

Confidential inquiry into quality of care before admission to intensive care

Peter McQuillan, Sally Pilkington, Alison Allan, Bruce Taylor, Alasdair Short, Giles Morgan, Mick Nielsen, David Barrett, Gary Smith

Abstract

Objective: To examine the prevalence, nature, causes, and consequences of suboptimal care before admission to intensive care units, and to suggest possible solutions.

Design: Prospective confidential inquiry on the basis of structured interviews and questionnaires.

Setting: A large district general hospital and a teaching hospital.

Subjects: A cohort of 100 consecutive adult emergency admissions, 50 in each centre.

Main outcome measures: Opinions of two external assessors on quality of care especially recognition, investigation, monitoring, and management of abnormalities of airway, breathing, and circulation, and oxygen therapy and monitoring.

Results: Assessors agreed that 20 patients were well managed (group 1) and 54 patients received suboptimal care (group 2). Assessors disagreed on quality of management of 26 patients (group 3). The casemix and severity of illness, defined by the acute physiology and chronic health evaluation (APACHE II) score, were similar between centres and the three groups. In groups 1, 2, and 3 intensive care mortalities were 5 (25%), 26 (48%), and 6 (23%) respectively ($P=0.04$) (group 1 versus group 2, $P=0.07$). Hospital mortalities were 7 (35%), 30 (56%), and 8 (31%) ($P=0.07$) and standardised hospital mortality ratios (95% confidence intervals) were 1.23 (0.49 to 2.54), 1.4 (0.94 to 2.0), and 1.26 (0.54 to 2.48) respectively. Admission to intensive care was considered late in 37 (69%) patients in group 2. Overall, a minimum of 4.5% and a maximum of 41% of admissions were considered potentially avoidable. Suboptimal care contributed to morbidity or mortality in most instances. The main causes of suboptimal care were failure of organisation, lack of knowledge, failure to appreciate clinical urgency, lack of supervision, and failure to seek advice.

Conclusions: The management of airway, breathing, and circulation, and oxygen therapy and monitoring in severely ill patients before admission to intensive care units may frequently be suboptimal. Major consequences may include increased morbidity and mortality and requirement for intensive care. Possible solutions include improved teaching, establishment of

medical emergency teams, and widespread debate on the structure and process of acute care.

Introduction

Seriously ill patients may be identified by the clinical signs of life threatening dysfunction of the airway, breathing, or circulation, but these may be missed, misinterpreted, or mismanaged by clinicians of all grades. Avoidable components therefore contribute to physiological deterioration, with major consequences on morbidity, mortality, requirement for intensive care, and cost. Such deficiencies may be described as suboptimal care.¹⁻⁶ We aimed to investigate the prevalence of suboptimal care before admission to intensive care, to examine its nature, causes, and consequences, and to suggest possible solutions.

Subjects and methods

We prospectively studied the quality of care received by 50 consecutive, adult emergency patients before their admission to intensive care units in each of two centres (Portsmouth and Southampton). The study was conducted in the winter of 1992-3 after approval by local ethics committees and all acute unit consultants.

On the basis of methodology used for confidential inquiries^{1,2,6} detailed questionnaires were completed by us during structured interviews with (a) the admitting clinical team and (b) the intensive care team. The interviews concentrated on events between hospital admission and admission to intensive care. The questionnaires comprised tick and data entry boxes and a page for summarising history, clinical findings, assessment, thought processes, resuscitation, treatment, and response to treatment. Emphasis was placed on the recognition, investigation, monitoring, and management of abnormalities of airway, breathing, circulation, and oxygen therapy and monitoring. Interviews took place as soon as possible after a patient's admission to intensive care, which ranged from minutes to days. Severity of illness was recorded using the acute physiology and chronic health evaluation (APACHE II)⁷ scoring system, using most extreme values in the first 24 hours in intensive care. Data on duration of stay in intensive care and intensive care and hospital outcomes were also collected. Casemix adjusted expected mortality was calculated from the

*Editorial by
Garrard and Young*

Department of
Intensive Care
Medicine, Queen
Alexander Hospital,
Cosham,
Portsmouth,
Hampshire
PO6 3LY

Peter McQuillan,
*consultant in
intensive care and
anaesthesia*

Sally Pilkington,
*senior registrar in
anaesthesia*

Alison Allan,
*registrar in
anaesthesia*

Bruce Taylor,
*consultant in
intensive care and
anaesthesia*

Gary Smith,
*director of intensive
care*

Intensive Care Unit,
Southampton
General Hospital,
Southampton
SO16 6YD

Mick Nielsen,
*consultant in
intensive care and
anaesthetics*

Intensive Care,
Broomfield
Hospital,
Chelmsford, Essex
CM1 7ET

Alasdair Short,
*consultant in
intensive care*

Intensive Care,
Royal Cornwall
Hospital, Treliске,
Truro, Cornwall
TR1 3L

Giles Morgan,
*consultant in
anaesthesia and
intensive care*

continued over

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School of
Mathematical
Studies, University
of Portsmouth,
Mercantile House,
Hampshire Terrace,
Portsmouth,
Hampshire
PO1 2EG

David Barrett,
senior lecturer

Correspondence to:
Dr McQuillan

Table 1 Patient demographic data, assessor opinions on appropriateness of admission and linear analogue scores, and mortality

	All patients	Group 1	Group 2	Group 3	P value*
No of patients	100	20	54	26	
Median age (years) (interquartile range)	61.5 (43.5-73.3)	61 (44.3-71)	62 (48.3-74.8)	55.5 (35.8-71.8)	0.34
No of males (%)	65	75	69	50	
Median APACHE II score† (interquartile range)	16.5 (9.8-25)	16.5 (8.8-22.3)	19.5 (13-25)	13 (9-20.5)	0.18
Median source time‡ (interquartile range)	1.75 (0.35- 5)	0.75 (0.04-2)	2.25 (0.81-7)	1.0 (0.26-3.75)	0.006
Median No of days in intensive care§ (A) (interquartile range)	2 (1-6.25)	2 (1-3.25)	2 (1-4.1)	4 (1-11)	0.38
Median No of days in intensive care§ (B) (interquartile range)	3 (1-6.5)	2.9 (1-3)	9 (1.75-12.75)	7.3 (1-10)	0.55
Admission (%):					
Appropriate	89	19	48	22	$\chi^2=0.68$
Disagree	7	1	3	3	
Inappropriate	4	0	3	1	
Timing of admission (No) (%):					
Late	39 (39)	0	37 (69)	2 (8)	$\chi^2<0.0001$
Disagree	25 (25)	0	15 (28)	10 (38)	
Not late	36 (36)	20 (100)	2 (4)	14 (54)	
Linear analogue scale 0-10 cm (median) (interquartile range):					
Oxygen therapy	5.77 (3.4-8.3)	8.92 (8.1-9.3)	3.67 (1.7-5.7)	6.86 (5.7-8.5)	<0.0001
Airway	5.62 (3.6-8.5)	8.97 (8.2-9.2)	4.11 (2.7-5.2)	7.23 (5.7-8.9)	<0.0001
Breathing	5.59 (2.7-8.0)	8.92 (7.9-9.2)	3.38 (2.2-5.0)	6.79 (5.7-8.3)	<0.0001
Circulation	4.78 (1.7-7.3)	8.63 (7.9-9.1)	1.87 (0.9-4.5)	5.90 (4.6-7.2)	<0.0001
Monitoring	4.45 (2.3-7.0)	8.63 (7.6-9.1)	2.50 (1.7-4.2)	5.49 (4.3-6.9)	<0.0001
Overall	5.26 (2.8-7.5)	8.75 (8.1-9.1)	2.80 (2.3-4.1)	6.73 (5.5-7.6)	<0.0001
Intensive care mortality (%)	37 (37)	5 (25)	26 (48)	6 (23)	$\chi^2=0.04$ (group 1 v group 2=0.07)
Hospital mortality (%)	45 (45)	7 (35)	30 (56)	8 (31)	$\chi^2=0.07$
Hospital mortality ratio (95% CI)	1.32 (0.96 to 1.76)	1.23 (0.49 to 2.54)	1.4 (0.94 to 2.0)	1.26 (0.54 to 2.48)	

*From Kruskal-Wallis test unless stated otherwise.

†Severity of illness according to acute physiology and chronic health evaluation score.

‡No of days between admission to hospital and intensive care.

§A includes non-survivors, B excludes non-survivors.

APACHE data⁷ and compared with actual mortality to produce a standardised mortality ratio.

Data from the questionnaires were made anonymous and sent to two extraregional intensivists assessors (GM, primary specialty anaesthesia and AS, primary specialty nephrology). Clinical notes were not included.

The assessors specifically considered quality of medical care and appropriateness and timeliness of admission to intensive care. Care considered suboptimal was defined and the causes outlined. A 10 cm linear analogue scale was used to score the adequacy of management of (a) oxygen therapy, (b) airway, (c) breathing, (d) circulation, and (e) monitoring.

The database was analysed with Microsoft Excel (Microsoft, Seattle, WA) and Minitab (Minitab, PA). Non-parametric data were compared using χ^2 and Kruskal-Wallis tests. A sample size of 100 was arbitrarily chosen and no estimate of clinical effect or power analysis was undertaken.

Results

Of the 100 patients admitted to intensive care, 51 were general medical, 28 general surgical, eight orthopaedic, three obstetrics and gynaecology, three urology, two neurosurgery, two ophthalmology, one ENT, one haematology, and one thoracic surgery. No significant differences were found between the two centres in age, sex distribution, incidence of inappropriate admission, late admission, or suboptimal care, and the casemix was broadly similar. Severity of illness was greater in Portsmouth than in Southampton (median APACHE scores 21.6 and 16 respectively) ($P=0.03$).

The assessors agreed that 20 patients (group 1) were well managed and that 54 patients (group 2) received suboptimal care. They disagreed on the quality of care before admission to intensive care in 26 patients (group 3) (table 1). For internal validation, assessors were separately asked to classify patients according to quality of care: 10.5% received excellent care (AS 4%, GM 17%), 21.5% received good quality care (AS 20%, GM 23%), 17.5% received adequate care (AS 25%, GM 10%), and 50.5% received inadequate care (AS 51%, GM 50%). In each quality of care group the casemix was broadly similar, with no significant differences in APACHE II scores between groups (table 1).

Agreement between assessors was moderate⁸: κ values for questions on late admission, appropriateness, and suboptimal care were 0.50, 0.50, and 0.42 respectively. The weighted κ value for categorisation into excellent, good, adequate, or inadequate care classes was 0.53. In groups 1, 2, and 3 intensive care mortalities were 5 (25%), 26 (48%), and 6 (23%) respectively ($P=0.04$). By partitioning the 3×2 table (mortality in table 1) into two separate 2×2 tables,⁹ a comparison of groups 1 and 2 gave a P value of 0.07. Hospital mortalities were 7 (35%), 30 (56%), and 8 (31%) ($P=0.07$) (table 1), and standardised mortality ratios were 1.23 (95% confidence interval 0.49 to 2.53), 1.4 (0.94 to 2.00), and 1.26 (0.54 to 2.48) respectively. More patients received suboptimal care (agreed by both assessors) before admission to intensive care in the intensive care non-survivors group (26/37, 70%) than in the survivors group (28/63, 44%) ($P=0.04$).

Admission to intensive care was considered avoidable definitely in 4.5% of patients, probably in 4%, and possibly in 32.5%, and in 7.5%, 7.5%, and 41.5%

respectively of group 2 (table 2). A minimum of 4.5% (definitely avoidable) and a maximum of 41% of adult emergency patients (sum of definitely, probably, and possibly avoidable) might have avoided admission to intensive care with better management of airway, breathing, and circulation.

The assessors agreed that 39% of the patients were admitted late in the clinical course, and disagreed on a further 25% of the patients (table 1). All patients in group 1 were admitted to intensive care at a time considered appropriate by the assessors. Of group 2 patients, 37 (69%) were admitted late ($P < 0.0001$), the source time (period between hospital admission and admission to intensive care) being longest in this group (table 1). Length of stay in intensive care was not significantly different between groups whether non-survivors were included ($P = 0.38$) or excluded ($P = 0.55$) (table 1).

Of the patients in group 2, the assessors concluded that suboptimal care contributed to morbidity or mortality definitely in 32.5%, probably in 21%, and possibly in 32.5% (table 2). Scores for management of oxygen therapy, airway, breathing, and circulation, and monitoring (table 1) were all lowest in group 2 patients ($P < 0.0001$).

Suboptimal care in group 2 patients occurred in similar proportions in the general medical (24/51, 47%) and general surgical (18/28, 64%) subpopulations (data not shown). Using APACHE II point deciles to divide the 100 patients into groups on the basis of severity of illness, the assessors agreed that suboptimal care occurred in 41-64% of patients in each decile (table 3).

The principle causes of suboptimal care were failure of organisation, lack of knowledge, failure to appreciate clinical urgency, lack of experience, lack of supervision, and failure to seek advice (table 4).

Discussion

Hospital mortality for critically ill patients is a complex function of age, surgical or medical status, elective or emergency status, comorbidities, physiological reserve, nature and severity of acute illness, and quality of care.⁷ Apart from long term sociopolitical strategies to improve the health of the nation,¹⁰ only quality of care and perhaps severity of illness (by earlier recognition of critical illness, intervention, and referral to intensive care) may potentially be influenced by clinicians.

The assessment of quality (and the quality of measuring it) is difficult and examination of the process may be more sensitive than measures of outcome.^{11, 12} All have limitations. This study, modelled on an earlier inquiry,¹ is subject to similar limitations of power and outcome bias. Like other studies^{1, 2} we relied on the opinions of assessors on what constituted suboptimal care and its causes (table 4), as objective definitions for all conceivable scenarios were impractical. Other limitations included assessor agreement (the existence of group 3 reflecting reality, where even experts frequently disagree), small patient numbers, and wide confidence intervals. These factors may explain why the mortality of group 3 was similar to group 1 rather than occurring between groups 1 and 2.

The statistically insignificant effect (at the 5% level) of gross variations in quality of care before admission

Table 2 Opinions of two independent extraregional assessors (AS and GM) on avoidability of admission to intensive care and how far suboptimal care contributed to morbidity or mortality

	Definitely	Probably	Possibly	Not at all	Total*
Admission avoidable?					
All patients (%):					$\kappa=0.43$
Assessor AS	1	5	37	57	100
Assessor GM	8	3	28	61	100
Overall mean (%)	4.5	4	32.5	59	100
Group 2 (No) (%):					
Assessor AS	1 (2)	5 (9)	27 (50)	21 (39)	54 (100)
Assessor GM	7 (13)	3 (6)	18 (33)	26 (48)	54 (100)
Overall mean (%)	7.5	7.5	41.5	43.5	100
Suboptimal care contributed to morbidity or mortality? (No) (%):					
Assessor AS	13 (24)	14 (26)	17 (31)	10 (19)	54 (100)
Assessor GM	22 (41)	9 (17)	18 (33)	5 (9)	54 (100)
Overall mean (%)	32.5	21	32.5	14	100

* κ weighted for interrater agreement.

Table 3 Stratification by APACHE II* deciles

APACHE decile	No of patients	Mortality†	No (%) of patients		
			Group 1	Group 2	Group 3
0-10	27	15 (19)	8 (30)	11 (41)	8 (30)
11-20	34	26 (35)	5 (15)	18 (53)	11 (32)
21-30	28	61 (68)	6 (21)	18 (64)	4 (14)
31-40	10	60 (80)	1 (10)	6 (60)	3 (30)
41-50	1	100 (100)	0	1 (100)	0
Total	100	37 (45)	20	54	26

*Acute physiology and chronic health evaluation score.

† Percentage of patients dying in intensive care (hospital).

Table 4 Causes of suboptimal care, and agreement between assessors

Causes	No agree "yes" (%)	No agree "no" (%)	No disagree (%)	No "yes" by at least one assessor (%)
Failure of organisation	37 (68)	3 (6)	14 (26)	51 (93)
Lack of knowledge	38 (70)	4 (7)	12 (22)	50 (93)
Failure to appreciate urgency	35 (65)	4 (7)	15 (28)	50 (93)
Lack of experience	16 (30)	12 (22)	26 (48)	42 (78)
Failure to seek advice	8 (15)	20 (37)	26 (48)	34 (63)
Lack of supervision	13 (24)	21 (39)	20 (37)	33 (61)
Medical staff not available	6 (11)	33 (61)	15 (28)	21 (39)
Other	0 (0)	44 (82)	10 (18)	10 (19)
Failure of equipment	1 (2)	50 (93)	3 (6)	4 (8)
Non-availability of equipment	0 (0)	47 (87)	7 (13)	7 (13)
Fatigue	1 (2)	48 (89)	5 (9)	6 (11)
Non-medical staff not available	1 (2)	51 (94)	2 (4)	3 (6)

to intensive care on mortality and standardised mortality ratios generated from the APACHE scoring system, may have several possible explanations: inadequate sample size (including the existence of group 3), APACHE is insufficiently sensitive for detecting the effect, quality of care before admission to intensive care has no impact on mortality, or greater mortality prevented by intensive care and post-intensive care factors.

As an index of quality of care in intensive care the reliability of APACHE and standardised mortality ratios have been criticised.¹⁵ APACHE purports to predict hospital outcome for populations of patients, therefore reflecting the totality of quality of hospital care. This study suggests that the quality of care before admission to intensive care may influence outcome. Casemix adjustment for the adult emergency patient at high risk may prove inadequate using APACHE as

Suggestions to improve quality of care before admission to intensive care

General

Recognition by referring teams that a problem of quality of care exists
Increased emphasis on care of critically ill patient by royal colleges in teaching and exams

Organisation and structure

Trainee intensive care posts open to all specialties in larger centres
Recognition of intensive care as a specialty
House officer posts in intensive care or anaesthesia for 3 months
Appointment of acute care (general) physicians to deal with acute medicine
Emphasise that prime roles of consultants are patient care (supervision of juniors) and teaching
Expansion of continuing medical education to a maintenance of standards programme allowing consultants to spend time accompanying and observing other clinicians' practice, including other specialties and subspecialties
Alter consultant sessions to recognise need to be involved in acute care and supervision and teaching of trainees
Multidisciplinary rotations of senior house officers: intensive care, accident and emergency, and major specialties
Expansion of accident and emergency departments to include acute admissions/high dependency unit facilities
Expansion of intensive care and high dependency unit facilities (close to intensive care). Rotate high dependency unit nurses into intensive care periodically

Clinical process

Improved recognition of serious illness, physiological derangements of airway, breathing, and circulation—make clinicians extra vigilant to physiological abnormalities ("physiology police")
Change the acute care ethos: when patients or volume of work are difficult call in a senior staff member
Increased hands on involvement of consultant in acute care
Acute care trainees require accreditation in appropriate advanced life support course (or should be sent on such course)
Extensive initial preparation programme for new doctors. Junior doctors should not be given responsibility unprepared and unsupported
Improved teaching of all grades of staff including medical students. House officers and senior house officers to spend a week in intensive care unit during medical and surgical posts
Replace cardiac arrest teams with medical emergency teams with defined calling criteria (see table 5)

Guidelines and audit

Cross specialty audit and morbidity, mortality, and critical incident meetings
Greater development of guidelines and best practice for patient management
Audit adherence to standards and guidelines
Consider peer review sessions to examine delivery of care
Recognise everyone makes mistakes and it is usually more educational to examine our errors than our successes. The emphasis should be on education and not vilification

elective and paediatric patients have low mortalities. These factors may explain the apparently high standardised mortality ratio of 1.23 in group 1, a figure identical to the standardised mortality ratio in the southwest Thames audit group (17 intensive care units, including Portsmouth¹⁴). The validity of standardised mortality ratios may also be compromised by lead time bias,¹⁵ where resuscitation instigated in intensive care may ameliorate physiology (and APACHE score) before transfer to intensive care,^{16 17} and the limited applicability of data, casemix, and practice from the United States to Britain.

The relevance of the suboptimal care received by 54% of this cohort before admission to intensive care is not negated by the lack of statistical significance for effect on outcome. The assessors believe suboptimal

care had a substantial impact on individual morbidity, mortality, and requirement for intensive care resources (avoidable admissions). Furthermore, in a more recent study in which 32 of 87 (37%) patients admitted to intensive care from the ward suffered suboptimal care, McGloin et al blinded their assessors to outcome, had a no disagree group, and found a highly significant increase in mortality in the group receiving suboptimal care.¹⁸ Although we believe our local situation has improved, McGloin et al's study suggests this may not be so universally. Clinically significant effects also occur if appropriate referrals to intensive care are delayed, refused, or transferred elsewhere, elective surgery is disrupted, and if direct or medicolegal costs are raised. Ethical dilemmas arise as to what, how, and by whom information on deficiencies of care should be imparted to patients and their families.

Suboptimal care occurred in 41-64% of patients in each APACHE decile—that is, at all levels of severity of illness. It is therefore probable that a similar pattern occurs in patients not referred to intensive care, a contention supported by others although not specifically addressed by this study.^{1 2 6}

Although length of stay in intensive care was not statistically different, the assessors believed between 4.5% and 41% of admissions were potentially avoidable. Thus better care before admission to intensive care may reduce intensive care bed days.

Failings of clinicians of all grades over a wide range of tasks and knowledge have been shown.¹⁹⁻²⁴ This study suggests a fundamental problem of failure to appreciate that airway, breathing, and circulation are the prerequisites of life and that their dysfunction are the common denominators of death. The assessors' conclusions on the causes of suboptimal care (table 4) suggest multifactorial organisational (structure) and clinical (process) problems. The box shows possible solutions.

The national confidential inquiry into peri-operative deaths recommends that surgical trainees should be actively trained, should readily seek senior advice, and should not operate unsupervised at night.¹

Table 5 Suggested minimum calling criteria for medical emergency team (modified from Lee et al²⁴)

Airway threatened by:
Impaired patency, obstruction eg stridor, burns, trauma
Impaired protection, eg depressed consciousness, bulbar dysfunction
Breathing:
Respiratory arrests
Respiratory rate <8 or >30
Acute hypoxia: partial pressure of oxygen <8 kPa on fractional inspired oxygen 0.6 (maximum possible on ward)
Acute hypercapnia: partial pressure of carbon dioxide >6.5 kPa
Circulation:
Cardiac arrest
Pulse (in sinus rhythm) <40 or >140 beats/min
Systolic blood pressure ≤90 mm Hg
Acidaemia: pH <7.20 (hydrogen ions >62 nmol/l)
Urine:
Acute oliguria: <30 ml/hour or <0.5 ml/kg/hour
Consciousness:
Glasgow coma score <12 or fall of 2 or more points
Repeated or prolonged seizures
Miscellaneous:
Patient causing concern to medical, nursing, or physiotherapy staff

Trauma reports recommend senior experienced input.²⁵ Few equivalent studies or recommendations to set standards for medical patients exist. In our cohort the majority of patients were treated predominantly by trainees, often unsupervised.²⁶ Some consultants acknowledge that their skills in acute general medicine could be improved.²⁷

With the exception of infarct related ventricular fibrillation, the outcome after cardiorespiratory arrest is fairly poor and most of these patients (60-80%) show premonitory signs.²⁸⁻³³ This supports changing emphasis from the traditional cardiac arrest team to a medical emergency team,³⁴⁻³⁶ aiming at early recognition of sick patients and prevention of cardiorespiratory arrest. Such a team, including an intensive care specialist registrar or consultant and medical specialist registrar or acute care physician, would attend all potentially life threatening abnormalities of airway, breathing, or circulation. Table 5 shows possible referral criteria. Pre-emptive action by the medical emergency team—that is, early recognition, referral, and decision making for sick patients, should enhance acute intensive medical care that is proactive. Adaptation to the rise in emergency work³⁷ has been advocated,³⁸⁻⁴⁰ and the recent Royal College of Physicians report is timely and welcome.⁴¹

All human practice (including that of doctors before, during, and after intensive care) has elements of excellence, adequacy, and deficiency, and the public deserves to know that quality of care is regularly examined. The study of error is not to apportion blame but to ask why and institute appropriate changes in organisation and clinical care.

Conclusion

In this study suboptimal care of severely ill patients before admission to intensive care was common and influenced morbidity, mortality, and requirement for intensive care. Remedial measures may substantially reduce emergency admissions to intensive care, and mortality. Although Osler noted many years ago that: "Patients do not die of their disease, they die of the physiologic abnormalities of their disease,"⁴² the concept of doctors as "physiology police" may have been lost. Training should emphasise that airway, breathing, and circulation are the prerequisites of life and their dysfunction are the common denominators of death. The greatest impact on the outcome from intensive care units may arise from improvements in input to intensive care particularly in the quality of acute care.

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Contributors: PMcQ conceived the idea, conducted a literature search, coordinated and participated in the design team, gathered half the data, assimilated and helped analyse the data, interpreted the results, and wrote the major drafts of the paper; he will act as guarantor for the paper. BT and GS were original core design team members, assimilated and analysed some of the data, and contributed to drafting the paper. SP assimilated and helped analyse the data and contributed to drafting the paper. AA gathered much of the data and commented on the paper. DB helped analyse the data. GM and AS helped in the later design stages, refined the data collection documents, assessed all the raw data, and contributed to the formulation of

Key messages

- Suboptimal management of oxygen therapy, airway, breathing, circulation, and monitoring before admission to intensive care occurred in over half of a consecutive cohort of acute adult emergency patients. This may be associated with increased morbidity, mortality, and avoidable admissions to intensive care
- At least 39% of acute adult emergency patients were admitted to intensive care late in the clinical course of the illness
- Major causes of suboptimal care included failure of organisation, lack of knowledge, failure to appreciate clinical urgency, lack of supervision, and failure to seek advice
- A medical emergency team may be useful in responding pre-emptively to the clinical signs of life threatening dysfunction of airway, breathing, and circulation, rather than relying on a cardiac arrest team
- The structure and process of acute care and their importance require major re-evaluation and debate

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Hormone replacement therapy and risk of hip fracture: population based case-control study

Karl Michaëlsson, John A Baron, Bahman Y Farahmand, Olof Johnell, Cecilia Magnusson, Per-Gunnar Persson, Ingemar Persson, Sverker Ljunghall on behalf of the Swedish Hip Fracture Study Group

Editorial by Khaw

Department of Orthopaedics, University Hospital, S-751 85 Uppsala, Sweden

Karl Michaëlsson
senior registrar

Departments of Medicine and Community and Family Medicine, Dartmouth Medical School, Hanover, New Hampshire, USA

John A Baron
professor

Department of Medical Epidemiology, Karolinska Institute Box 281, S-171 77 Stockholm, Sweden
Cecilia Magnusson
research fellow

Ingemar Persson
reader

Department of Epidemiology, Stockholm County Council, 171 76 Stockholm, Sweden

Bahman Y Farahmand
statistician

Per-Gunnar Persson
reader

continued over

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Abstract

Objective: To determine the relative risk of hip fracture associated with postmenopausal hormone replacement therapy including the effect of duration and recency of treatment, the addition of progestins, route of administration, and dose.

Design: Population based case-control study.

Setting: Six counties in Sweden.

Subjects: 1327 women aged 50-81 years with hip fracture and 3262 randomly selected controls.

Main outcome measure: Use of hormone replacement therapy.

Results: Compared with women who had never used hormone replacement therapy, current users had an odds ratio of 0.35 (95% confidence interval 0.24 to 0.53) for hip fracture and former users had an odds ratio of 0.76 (0.57 to 1.01). For every year of therapy, the overall risk decreased by 6% (3% to 9%): 4% (1% to 8%) for regimens without progestin and 11% (6% to 16%) for those with progestin. Last use between one and five years previously, with a duration of use more than five years, was associated with an odds ratio of 0.27 (0.08 to 0.94). After five years without hormone replacement therapy the protective effect was substantially diminished (-7% to 48%). With current use, an initiation of therapy nine or more years after the menopause gave equally strong reduction in risk for hip fracture as an earlier start. Oestrogen treatment with skin patches gave similar risk estimates as oral regimens.

Conclusions: Recent use of hormone replacement therapy is required for optimum fracture protection, but therapy can be started several years after the menopause. The protective effect increases with duration of use, and an oestrogen-sparing effect is achieved when progestins are included in the regimen.

Introduction

Menopause is accompanied by accelerated bone loss^{1,2} and by an increase in the incidence of fractures such as those of the hip.^{3,4} Many studies have shown that hormone replacement therapy can reduce bone loss^{5,6} and the risk of hip fracture.⁷ However, the dose and duration of treatment needed, the duration of the protective effect after treatment is stopped, the influence of age at which treatment is initiated, and the efficacy of different hormone replacement therapy regimens remain unclear. We carried out a large, population based, case-control study to evaluate these issues.

Subjects and methods

The study was conducted in the Swedish counties of Stockholm, Uppsala, Västmanland, Örebro, Göteborg, and Malmöhus. This largely urban area in the middle, west, and south of Sweden includes nearly half of the 8.6 million inhabitants of Sweden.

Cases

We aimed to ascertain all cervical, pertrochanteric, or subtrochanteric fractures of the proximal femur among women resident in the study area who were born in 1914 or after and treated during October 1993 to February 1995. Using hospital discharge records or operation registers in all 24 hospitals in the study area we identified 2597 possible incident cases. We excluded those with a fracture due to malignancy (n=26), high energy trauma (n=4), incorrect diagnosis (n=41), old fracture (n=10), blindness (n=5), birth outside of Sweden (n=202), a diagnosis of severe alcohol misuse, psychosis, or senile dementia (n=576) or death within three months of the fracture (n=123). All hospital records were scrutinised to confirm eligibility and to ascertain type of hip fracture and previous hip fracture.