads to less functional decline at discharge and a higher probability of returning home.

The 18% reduction in functional decline associated with acute geriatric units is similar to that found in a study of patients aged 65 or more with acute medical disorders who received physiotherapy within multidisciplinary care.[10] The benefit of returning home was also comparable to that reported in another study in the combined analysis of acute and subacute hospital care units.[1] Although the tendency towards a higher probability of living at home was maintained at three months after discharge from an acute geriatric unit, the reduction in functional decline was seen only at discharge. We did not find a reduction in case fatality either at discharge or at three months.

The studies reviewed provide limited information on the characteristics and form of operation of the conventional hospital units. This is important because the effect of acute geriatric units is measured by comparison with these units and could vary depending on the characteristics of conventional units. Although the acute geriatric units in this review included therapists, in general they did not have more staff than the conventional units so that differences seem to centre on specialisation and organisation of work. The distinctive feature of acute geriatric units is the comprehensive assessment and care focusing on patients' needs, interdisciplinary work carried out by a core team of professionals, and early planning of discharge. Other studies have evaluated partial aspects of this care, such as early discharge planning or physiotherapy alone,[10 11] without finding conclusive results, indicating that the benefit may derive from a combination of these interventions.[1] Specialisation in the care of elderly people and formal interdisciplinary meetings may contribute to the benefits of care in acute geriatric units, as has been shown in patients with stroke.[12] Another aspect of acute geriatric units that might contribute to their effectiveness is direct responsibility for the patient, which ensures compliance with diagnostic and therapeutic recommendations and the implementation of the care plan.[1 w29]

This review has some limitations. The number of randomised trials included is small, and our findings might reflect usual clinical practice until 2000 (date of the most recent randomised study in this review). Thus the effect of acute geriatric units compared with conventional hospital units may have changed. However, more recent controlled studies[w9 w10 w12] suggest that the differences between acute geriatric units and conventional units still remain. Finally, the studies evaluated do not provide data on the components of the intervention responsible for the benefits observed, nor do they permit us to draw firm conclusions on the effect of acute geriatric units on other relevant outcomes in the medium and long term, except for returning home to live.

In conclusion, acute geriatric units reduce functional decline at discharge and increase the probability of living at home at discharge and at three months after discharge without increasing case fatality or the costs of hospital care.

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Comparing hospital and telephone follow-up after treatment for breast cancer: randomised equivalence trial

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ABSTRACT

Objective To compare traditional hospital follow-up with telephone follow-up by specialist nurses after treatment for breast cancer.

Design A two centre randomised equivalence trial in which women remained in the study for a mean of 24 months.

Setting Outpatient clinics in two NHS hospital trusts in the north west of England

Participants 374 women treated for breast cancer who were at low to moderate risk of recurrence.

Interventions Participants were randomised to traditional hospital follow-up (consultation, clinical examination, and mammography as per hospital policy) or telephone follow-up by specialist nurses (consultation with structured intervention and mammography according to hospital policy).

Main outcome measures Psychological morbidity (state-trait anxiety inventory, general health questionnaire (GHQ-12)), participants' needs for information, participants' satisfaction, clinical investigations ordered, and time to detection of recurrent disease.

Results The 95% confidence interval for difference in mean state-trait scores adjusted for treatment received (−3.33 to 2.07) was within the predefined equivalence region (−3.5 to 3.5). The women in the telephone group were no more anxious as a result of foregoing clinic examinations and face-to-face consultations and reported higher levels of satisfaction than those attending hospital clinics (intention to treat P<0.001). The numbers of clinical investigations ordered did not differ between groups. Recurrences were few (4.5%), with no differences between groups for time to detection (median 60.5 (range 37-131) days in hospital group *v* 39.0 (10-152) days in telephone group; P=0.228).

Conclusions Telephone follow-up was well received by participants, with no physical or psychological disadvantage. It is suitable for women at low to moderate risk of recurrence and those with long travelling distances or mobility problems and decreases the burden on busy hospital clinics.

Trial registration National Cancer Research Institute 1477.

INTRODUCTION

In many countries clinical examination, consultation, and routine mammography form the basis of routine follow-up for women in remission from breast cancer, with the primary objective of detecting recurrent disease. This form of surveillance is as effective in terms of overall survival and quality of life as more intensive approaches.[1] Recurrences often present as interval events and are not usually detected by clinical examination of patients without symptoms.[2-6] National guidelines in the United Kingdom state that intensive follow-up to detect metastatic disease is not beneficial, although patients should have continued access to specialist breast care nurses for advice and support.[7]

In the UK follow-up continues primarily in hospital clinics but breast care nurses are uniquely placed to address the information and psychosocial needs of affected women[8 9] and to provide follow-up services to deliver a structured intervention aimed primarily at meeting needs for information. Communication by telephone is internationally relevant, particularly for people in remote areas where travel to hospital is inconvenient, time consuming, and costly.

METHODS

In this equivalence trial[10] we examined whether patients in the telephone arm of the study had anxiety levels that were no different from those of patients in the hospital arm.

Study sites and sample

All participants had been treated for breast cancer in the north west of England. Inclusion criteria included completion of primary treatment (surgery, radiotherapy, chemotherapy), no evidence of recurrent disease, low to moderate risk of recurrence,[11] access to a telephone, and adequate hearing. We primarily determined the risk of recurrence using the Nottingham prognostic index, considering tumour size, spread to lymph nodes, and grade of cancer and HER2 status. We excluded inflammatory carcinomas and sarcocarcinomas. All participants had a low to moderate risk of recurrence.

We identified consecutive eligible patients in hospital clinics, discussed the study after appointments, and subsequently contacted individuals for verbal and written consent. Women who consented were randomised to telephone or hospital follow-up. Breast care nurses had no involvement in randomisation or data collection procedures.

Procedures and intervention

Participants randomised to the hospital group continued with standard hospital follow-up. At the district general hospital participants were reviewed every three months for two years, six monthly for two years, then annually for a further year. At the specialist breast unit they were reviewed annually for 10 years. Both study locations allocated 10 minutes for each individual hospital appointment.

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Participants randomised to telephone follow-up received telephone appointments from breast care nurses at intervals consistent with hospital follow-up. Each telephone appointment was allocated 30 minutes; 20 minutes for conducting the consultation and 10 minutes to dictate the outcome of consultations. Throughout the study the same specialist nurse contacted each participant in the telephone group for all appointments.

We developed a structured telephone intervention from previous findings on information needs of women with breast cancer,[12 13] adapting a research instrument for use as a clinical guide.[14] Specific questions related to changes in condition, new symptoms, and information requirements about spread of disease, treatment and side effects, genetic risk, sexual attractiveness, self care (diet, support groups, finances), and family concerns.

Outcome measures

Outcomes included psychological morbidity, information needs, participants' satisfaction, clinical investigations ordered, and time to detection of recurrent disease. We measured psychological morbidity using two instruments: the Spielberger state-trait anxiety inventory (STAI) and the general health questionnaire (GHQ-12).

Clinical data were collected prospectively. We used two key index dates to establish time to diagnosis of recurrence: date of first presentation of symptoms (or indicator of recurrence) and date recurrence was confirmed to participants. Time to diagnosis of recurrence was taken as the difference between the two index dates. At the end of the study we retrospectively examined all participants' case notes to check accuracy of data on recurrence.

We sent initial questionnaires to patients immediately after randomisation, a minimum of three months before their next appointment. Questionnaires were also posted to participants at the middle and end of the trial.

Statistical analysis

Contrary to a standard comparative trial, an equivalence trial has an alternative hypothesis of no difference between treatments or services.[15] We entered and analysed data with SPSS, release 15. Our study was powered on the basis of a 95% equivalence region of −3.5 to 3.5 for the difference in mean state-trait scores between groups at the end of the trial, 3.5 being 10% of the expected control mean, with an expected SD of 10.0.

Table 1 | Satisfaction with information received by randomised group (intention to treat analysis). Figures are numbers (percentages) of women

			Between groups comparison P value	
Level of satisfaction	Hospital	Telephone	All categories*	First 4 categories
Start of trial				
Very satisfied	79 (46)	78 (45)		
Satisfied	67 (39)	71 (41)		χ^2_{trend}=0.31, 0.576
Not very satisfied	4 (2)	8 (5)		
Very unsatisfied	1 (1)	0 (0.0)		
Did not receive information	10 (6)	6 (4)	0.671	—
Did not need information	10 (6)	10 (6)		—
Overall	171 (100)	173 (100)		—
Middle of trial				
Very satisfied	57 (49)	110 (80)		
Satisfied	41 (35)	22 (16)		χ^2_{trend}=19.07, <0.001
Not very satisfied	7 (8)	3 (2)		
Very unsatisfied	3 (3)	1 (1)		
Did not receive information	4 (3)	0 (0)	<0.001	—
Did not need information	4 (3)	1 (1)		—
Overall	116 (100)	137 (100)		—
End of trial				
Very satisfied	78 (55)	121 (80)		
Satisfied	47 (33)	25 (16)		χ^2_{trend}=14.33, <0.001
Not very satisfied	8 (6)	3 (2)		
Very unsatisfied	1 (1)	1 (1)		
Did not receive information	7 (5)	0 (0)	<0.001	—
Did not need information	1 (1)	2 (1)		—
Overall	142 (100)	152 (100)		—

*Fisher's exact test.

RESULTS

Recruitment took place between March 2003 and August 2005. Data collection continued until October 2006; patients remained in the study for a mean of 24 months (range 2-43 months). Most patients approached who met the inclusion criteria were willing to participate (374/629, 60%); 215 patients who did not take part provided sociodemographic and treatment information and a reason for refusal. Reasons included: preference for face-to-face consultations; preference for clinical examination; and family members fearing exclusions from consultations if the appointment was conducted by telephone. Participants were randomised to hospital (183, 49%) or telephone (191, 51%) follow-up. Sociodemographic and clinical characteristics for those randomised were broadly similar in the two study groups. The sample was representative of the UK breast cancer population in terms of age, with more participants in the 55-64 year age group than the other age group categories, in line with data from the UK Office for National Statistics.[16] Participants were a median of 20 months from diagnosis, although most (63%) were 24 months or less from diagnosis Those who refused to take part differed from participants in study site, social class, and follow-up status. Patients at the specialist breast unit (71%) were more likely to want to participate than those at the district general hospital (61%, χ^2=5.01, df=1, P=0.025), participants from higher social classes (professional occupations) were more likely to want to participate than those from lower social classes (χ^2=15.77, df=8, P=0.046), and

participants with three to 12 months between visits (67.7%, 70.6%) were more likely to participate than those on six monthly follow-up (58.1%, χ^2=7.66, df=2, P=0.022). Time from diagnosis did not differ significantly for those who did or did not take part (t=−0.26, P=0.80)

Sociodemographic and clinical data were collected for all randomised participants. Eight patients from the specialist breast unit and 17 from the district general hospital did not return questionnaires at any time point. Those participating at the end of the trial had a shorter time from diagnosis at the start of the trial (median 18 months) than those who had dropped out after participating at least once (median 25.5 months, Mann-Whitney U=5902.5, P=0.019), and a shorter time from post-treatment visit at the start of the trial (15 *v* 25 months, U=6046.0, P=0.033).

Psychological morbidity

Differences between groups in state-trait score were not significant at the start, middle, or end of the trial under intention to treat or adjusted treatment received analyses, although means were consistently lower for the telephone group (see bmj.com). Mean score did not significantly improve during the trial and the 95% confidence intervals for the differences between mean values (hospital *v* telephone) of state-trait scores for intention to treat and adjusted for treatment (for instance, −3.33 to 2.07 for) were within the prestated equivalence region indicated equivalence (see bmj.com for further details).[15]

Information needs

Within both randomised groups, information needs reduced over time for all items, and there was little difference between the groups in information needs. The need for information on genetic risk remained the highest at the end of the trial, with 92 of the 296 respondents to the question (31%) still requiring information.

Participants' satisfaction

There were no significant differences between randomised groups initially regarding satisfaction with information received (table 1). The telephone group showed significantly more satisfaction at the middle and end of the trial (P<0.001). Participants were asked if they had thought that the appointment had been helpful in dealing with their concerns. There was no difference between groups initially but at the middle and end of the trial, responses were significantly more positive in the telephone group, with a higher percentage reporting "very helpful" and few with negative responses (table 2).

There were no significant differences between groups in terms of contact at any time point. Women who had contact with their general practitioners, however, tended to have been diagnosed more recently (median 10 months compared with 20 months for those with no reported contact, Mann-Whitney U=2044.0, P=0.004). Women who had contact with breast care nurses between appointments also tended to have been diagnosed more recently (median 6.5 months compared with 20 months for those with no reported contact, U=1488.5, P=0.001). Contact with lymphoedema nurses was not associated with time from diagnosis (U=1895.5, P=0.244). There were few contacts with hospital doctors and administrative staff between visits.

Table 2 | Helpfulness in dealing with concerns at appointment by randomised group (intention to treat analysis). Figures are numbers (percentages) of women

Level of satisfaction	Hospital	Telephone	χ^2_{trend}, P value
Start of trial			
Very helpful	44 (48)	44 (52)	0.69, 0.405
Helpful	36 (39)	31 (37)	
Not very helpful	10 (11)	9 (11)	
Very unhelpful	2 (2)	0 (0)	
Overall	92 (100)	84 (100)	—
Middle of trial			
Very helpful	28 (44)	80 (88)	28.27, <0.001
Helpful	26 (41)	9 (10)	
Not very helpful	9 (14)	1 (1)	
Very unhelpful	1 (2)	1 (1)	
Overall	64 (100)	91 (100)	—
End of trial			
Very helpful	42 (63)	84 (84)	10.35, 0.001
Helpful	15 (22)	13 (13)	
Not very helpful	10 (15)	2 (2)	
Very unhelpful	0 (0)	1 (1)	
Overall	67 (100)	100 (100)	—

Clinical investigations ordered

There were no differences between groups as to whether clinical investigations were ordered for participants as a result of appointments at the start (hospital 29% *v* telephone 24%, χ^2=1.10, df=1, P=0.294), middle (36% *v* 34%, χ^2=0.08, df=1, P=0.772), or end of the trial (40% *v* 43%, χ^2=0.32, df=1, P=0.574). In most cases, investigations comprised routine mammograms. Other investigations mentioned by both groups at all stages of the study included 18 non-routine mammograms, 13 blood tests, nine chest x ray investigations, nine bone scans, six fine needle aspirations/biopsies, and one magnetic resonance imaging scan.

Time to detection of recurrence

Only 17 participants (5%) had a confirmed recurrence of cancer during the trial: six in the hospital group and 11 in the telephone group (see bmj.com). The difference between randomised groups was not significant (χ^2=1.33, df=1, P=0.250). The median time to confirmation was 60.5 days (range 37-131 days) in the hospital group and 39.0 days (10-152 days) in the

WHAT IS ALREADY KNOWN ON THIS TOPIC

UK national guidelines recommend that routine long term follow-up after treatment for breast cancer is not effective at prolonging survival

Brief consultations aimed at detection of recurrence do not provide opportunities for discussion of information and psychosocial needs

WHAT THIS STUDY ADDS

Participants in a telephone follow-up group were no more anxious as a result of foregoing clinical examinations and face-to-face contact

Telephone follow-up was associated with high levels of satisfaction in patients

Telephone follow-up might decrease the burden on busy hospital clinics

telephone group (Mann-Whitney U=21.0, P=0.228, for difference).

DISCUSSION

Telephone follow-up by specialist breast care nurses has benefits for women with breast cancer. The telephone intervention provided a service to women that met their needs, with no evidence of physical or psychological disadvantage. We were therefore able to show equivalence, in terms of psychological morbidity, between hospital and telephone follow-up.

Scores on the state-trait anxiety inventory did not significantly improve in either group during the trial, although this measure has been used successfully in patients with breast cancer in previous studies. Findings for the anxiety inventory and GHQ-12 indicated that there were no differences between scores for study groups at any point in the trial.

Those in the telephone group reported greater satisfaction with the information received and reported appointments as more helpful in meeting their needs. There were no differences in terms of investigations ordered between groups. These findings, however, are based on participants' retrospective recall of investigations ordered; response might have been subject to inaccuracies. Participants in the telephone group were no more likely to consult with other health professionals between visits than those in the hospital group and so were not using additional healthcare resources.

Only 17 (4.5%) recurrences were detected. These were mostly interval events; no recurrences were detected in patients without symptoms at routine appointments. There were no differences in time to detection of recurrence between the groups. Follow-up does not usually have a different format for high risk groups but at this stage our findings can be applied with confidence only to women at low risk of recurrence.

Alternating telephone and hospital follow-up, according to patients' preferences, could be a suitable approach, while hospital follow-up might continue to be preferred by those who do not feel comfortable discussing their concerns over the telephone. Telephone follow-up is convenient, especially in rural areas where patients might have to travel long distances for hospital appointments and for those with limited mobility. Telephone follow-up might have broader applicability to other groups of patients. There are nurse specialists for many diseases and their skills could be harnessed to provide a quality service while reducing the burden on busy hospital clinics.

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Long term survival after evidence based treatment of acute myocardial infarction and revascularisation: follow-up of population based Perth MONICA cohort, 1984-2005

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ABSTRACT

Objective To examine trends in long term survival in patients alive 28 days after myocardial infarction and the impact of evidence based medical treatments and coronary revascularisation during or near the event.

Design Population based cohort with 12 year follow-up.

Setting Perth, Australia.

Participants 4451 consecutive patients with a definite acute myocardial infarction according to the World Health Organization MONICA (monitoring trends and determinants in cardiovascular disease) criteria admitted to hospital during 1984-7, 1988-90, and 1991-3.

Main outcome measures All cause mortality identified from official mortality records and the hospital morbidity data, with death from cardiovascular disease as a secondary end point.

Results In the 1991-3 cohort, 28 day survivors of acute myocardial infarction had a 7.6% absolute event reduction (95% confidence interval 4% to 11%) or a 28% lower relative risk reduction (16% to 38%), unadjusted for risk of death, over 12 years after the incident admission compared with the 1984-7 cohort, similar to the survival of the 1988-90 cohort. The improved survival for the 1991-3 cohort persisted after adjustment for demographic factors, coronary risk factors, severity of disease, and event complications with an adjusted relative risk reduction of 26% (14% to 37%), but this was not apparent after further adjustment for medical treatments in hospital and coronary revascularisation procedures within 12 months of the incident myocardial infarction.

Conclusion The improving trends in 12 year survival after a definite acute myocardial infarction are associated with progressive use of evidence based treatments during the initial admission to hospital and in the 12 months after the event. These changes in the management of acute myocardial infarction are probably contributing to the continuing decline in mortality from coronary heart disease in Australia.

INTRODUCTION

The long term decline in mortality from coronary heart disease in Australia and elsewhere has been widely attributed to both declining incidence and advances in medical treatment.[1 2] Previous studies in Perth, including the World Health Organization MONICA project (monitoring trends and determinants in cardiovascular disease), have shown rapid and progressive uptake in aspects of medical care shown in randomised clinical trials to reduce both acute and medium term mortality after acute myocardial infarction.[3-5] Such treatment included antiplatelet therapy, thrombolysis, β blockers, lipid lowering drugs, angiotensin converting enzyme inhibitors, and coronary artery revascularisation.[6-10] There are, however, few studies documenting the long term impact at the population level on survival after acute myocardial infarction or on death rates from coronary heart disease.

We examined trends in long term survival in people registered as having an acute myocardial infarction over a 10 year period in Australia.

METHODS

Study population—The study population comprised all residents of the Perth Statistical Division (population size 1.19 million in 1991) aged 35-64 who were admitted to hospital with a first non-fatal definite acute myocardial infarction, and with no admission for ischaemic heart disease in the previous four years, registered by the Perth MONICA project during 1984-93.[11] Only individuals who survived 28 days after an incident acute myocardial infarction were included.

Data sources and record linkage—We linked records in the Perth MONICA register to a file of all hospital admissions for cardiovascular disease and related deaths in Western Australia from 1980-2005, representing a minimum follow-up period of 12 years.

Follow-up and end points—Our principal end point was all cause mortality, with death from cardiovascular disease as a secondary end point. We examined the incidence of coronary artery revascularisation within a year of an index event as a covariate relating to survival after one year.

Possible factors influencing long survival after acute myocardial infarction—We divided the cohort into three subcohorts (1984-7, 1988-90, and 1991-3). Other factors selected for analysis included age and sex, smoking status, medical history, and measures of disease severity and treatment including selected drugs used during the acute event, or at discharge, or coronary artery revascularisation within 12 months.

Analysis of data—We examined differences in the distribution of demographic and clinical characteristics for the three subcohorts (1984-7, 1988-90, 1991-3) and plotted Kaplan Meier curves of time to death to determine differences in survival. We used Cox regression to examine the hazard ratio for death over

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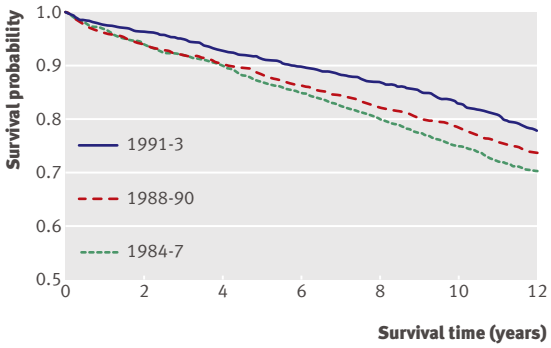

Fig 1 | Kaplan-Meier all cause mortality in 28 day survivors of acute myocardial infarction: Perth MONICA cohort 1984-93

12 months and 12 years, with adjustment for possible factors influencing survival.

RESULTS

Baseline characteristics—From 1984 to 1993, 5340 people were admitted to hospital with first acute myocardial infarction and survived at least 28 days. Some 889 (16%) were excluded for admission to hospital with ischaemic heart disease within four years of the index event. Their mean age was 54.4 (SD 7.3) years. Overall, 18% were women, 10% had a history of diabetes, 51% were current smokers, and 40% had a history of hypertension. The prevalence of diabetes increased with each successive subcohort, smoking decreased, and hypertension was unchanged. While the median creatine kinase ratio was unchanged over time, the prognostic markers of Q wave acute myocardial infarction and ST deviation successively fell with each subcohort. This was associated with complementary changes in the electrocardiogram score. Likewise, the proportion with changes on anterior electrocardiogram increased after the first subcohort. There were significant changes in treatment with each successive subcohort: a marked increase in the use of β blockers, antiplatelets, and thrombolytic treatment during the acute episode, and significant uptake of antiplatelets, angiotensin converting enzyme inhibitors, β blockers, and lipid lowering drugs at the time of discharge from hospital.

Trends in revascularisation—The proportion of revascularisation within 12 months was 2% in 1984-7, 31% in 1988-90, and 38% in 1991-3 ($P<0.001$ for trend). Surgical revascularisation in the 12 years of follow-up was highest in the 1984-7 subcohort, whereas percutaneous coronary intervention was highest during the first 12 months in the 1991-3 subcohort. While the frequency of coronary artery bypass graft was more than twice that of percutaneous coronary intervention in the 1984-7 subcohort, by 1991-3 equal proportions of coronary artery bypass graft and percutaneous coronary intervention procedures (29% each) were performed. In 1984-7, 1988-90, and 1991-3 the proportions of each subcohort undergoing coronary artery revascularisation were 26%, 52%, and 59%, respectively.

Factors increasing risk of death—Hazard ratios for death were adjusted for age, sex and subcohort. Over a 12 year follow-up having a history of diabetes or hypertension, being a current smoker, and having a higher electrocardiogram score with predicting risk of death in cardiac disease tool were all associated with a significantly increased risk of death. Survival was lower in patients with evidence of heart failure or cardiogenic shock within 28 days of the acute myocardial infarction or tachycardia, whereas a systolic blood pressure of <100 mm Hg on presentation had no effect. Interventions associated with a significantly lower risk of death over 12 years included at least two drug treatments in hospital, one or two drugs prescribed at discharge, and coronary revascularisation within 12 months of the incident acute myocardial infarction.

Trends in one year survival—In the 1991-3 subcohort, people surviving at least 28 days had a lower unadjusted all cause mortality at one year compared with patients from the 1984-7 subcohort, with a relative risk reduction of 40% (95% confidence interval 10% to 60%). This survival benefit persisted after adjustment for demographic characteristics and coronary risk factors but was reduced to 34% (0% to 56%) after further adjustment for severity of disease and clinical complications, and to 0 (−65% to 39%) after further adjustment for medical treatment during admission to hospital. There was non-significant improvement in survival over one year between 1984-7 and 1988-90 subcohorts.

Trends in 12 year survival—People in the 1991-3 subcohort alive at one year after the incident event experienced a lower unadjusted 12 year all cause mortality compared with patients in the 1984-7 subcohort, with a relative risk reduction of 28% (16% to 38%) equivalent to an absolute event reduction of 7.6% (4% to 11%). This difference in survival persisted after adjustment for demographic variables, coronary risk factors, severity of disease, and clinical complications, with a relative risk reduction of 26% (14% to 37%), but was no longer apparent after further

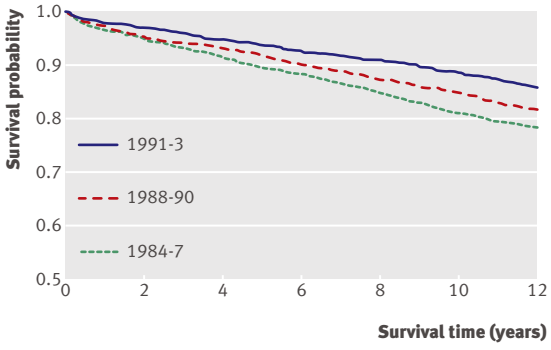

Fig 2 | Kaplan-Meier cardiovascular mortality in 28 day survivors of acute myocardial infarction: Perth MONICA cohort 1984-93

adjustment for medical treatment during admission and coronary artery revascularisation within 12 months of the incident acute myocardial infarction. The improvement in survival over 12 years between the 1984-7 and 1988-90 subcohorts was borderline (P=0.055) (fig 1). Twelve year survival trends for cardiovascular death by subcohort were comparable with findings for all cause mortality (fig 2). The proportion of total deaths after 12 years caused by cardiovascular disease in first, second, and third subcohorts was 70%, 66%, and 61%, respectively.

DISCUSSION

This population based study shows improving trends in one and 12 year survival in those alive at least 28 days after a definite acute myocardial infarction. Improved survival in the early 1990s over the early 1980s corresponds with the introduction of new treatments rather than changes in risk factors before the infarction or severity of infarction.

Strengths and weaknesses of study

Our study covers a 10 year period during which treatment for coronary heart disease was changing rapidly in response to published research. We applied unchanging criteria for definite acute myocardial infarction which would overcome diagnostic drift over time. Near complete follow-up (estimated at 99%) was achieved. Our analysis reconfirmed the main predictors of survival after acute myocardial infarction, similar to previous studies[12 13] but over a longer term.

The use of proved medical treatment, as exemplified by antiplatelets, thrombolysis, and β blockers during admission to hospital, and performance of coronary artery revascularisation within 12 months after an incident acute myocardial infarction accounted for the greatest improvement in survival over 12 years. Proportionately 9% fewer cardiovascular deaths occurred over 12 years in the 1991-3 subcohort than in the 1984-7 subcohort.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Medical care and control of coronary risk factors both contribute to the decline in mortality from coronary heart disease

Little is known about the impact of adopting robust evidence from clinical trials on long term survival after acute myocardial infarction

WHAT THIS STUDY ADDS

Patients with acute myocardial infarction who receive drug treatments of proved value during presentation to hospital and undergo coronary revascularisation within 12 months are more likely to survive over 12 years

Evidence based treatment of acute myocardial infarction is associated with improved long term survival and probably contributes to the continuing decline in mortality from coronary heart disease in Australia

This study has some limitations. Severity of disease did not account for differences in survival between the subcohorts. More sophisticated and comprehensive measures of disease severity might indicate a contribution of altered severity to the change in longer term survival. Although our findings involve a relatively younger population (age 35-64) they are consistent with findings from an unrestricted cohort of adults in Scotland.[14] Our study was observational in nature and the results should be interpreted with caution.

Relevance of our findings

Other studies have reported improvements in survival after acute myocardial infarction during similar historical periods, with improvement in short term survival attributed to treatment, and the long term survival advantage linked to diet, smoking cessation, and continuing treatment with aspirin and β blockers.[14 15] A registry study of residents with acute myocardial infarction from Gerona, Spain, showed no significant differences in the three year mortality in 28 day survivors between periods 1978-85 and 1986-8,[16] although the observational period in this study were before the widespread uptake of thrombolytic treatment, antiplatelets, and coronary artery revascularisation. Improvements in long term survival are probably attributable to a combination of various treatments rather than any single treatment.

Prescriptions for lipid lowering drugs and angiotensin converting enzyme inhibitors have increased nearly 20-fold from 1991 to 2004. This suggests that patients in the 1991-3 subcohort were probably exposed to greater use of such drugs than those in the earlier subcohorts. Changes in lifestyle characteristics and dietary practices might also have contributed to trends in survival.[17 18] We have controlled for hypertension and diabetes mellitus that are partly consequences of overweight and lifestyle. Data on body mass index, physical inactivity, and smoking were not available and so cannot directly be adjusted for.

Changes in severity of disease could also improve long term survival, though we found no change in creatine kinase ratios from the 1984-7 to the 1991-3 subcohort. Adjustment for markers of disease severity did not alter the one and 12 year survival differences seen between the 1991-3 and 1984-7 subcohorts.

Conclusion

One and 12 year survival increased in patients aged 35-64 who were alive 28 days after an incident acute myocardial infarction from 1984 to 1993. The improvement is associated with changes in treatment during and within 12 months of the event. The magnitude of the contribution of evidence based treatment to the decline in mortality from coronary heart disease remains unanswered as does the contribution of chronic cardioprotective pharmacotherapy.

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Competing interests: None declared.
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CORRECTIONS AND CLARIFICATIONS

Why Oregon went wrong

In this Feature article by Vidhya Alakeson (*BMJ* 2008;337:a2044, 14 Oct; doi:10.1136/bmj.a2044) an "s" was missing from the author's email address. The correct address is alakesonvidhya@yahoo.co.uk.

Trust decides against legal action to force girl to receive heart transplant

In the final paragraph of this News article by Clare Dyer (*BMJ* 2008;337:a2526, 12 Nov; doi:10.1136/bmj.a2526) we gave the wrong legal position on consent and child patients. The correct position in English law is that a parent may give a valid consent to treatment even though the child refuses it, and a child's refusal can also be overridden by the court.

However, doctors would be unlikely to perform surgery such as heart transplantation in an unwilling teenage patient merely on the consent of the parents and without the authorisation of the courts. And, although they undoubtedly have power to do so, the case of Re M in 1999 (*BMJ* 1999;319:209) indicates that the courts are reluctant to exercise their inherent jurisdiction to override a child's refusal if the child is old enough and capable of making an informed choice.

In that case, where the parents wanted the heart transplant surgery and the teenage patient refused, although the court had power to override her decision, the judge and the official solicitor took steps to find out whether she was capable of making an informed choice and decided that she was not.

Joking apart

During the editing of this Review of the Week by Richard Smith (*BMJ* 2008;337:a2719, 9 Dec; doi:10.1136/bmj.a2719), the author's term "pisshouse" was changed to "pub" in the sentence: "Then, in true British and male style, Hammond met Ian Hislop, editor of *Private Eye*, in the pub and did a deal." However, a pisshouse is apparently a gentleman's toilet, and (in the author's social circle at least) the phrase "pisshouse deal" is well known. (It alludes to the tendency of men to make deals while standing side by side and urinating.) In the more genteel confines of the *BMJ* Editorial Office, however, this term was unknown and a mistake was made in translating it into more standard English. We apologise for any misunderstanding this may have caused.

Minerva

A typing error during production of this Minerva picture by Hawraman Ramadan and colleagues (*BMJ* 2008;337:a3007, 23 Dec; doi:10.1136/bmj.a3007) led to the text for the picture mentioning "no papillary defect." This should, of course, be "no pupillary defect."

Antibiotics for spontaneous preterm birth

In their editorial (*BMJ* 2008;337:a3015, 30 Dec; doi:10.1136/bmj.a3015) Andrew Shennan and Manju Chandiramani wrote: "ORACLE 1 did not show any increase in cerebral palsy (when fetal membranes were ruptured)." This is a mistake, and the sentence should begin: "In the ORACLE 1 study, antibiotics did not increase the risk of cerebral palsy…".