



Research | CAHTA 1998 Call for Grants

Scientific Report

The Catalan Agency for Health Technology Assessment and Research is a public non-profit organisation created in May 1994. Its mission is to promote the introduction, adoption, dissemination and use of medical technology in accordance with criteria of proven efficacy, safety, effectiveness and efficiency, and to promote research geared towards the health needs of the population and those of knowledge of the health system. The Agency is a collaborating centre of the World Health Organisation in the assessment of medical technology, it is a founding member of the International Network of Agencies for Health Technology Assessment (INAHTA), and is a Coordinating centre of the Network of Cooperative Research for Investigation in Health and Health Service Research (IRYSS Network).

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Preface

In 2001 we presented the results of the call for research issued by CAHTA in 1996 with the support of CatSalut, the Catalan Health Service. To do this, we organized a special open session and published a scientific report. Now, we are pleased to do the same for the results of the call for research of 1998, issued with the support of the CatSalut and of the CIRIT of the Department of Universities, Research and the Information Society. Five years may seem a short time, but the fact is that the CAHTA, which closely monitors the projects in its annual scientific reports, has been witness to the impressive progress made. Indeed, some of the finished projects, under the direction of the researchers themselves, have been published by the CAHTA as brief reports (Breus).

Publicizing the results and presenting succinct but accurate summaries of the results of the research projects reflects the agency's desire for transparency and openness. After all, these projects are being funded by public money. Specific thematic areas are chosen for the calls for applications and the projects are selected via a process of peer review in which the quality of the projects and the abilities of the research team are assessed. If we look back to the call for applications of 1998, 51 projects were proposed for the 20 thematic areas, and in the end 20 of the projects were awarded funding in excess of 85 million pesetas (510,860 euros).

The importance of the thematic areas proposed seemed to be beyond question. But it is only in the examination of the results that a definitive assessment of their value can be made. By their value we mean not only the considerable level of scientific production and their achievement in bringing the scientific community to a wider audience, but also the impact of the results, that is, whether they are able to establish themselves in medical practice and contribute to its advancement. Indeed, the result that really matters is whether or not we are able to increase the efficacy and efficiency of the care we offer to the sick.

The search for answers to questions referring to the effects of medical interventions is inherent to the practice of medicine itself: even more so in an era of such rapid scientific and technological change. We hope that this report of the CAHTA (CatSalut-CIRIT) call for research of 1998 will be a reflection, albeit a partial one, of the will of the scientific and medical community of our country to find answers to these questions that continue to fascinate us.

Joan MV Pons

Director

Presentation

The presentation of the report of the projects funded in 1998 fulfils CAHTA's undertaking to publish information on the resources invested. The decision to grant funding to some projects and not to others was the result of a careful process of evaluation and prioritization by the CAHTA and the scientific committee. Whether or not the right decisions were taken is something that can only be judged in the long term, once the results of the projects have been assessed. This report closes this process and allows us to appraise the results achieved.

In addition to this report, the CAHTA is holding an open session in which the leaders of the projects present their most important results. For the research groups that obtained funding, the report and the open session represent the important moment in which they justify the aid that they received.

However, the lasting impact of their efforts will depend on the extent to which the information contained in this document actually becomes a useful vehicle for improving this function of commissioning research projects in important areas of health and health care in our country. For this reason we hope that this report will be an invitation to the professionals, institutions and organizations involved in improving health care to let us know their opinions and proposals for future calls for applications.

As we all know, one of the CAHTA's most important aims is to improve the services provided by evaluating their efficacy and efficiency. The processes through which the results of the evaluations lead to improvements of services are by no means simple and the results of the research are often lost in the immense sea of information available today. In this respect as well this report is an invitation to see the results of the various projects and the experience acquired by the authors as potentially relevant inputs for the improvement of our health care services.

Our sincere thanks to all those who have contributed to this report and, especially, to all CAHTA members.

Josep M. Antó

President of the Scientific Committee

Projects |

Scientific Report



VARIABILITY IN HEALTH CARE PRACTICE AND OUTCOMES OF TRAUMA CARE IN ROAD TRAFFIC INJURY CASES IN CATALONIA, SPAIN. A MULTICENTER STUDY

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Objective

- to assess and describe the variations in practices and results of care provided to road trauma patients by five different health care systems in Catalonia
- to promote the creation of population information systems to facilitate the study of the incidence, severity and outcomes of injuries in the general population
- to describe variations in basic pre-hospital and hospital care procedures
- to describe variations in expected survival according to injury severity and location, for each care system
- to describe variations in injury outcomes regarding quality of life and disabilities taking into account patient characteristics

Design

- cross-sectional study at the individual level, using information collected in the different trauma care systems among road injury cases
- use of the TRISS methodology to assess the probability of survival
- use of the SF-36 questionnaire to assess the impact of injury at discharge and six months after the injury.

Results

1. Trauma care:

- 1.1 There were significant variations ($p < 0,01$, Kruskal Wallis test) in the time elapsed between the crash and the arrival at the hospital of the injury case, either when taking into account the receiving hospital or the pre-hospital acting system.
- 1.2 The profile of the medical team varied by center and patient.
- 1.3 There were no significant differences among centers regarding the time elapsed until the performance of a cranial CAT-scan in patients with a GCS < 12.
- 1.4 Forty five per cent of patients with injuries in AIS 1 and 2 regions wore a cervical collar at their arrival to the hospital.
- 1.5 There were no significant differences among centres in the time to treatment in case of internal injuries or open fractures.

2. Survival after injury:

The application of the TRISS methodology, using available regression coefficients, indicated that all centers reached standard survival rates, although there were substantial differences between them. The overall observed survival exceeded by 6,6% the expected standard survival probability.

3. Disability after injury:

The use of the SF-36 questionnaire while in the hospital to measure pre-injury health status yielded values similar to the baseline values measured for the Spanish population according to age. Mean values for each dimension decreased significantly at 6-months after the crash. This was especially the case for the physical role –changing from 94,7 to 31,9- and the emotional role –from 96,6 to 48,9. At six months, only 32% of patients returned to their previous occupation. Forty-four percent of patients were still on leave of absence from work, while 8% had changed their job; three percent were in a permanent disability status and 6% were unemployed.

Implications

It is necessary to coordinate prehospital and hospital care to the injured. It is also necessary to implement clinical guidelines. It is necessary to develop trauma registry systems that allow us a better understanding of trauma pathology and to evaluate the obtained outcomes.

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ANALYSIS AND CLASSIFICATION OF HOSPITAL EMERGENCIES BY MEANS OF THE AMBULATORY PATIENT GROUPS (APG)

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Introduction

Patients' classification systems (PCS), as diagnosis related groups (DRG), allow for the measurement of hospital resources' use. However, the increasing importance of ambulatory care, raise the need to develop and test new PCS that provide an accurate measure of these activities. Information systems are less developed in this field, and reimbursement is based on a fixed price system, unrelated to the clinical complexity of each case and resources use.

Since 1980, there are some ambulatory PCS, like the Adjusted Clinical Groups (ACG), useful in primary health care, and the Ambulatory Patient Groups (APG), useful in hospital outpatient's care.

The aim of the present study is to describe the feasibility and the results of the application of APG system to patients seen in the Emergency Departments (ED) of five large teaching Hospitals in Barcelona (Spain), and to evaluate the comprehensiveness, amount and quality of information recorded in the ED discharge reports.

Methods

Development of a specific Uniform Discharge Data Set for the ED activity (UDDS-ED). Pilot validation test (1999). Codification of the clinical variables of the UDDS-ED with ICD.9.CM (diagnosis) and with the Current Procedural Terminology (CPT-4) (procedures) of a random sample of emergency discharges, representative of each one of the participating hospitals (1999-2000) from the corresponding ED discharge reports. Assessment of the degree of legibility and comprehension of the report. Application of the APG system to the selected episodes.

Results

We analyzed 11.188 reports of patients treated and discharged from ED in the five participating hospitals. Mean age of the patients was 36 years (SD: 26 years). 27% were included in the age group under 15 years (pediatric group). The 15 more common diagnostics identify 25% of all episodes. The most frequent conditions are acute bronchitis, gastroenteritis, fever, nasopharyngitis/common cold, acute otitis media, chest pain, low back pain and renal colic. Up to 50% of all procedures were basic and common procedures. Fifteen APG account for 50% of ED episodes. The more frequent APGs were those related with upper respiratory tract infections and flu-like symptoms, mild gastrointestinal diseases, exacerbations of chronic respiratory conditions, eye and skin diseases and minor bone and joint disorders. Thirty-nine per cent (39%) reports were found to have enough and readable information. However, the interpretation of the written information was deemed to be fairly difficult in 46% cases and very difficult in the remaining 15% of reports.

Implications

The UDDS-ED is a valid instrument to describe the case mix of the ED activity. Its classification with APG fulfills clinical and specificity criteria. Formal quality and comprehensiveness of the information included in ED discharge reports is a critical factor for the precision and usefulness of any registry of data and patients classification systems where the use of a UDDS is necessary. The widespread application of systems like APG in ED requires a prior validation of the USA weight (resource use indicator) values in our setting. It is also necessary to take into account the availability of human and technical resources needed to guarantee the quality and continuity of a registry of these characteristics.

Publications

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SECONDARY PREVENTION OF MYOCARDIAL INFARCTION AND HEALTH RELATED QUALITY OF LIFE

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Introducció

Good evidence from randomised controlled trials have found that pharmacological interventions in people with established ischaemic coronary events substantially reduces the risk of cardiovascular mortality and morbidity. Nevertheless, it is also true that results from clinical trials sometimes are difficult to implement in clinical practice. The objective of this study is to assess the level of control of modifiable risk factors, of prophylactic treatment and of quality of life in patients with a first myocardial infarction.

Methods

Prospective study, of two years of follow-up, carried out in 4 public hospitals and in the primary care centers of the reference area of these hospitals, in Catalonia.

Results

618 patients were included, 76% were male, mean age of 64 years. Patients were mostly followed at the same time by general practitioners and specialist, and the prevalence of risk factors was as follows: 54% of the patients had hypercholesterolemia, 41% were hypertensives, 11% were smokers, 76% were overweight and 19% were obese. Concerning prophylactic treatment, lipid lowering drugs were prescribed in 52% of the patients, beta-blockers in 50%, antiplatelets drugs in 87%, ACE inhibitors in 32%, nitrates in 52%, and calcium antagonists in 31%, and anti-coagulants in 8%. Mean scores of quality of life questionnaire were 5,34, 5,42 and 5,63 for the emotional role, physical role and social role respectively, being worst the subgroup of patients who were hospitalised during the follow up.

Implications

There is still a considerable potential to gain in secondary prevention of myocardial infarction, either in raising prophylactic treatment or in the control of risk factors. Health-related quality of life in patients two years after myocardial infarction is fairly good, although differences in subgroups of patients were observed.

Publications

Investigation Group of PREMISE Study. Prevención secundaria del infarto de miocardio y calidad de vida relacionada con la salud. *Med Clin* 2002;119:9-12.

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MANAGEMENT OF HEART FAILURE: COORDINATION BETWEEN HOSPITAL AND PRIMARY CARE.

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Introduction

A very important aspect in the treatment of heart failure (HF) is the knowledge of characteristics and evolution of real clinical practice patients, who are usually different from those of clinical trials. The objective of this study was to assess the process of care of patients with heart failure attended in a tertiary hospital and follow up at the primary care level.

Methods

Prospective 18-month follow up study. The clinical records of the patients admitted to Hospital General Vall d'Hebron between July 1st and December 31st, 1998, where HF was mentioned as a first or second discharge diagnosis and that fulfilled the inclusion criteria were identified and included. The patients were interviewed by phone 18 months after discharge in order to get information about their care process during that period.

Results

265 patients were included in the study. Mean age was 75 years, 42% were male, 19% had been admitted for conditions different from HF, and 62% had significant comorbidity. In 68% ventricular function was assessed (basically in those with a better prognosis) and it was normal in 41%. Angiotensin converting enzyme inhibitors or angiotensin II antagonists were administered in 54% and beta-blockers in 4%. Follow up data were obtained from 92% of patients. 18-month mortality rate was 46%; in 77% of these, death was due to cardiac causes. The independent predictors of mortality were older age, biventricular HF, past history of HF and comorbidity. Eighteen months after discharge, 69% of survivors had functional class I or II. 38,5% had been readmitted for HF, 72% were seen by the general practitioner, and 43% in the hospital outpatient clinic. 33% were seen by a cardiologist outside the hospital. In only 6% of survivors, ventricular function was assessed in primary care. Drug therapy prescribed at discharge was essentially maintained during follow up. Eighteen months after discharge, 76% walked outdoors daily and 25% were doing recreational activities or physical exercise.

Implications

The patient population cared for HF has advanced age, high comorbidity rate and a poor prognosis, needing a remarkable amount of health care expenditure, both at the hospital and after discharge. The observed management patterns showed much room for improvement and prescribed drug therapy was suboptimal. Comorbidity had a substantial impact on prognosis. In a remarkable proportion of survivors, everyday activities were preserved

Scientific publications

Permanyer G, Soriano N, Brotons C, Moral I, Pinar J, Cascant P et al. Características basales y determinantes de la evolución en pacientes ingresados por insuficiencia cardíaca en un hospital general. *Rev Esp Cardiol* 2002;55(6):571-8.

Soriano N, Brotons C, Permanyer G, Moral I, Alegre I, Martí J. La atención médica de los pacientes con insuficiencia cardíaca: características clínicas, determinantes del pronóstico y seguimiento en la atención primaria. *Aten Primaria* 2002; 29(9): 531-539.

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PROSPECTIVE STUDY OF THE RISK OF NOSOCOMIAL HEPATITIS C INFECTION

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Introduction

Nosocomial transmission of hepatitis C virus (HCV) has been well documented in last years. These evidences generate social alarm and have become a major concern among health-care workers and health authorities about the magnitude of the risk, the main transmission routes and the control measures effectiveness in the hospital setting. Available information refers to sporadic cases or puntual outbreaks, but there are no studies assessing the actual incidence of the problem. Nearly 50% of patients with HCV do not report known risk factors and history of previous surgery or invasive procedures is commonly described. The objective of this study is to know the incidence of nosocomial HCV infection in patients undertaking surgical or invasive procedures .

Methods

Observational prospective study in patients admitted to Vall d'Hebron Hospital and with surgery or invasive procedures performed during hospitalization (gynecology, obstetrics, cardiac, gastrointestinal and traumatologic surgery, digestive endoscopic procedures, angiography and cardiac catheterism). An epidemiological survey including possible risk factors was performed to all patients. A basal blood sample to determine previous hepatitis C infection and a second determination 30-90 days later to analyze a posible seroconversion (anti-HCV antibodies and HCV-RNA) were carried out. Serological examination was accomplished by a third-generation enzymeimmunoanalysis and confirmation test was performed by RIBA III.

Results

Since december 2000, 1.649 patients were included (851 attended in Obsterics and 798 in Ginecology Department). Benign tumors were the most frequent cause of ginecological surgery (51,6%) and eutocic delivery in Obstetrics (32,8%). Previous HCV infection was reported in 0,4% of the patients. Basal HCV infection prevalence was 0,97% (95%CI:0,56-1,57) (16 patients); higher percentatges were found in ginecological patients (1,75%; 95%CI:0,96-2,92) than in obstretrics ones (0,24%; 95%CI:0,03-0,84) ($p<0,01$). Age (mean: 56,5 years among infected patients vs 39,2 among those non infected) ($p<0,001$) and previous patient knowledge of the infection (25% vs 0,18%) ($p<0,001$) were the only risk factors associated with the presence of HCV infection. 75% of seropositive patients did not know their serologic status. Follow-up has been completed in 697 patients and no cases of nosocomial HCV transmission has been detected.

Implications

Despite the studied sample is still insufficient to draw conclusions, preliminary results suggest that HCV prevalence in these subgroup of patients is similar to those of general population. A favourable evolution towards decreasing HCV infection prevalence has been observed among the youngest cohorts. Important limitations appeared during study development, including professional consent to go on with the study and the patients follow-up. Currently, pediatric patients are being included.

Scientific publications

Campins M, Reina MD, Vaqué J, Elorza JM, Esteban I, Cabero L, Xercavins J. Prevalencia de infecció per el virus de la hepatitis C en pacients sometidos a cirurgia obstetrícia y ginecológica en un hospital de tercer nivel. Prog Obst Ginecol

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EPIDEMIOLOGY OF BACTERIAL RESISTANCE IN THE AREA OF BAIX LLOBREGAT

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Introduction

Infection caused by resistant microorganisms, either in the community or in the hospital setting, is a current problem that produces important healthcare expenses. The main factors that contribute to the appearance of this resistance are: microorganism factors, host factors and antibiotic consumption.

Methods

Prospective study of 5.142 episodes of bacteremic infection during the period 1999-2001, with the following participating hospitals: Hospital de Bellvitge, Hospital de Viladecans and Hospital de La Creu Roja de l'Hospitalet. A clinical-epidemiological study, a microbiological investigation of the isolates and an analysis of antibiotic consumption are included.

Results

In community-acquired bacteremic infection, the prevalence of antibiotic resistance was similar in the three centers.

Overall, *Escherichia coli* was resistant to ampicillin in 62%, to cotrimoxazol in 31%, to ciprofloxacin in 19% and to amoxicillin-clavulanic in 9%. An increase in the resistance to ciprofloxacin and amoxicillin-clavulanic was observed in parallel with an increase in the consumption of these antibiotics.

Resistance of *Streptococcus pneumoniae* to penicillin has remained stable at around 30-40%. Resistance to macrolides and cephalosporins reached levels of 20%. Resistance to cephalosporins was not associated with an increased mortality. The most important risk factors of resistance to cephalosporins were prior antibiotic use and infection caused by certain serotypes.

Regarding hospital-acquired infections, great differences have been observed between the three hospitals due to the characteristics of each center and their inpatients.

Overall, *Staphylococcus coagulase negative* has maintained a resistance to cloxacillin around 60-70%. Resistance of *Staphylococcus aureus* has undergone variations depending on the epidemic strains, maintaining a resistance level to cloxacillin around 20%, being most of these strains multiresistant. No vancomycin-resistant enterococci isolates were found and resistance to gentamicin was 24%.

Pseudomonas aeruginosa has reached levels of resistance to imipenem of 16%, to ceftazidime of 15%, to gentamicin of 26% and to ciprofloxacin of 21%. Infection by *Acinetobacter baumannii* has been an important problem, with more than 80% of the strains resistant to imipenem and to other antibiotics.

The overall consumption of antibiotics between 1992 and 2001 in the Costa de Ponent Healthcare Area (community consumption) ranged from 14 to 17 DDD/1000 persons/day. An increase in the consumption of amoxicillin-clavulanic, oral cephalosporins (cefixime, cefuroxime) and new macrolides (clarithromycin and azithromycin) has been observed. The global consumption of quinolones increased during the 80s and it has become stable in recent years, with a decrease in the consumption of urinary quinolones and an increase in systemic quinolones.

The consumption of antibiotics in the hospital increased from 56,5 DDD/100 admissions/day in 1990 to 64,59 DDD/100 admissions/day in 2001. Among penicillins, there was an increase in amoxicillin-clavulanic and piperacilin-tazobactam, whereas classic penicillins decreased. Consumption of cephalosporins decreased particularly due to the first-generation cephalosporins and most recently, to the third-generation cephalosporins. Consumption of quinolones increased significantly, glycopeptides consumption remained low and aminoglycoside consumption decreased.

Implications

The prevention of the infection caused by resistant microorganisms should be a priority issue in the community as well as in the hospital setting and it has to be considered from a multidisciplinary approach. The appropriate prescription of antibiotics and the implementation of measures to prevent the transmission of these microorganisms in the healthcare setting is essential. The data from our study have shown the prevalence of antibiotic resistance and its correlation with antibiotic consumption in our area.

This study has also demonstrated that the increase in pneumococcal resistance to cephalosporins is not associated with an increased mortality. These data were presented at the NCCLS Experts Committee (National Committee for Clinical Laboratory Standards, USA; <http://www.nccls.org>) and have contributed to change the resistance definitions or "breakpoints" to cephalosporins for the non-meningeal pneumococcal infections.

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DETERMINATION OF THE CRITERIA FOR QUALITY IN EMERGENCY HEALTH CARE SERVICES: INDICATORS

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2. Avedis Donabedian Foundation

Introduction

Emergency Hospital Services (EHS) constitute the area of health care which has experienced the quickest and most profound changes during the second half of the 20th century, caused by the rapid increase in demand, among other factors. Thus, the frequency of hospital emergencies in Catalonia has experienced an almost 20% increase between the years 1992-1998, with 3,653,507 visits in the year 1998 alone (20.7% of all the hospital emergencies in the Spanish state).

Emergency health care is constantly subjected to evaluation and critique by both its users and its doctors who continue to care for the patient once he or she has been taken care of by the Emergency Service.

This work constitutes an exhaustive reference of quality indicators applied to Emergency Medicine, and it is fundamentally a work reached by consensus, in which numerous professionals in our country have participated as part of a working group or as consultants, following a rigorous methodology that has included many different types of assessments and contributions that have contributed to enhancing its value.

Objective

1. Based on the scientific evidence available, to reach consensus on the criteria for quality in emergency health care services.
2. To design indicators for measuring these agreed-upon criteria.

Methods

This work has been carried out by a group of 11 professionals in emergency hospital care, with coordination and methodological advice from the Avedis Donabedian Foundation. This was complemented by 21 professionals who acted as consultants in the areas of: internal medicine, surgery, paediatrics, psychiatry, nursing, traumatology, gynaecology and central services. Nine successive meetings were held in which the prior individual work of each of the participants was integrated via consensus, reaching an initial draft with 118 indicators.

First, the aspects related to care based on pathologies tended to in emergencies, types of activities carried out, and the areas in which these activities were chosen. Then, a selection was made according to risk, prevalence and degree of variability in clinical practice.

The indicators were approved after reaching consensus in the working sessions, where the indicators that best met the conditions of validity, sensitivity, specificity and feasibility were included. They were then passed on to each consultant for his or her revision. After that, a twofold stage of consensus was begun following the delphi technique, with participation by the 36 hospitals.

Results

The final document consists of 103 indicators reached by consensus among all the participants. Their distribution according to quality dimensions is: 31 on effectiveness, 30 on safety, 13 on efficiency, 13 on appropriateness, 6 on accessibility, 5 on satisfaction and 5 on continuity of care. In addition, 5% are on organisation, 70% on processes and 5% on results.

Finally, there are 15 indicators which are considered fundamental, the application of which is recommended to all hospitals.

Implications

The use of these “indicators” by professionals will provide information on the quality level of the service being provided while at the same time identifying the weak points in patient care, resource management, satisfaction, and so forth. As these indicators are implemented by emergency services in Catalonia, a wide base of global data will be available, and benchmarking actions will also become feasible.

Scientific publications

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VARIATIONS IN THE USE OF RESOURCES FOR STROKE CARE: IMPACT ON COSTS AND OUTCOMES. (ACCIVAS STUDY)

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Objective

To quantify variations in the resources used and the costs of stroke care in four hospitals in Catalonia.

To assess variations in survival and quality of life of stroke patients after the initial hospital admission, and after three and twelve month follow-up.

To measure the impact of variations in care on mortality, disability and quality of life.

Methods

Design, setting and patients: the study had a longitudinal design. For a period of one year, patients admitted in any of the four participating hospitals in the study were included. Cases were detected through daily review of emergency services and admission registry. Information for each patient was collected during the initial hospital stay at three and twelve months.

Data collected: Socio-demographic data, stroke risk factors, severity of stroke and clinical results, including mortality, Barthel and Rankin index, utilization of resources in the hospital, at primary care and community level, and of patient and caregiver were collected by a nurse.

Analysis: For categorical data analysis we used Chi-Squared test and logistic regression. To assess variations in survival and the relationship with health care or stroke risk factors, Kaplan Meier and Cox regression models were used respectively.

Results

A total of 637 (51% male and 49% female) patients were included in the study. In hospital A, 85% of patients were admitted to Internal Medicine in contrast to 15% in hospital B, 92% in hospital C, and 49% in hospital D. Only hospital B had 25% of patients admitted to a Neurology ward. There were huge variations in the provision of rehabilitation services. The mean number of sessions provided ranged from 4 to 52% for physiotherapy and from 0 to 9% for speech therapy. Mean length of stay inclusive of death ranged from 15 to 28 days. The percentage of patients dying in the hospitals differed significantly between hospitals, ranging from 12 to 25% ($p=0,03$) at discharge and ranging from 18 to 32% ($p=0,045$) at three months. However, in a Cox proportional hazards model we could not find significant differences in survival between hospitals. However we found significant differences within hospital wards in hospital D. In this hospital the RR of dying was 4,68 (CI 95% 1,32 – 4,90) if the patient was admitted in wards other than internal medicine or geriatrics. The strongest factors predicting survival were age and level of consciousness.

Implications

The aspects of care that need to be modified to improve outcome remain unclear despite detailed data collection. From these results, we can not advice on rational policy decisions to be made. Further analysis is being carried out in order to improve the knowledge about the implications of the variations in care.

Scientific publications

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ANALYSIS OF THE PRE-HOSPITAL AND IN-HOSPITAL CARE OF CANCER PATIENTS. IDENTIFICATION OF DEFICIENCIES IN THE COORDINATION OF THE VARIOUS LEVELS OF CARE IN ONCOLOGICAL DISEASES

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Introduction

The aim of the present study was to evaluate the care process (pre-hospital and in-hospital levels) experienced by individuals diagnosed and treated for cancers in a hospital (lung, digestive tract, ENT, and urological), identifying the temporal aspects, visits and diagnostic tests performed in both care levels during this process.

Method

The study included all incident cancer cases in the Hospital del Mar for the following cancers: lung, digestive tract (oesophagus, stomach, small intestine, colon, rectum), urological (prostate, bladder), and ENT (mouth, pharynx, larynx) diagnosed between 1 January 2000 and 30 April 2001, residents in the catchment area (Ciutat Vella with 5 Primary Care Centres, and Sant Martí with 10). Cases were identified using information available to the Hospital del Mar Tumor Registry (discharges, pathology reports, tumor committees). The procedure applied to each case identified included: a) face to face interview using a structured questionnaire; reliable interviews were obtained from 58% of patients; b) data from the primary care information system was collected for 90% of cases (at one year prior to the date of diagnosis); c) review of the primary care clinical record, carried out in 77%; and d) review of the hospital clinical record, carried out in 100% of patients.

Various time intervals were measured relating to the Symptom-Diagnosis-Treatment process, and analysed in terms of type of neoplasm, sex, most prevalent symptom, diagnostic process (not including extension diagnoses), the different visits and tests, type of admission (emergency or programmed), and the level of coordination between Hospital and Primary Care Centre (i.e. assessment of implementation of Reformed Primary Care).

Results

Initially, 506 patients were recruited, of whom 75 were excluded due to errors in the address, date of diagnosis being prior to the study period, because the primary cancer was of another site, or because the cancer had been diagnosed in the hospital with no pre-hospital or symptomatic phases. Hence a total of 431 patients were finally analysed 79,4% men, and 20,6% women. The median age was 68,6 years. Tumour distribution by site was: 34,1% digestive tract, 28,8% lung, 27,3% urological, and 9,7% ENT. Ciutat Vella district accounted for 56,1% of cases, and Sant Marti 43,9%. Reformed Primary Health Care centres accounted for 71,4% of cases.

Interval from symptom to first contact with health system: median of 31 days over all sites: among digestive tract cases, the median was 34 days, 68% presented toxic syndrome; lung cancer cases had a median of 27 days, 78% presented toxic syndrome; prostate cancer 24 days, 39% presenting prostatic syndrome; bladder cancer 30 days and 80% presenting hematuria; finally, in ENT cancer cases the median was of 49 days, 44% presented dysphonia.

The interval between first contact and histological diagnosis had a median over all sites of 74 days: digestive tract 75 days, lung 55 days, prostate 111 days, bladder 90 days, and ENT 61 days. We observed that 80% of patients visited their GP, even though only 59% of visits prior to diagnosis took place in primary care (47% GP, 12% a specialist) and 56% of patients went to the hospital emergency department. The variety and quantity of diagnostic tests carried out (8-22) is similar for all cancer sites. In the analysis of this interval by type of hospital admission we observe a median of 68 days for emergency admissions, and 80 days for those programmed ($p < 0,03$). In the analysis comparing Primary Care with Hospital/ Reformed Primary Care found a median of 71 days in Reformed Primary Care centres, compared to 85 days for non reformed centres.

The interval from diagnosis to first treatment had a median of 18 days over all sites: digestive tract 17 days, lung 18, prostate 18, bladder 39, and for ENT 14 days.

Implications

Given the data here presented we may affirm that for any one of the symptoms under consideration, most of the patients are visited in primary care, half of them within 30 days, not an excessive time if we take into account that for most sites the manifestation of symptom is unspecific.

On the other hand, the interval between first contact and histological diagnosis is the longest of the whole care process, although it becomes shorter if the patient goes to emergencies or comes to hospital via a Reformed Primary Care centre.

The variety and quantity of prior diagnostic tests and visits are the main culprit in the prolonging of this interval. To improve this situation it would be necessary to improve hospital-primary care coordination, with the aim of obtaining a rapid diagnosis, and to implement a unified circuit of tests and visits for patients of this type.

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ANALYSIS OF FACTORS DETERMINING THE APPEARANCE OF BACTERIAL RESISTANCES TO ANTI-BIOTICS IN GIRONA PROVINCE. MODELING AND PREDICTION USING TIME-SERIES MODELS

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SECTION A

Objective: A modification of the Andersen-Gill gamma shared frailty model was presented in these papers/presentations.

In particular, the variance of the frailty was directly modelled by means of a generalised linear model and also the EM algorithm was modified in order to simultaneously estimate a semiparametric model for the failure times, and a model for the variance of the frailty.

Methods: A simulation study was conducted to evaluate the performance of the proposed algorithm, which it is called the EMB algorithm, and to compare it with other methods, a marginal model (the Prentice, Williams and Peterson model) and a conditional one (the penalised Cox model).

Multivariate data from a nosocomial infection study was used to illustrate the methods.

Results: In both the simulation and the application, the EMB fit turned out to be better than the fit obtained from a marginal model (PWP) or from a conditional one (penalised Cox model). In this sense, the EMB provided the best fit (being the least overdispersed and having the highest AIC and the highest pseudo-R square) and estimated the parameters most efficiently.

Summarising, the proposed method in this paper is able to capture and to take into account unobservable random effects in semiparametric models.

SECTION B

Objective: Three objectives were addressed in these papers/presentations.

First, we would like to assess which factors, either those associated with patients (such as underlying health impairment and the disease process as well as the severity of disease) or those related to the ICU (such as the use of invasive devices or treatment methods) were the most relevant in explaining the occurrence of a nosocomial infection (NI) in the ICU of a medium-sized public hospital in Girona, Spain. In fact, we were not only interested in the occurrence of a NI but, above all, in the time to the onset of a NI. This fact demanded the use of proper statistical methods, say survival analysis.

Our second, and main objective, was a little more ambitious. A typical ICU patient has several episodes of infection during her/his stay. It is reasonable to assume that episodes within a patient stay would be dependent, i.e. the probability of a second episode would be higher than the probability of a first, and so on. Not taking into account of such dependence leads to misleading, i.e. biased, results. In these papers we introduced an original statistical method for obtaining adjusted risk factors for NI, that explicitly took into account the dependence between episodes within a patient stay. Furthermore, above all, our method allowed the factors that explain the dependence between recurrences (that is to say, subsequent episodes within a patient stay) to be determined. We hypothesized that the importance of the explanatory variables of both, the probability of an occurrence and the duration of a NI episode could differ depending if it was the first one or, otherwise, a recurrence. This could held in the development

of preventive measures and of techniques to modulate immune defences.

As a third objective we repeated our analysis with resistant NI, in order to estimate adjusted risk factors for them.

Methods: A prospective study was performed between March 15 and June 15, in 1999 and in 2000, including all patients admitted for at least 24 hours to the ICU. In order to obtain adjusted risk (hazard) factors for infection we followed a proportional setting that allows that dependence to be explained. Using this method we were also able to identify the factors that explained the dependency between recurrences

Results: Our main finding was that, even controlling for intrinsic risk factors, i.e. those associated with the susceptibility of the patients as a consequence of the severity of their illness, extrinsic factors, i.e. the diagnostic and therapeutic procedures used in ICU, led to a higher risk of i) the occurrence of ordinary and resistant nosocomial infections, and also of; ii) the probability of a recurrence, i.e. a subsequent infection, during the patient's stay in the ICU.

Scientific publications

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HOME HOSPITALIZATION OF EXACERBATED COPD PATIENTS. A RANDOMIZED CONTROLLED TRIAL OF CLINICAL EFFICACY AND COSTS OF SERVICES FOR CHRONICALLY ILL PATIENTS

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Objective

We postulated that home hospitalization (HH) of selected patients with Chronic Obstructive Pulmonary Disease (COPD) exacerbations admitted at the emergency room (ER) could facilitate better outcomes than conventional hospitalization at lower cost. Moreover, because of the high rate of early relapse (approximately one third of patients require re-admission within 8-weeks), the study aimed at the identification of independent predictors of relapse to generate specific recommendations for home-based healthcare services.

Methods

To this end, 222 COPD patients (age 71 ± 10 (SD) yrs) from two tertiary hospitals (35% of all screened COPD patients) were randomly assigned to HH (n = 121) or conventional care (CC n = 101). During HH, integrated care was delivered by a specialized nurse with patient's free-phone access to her ensured for a 8 weeks follow-up period.

Results

HH showed better outcomes than CC assessed by: 1) lower rate of ER visits ($0,13 \pm 0,43$ vs $0,31 \pm 0,62$, HH and CC, respectively) ($p < 0,01$); 2) noticeable improvement of quality of life (DSGRQ, $-6,9$ vs $-2,4$) ($p = 0,05$) not observed in the CC group; 3) better patient's knowledge of the disease (58% vs 27%) ($p < 0,001$) and enhanced self-management of his/her condition (81% vs 48%) ($p < 0,001$); and, 4) greater patient's satisfaction ($p = 0,03$).

The average marginal impact of the intervention (HH) on the individual cost of a patient with average severity, conditional on other patient characteristics, is a 35,9% cost decrease at 8 weeks ($p = 0,003$). The integrated HH intervention (HH) can be resource saving in comparison with CH in exacerbated COPD patients admitted in an emergency room. According to patient characteristics, the magnitude of monetary savings attributed to the HH intervention was even higher for more severe patients considered eligible for the intervention.

The analysis of independent predictors of early relapse (ER or hospitalization admission or death) showed that health related quality of life (HRQL) variables at entry were the main predictors (poor general condition, OR 3,72, $p = 0,005$; severe breathlessness, OR 3,07, $p = 0,031$; and, SF-12 physical domain, OR 0,96, $p = 0,051$). Because of their clinical relevance, previous hospitalizations during last year (OR 1,23, $p = 0,17$); and, FEV1 % pred. (OR 0,99, $p = 0,23$) were also included in the logistic model. A separate analysis was carried out to examine the explanatory role of the changes observed during the follow-up period. It is of note that among all covariates considered, the increase in physical activity during the 8-week period (OR 0,176, $p = 0,001$) was the only significant explanatory variable of early relapse. Followed by enhancement of arterial oxygenation (OR 0,99, $p = 0,081$) that showed a weaker association with lower re-admission rate.

Implications

We concluded that a comprehensive homecare intervention in selected COPD exacerbations appears as cost effective: the home hospitalization intervention generates better outcomes at lower costs than conventional care. The study provides evidence-based information to support the decision making process in exacerbated COPD facilitating specific recommendations for home-based care and it prompts speculations (cell hypoxia ?) that might help to explain poor outcomes in subgroups of COPD patients.

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EFFICACY AND EFFICIENCY IN PERCUTANEOUS TREATMENT OF HEPATIC TUMORS BY RADIOFREQUENCY

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Introduction:

Nowadays, there is a wide experience in percutaneous treatment of hepatic tumors with alcohol injection under ultrasound control. This method has shown an obvious efficacy, however, limitations in the number of sessions needed, the limited effective size of the tumor and the useless effect in metastases, has prompted the research of other physical methods aimed to obtain a complete necrosis of the tumor while preserving hepatic function.

Objective

To investigate the use of radiofrequency (RF) in the treatment of hepatocellular carcinoma (HCC) and hepatic metastases. Assessment of antitumoral efficacy, tolerance and cost. As a secondary aim, detection of malignant circulating cells in relation with the therapy.

Methods

Patients with HCC (unique <5 cm or 3<3 cm) histologically proved or with concordant positive imaging diagnosis plus AFP in the context of liver cirrhosis and patients with metastases confirmed through histology or assessed with diagnostic imaging in the context of known primary neoplasm, were included.

To evaluate circulating cells, two blood samples of 32 patient were obtained. RNA messenger corresponding to AFP in peripheral cells was analyzed.

In 20 patients, a biochemical evaluation of hepatic function was determined at 6 and 24 hours after the RF treatment.

RF was performed with Radionics® equipment provided with cool tip needles. Multiple insertions were performed to obtain a complete necrosis of the tumoral area. If persistence of tumor during the follow up at 24 hours and 1 month was detected (US-Doppler and CT), a new RF treatment was performed. In case of more than 90% necrosis, the viable tumor was treated by alcohol injection.

Criteria of exclusion: lesions in the proximity of great vessels, gallbladder and intestinal structures; arrhythmia and impaired coagulation.

Results

Twenty eight out of 44 consecutive patients were treated (64% applicability). Time employed in each treatment: 8 to 66 minutes. Mean insertions number: 1,9 per patient. Good tolerance and absence of changes in hepatic function. There was no increase in circulating malignant cells.

Complete response to treatment at 1 month was 64%, but during the follow up local recurrence or new lesions appeared. After 6 months, 46% of the patient were free of disease.

Despite short hospital stay, the cost of RF procedure was higher than the cost of PEI.

Late complications: at 6, 7 and 18 month, peritoneal seeding was detected in patients with subcapsular lesions treated with RF.

Implications

Criteria of inclusion and exclusion of the patients was newly defined.

Efficacy of the RF in a short series was assessed.

Evaluation of the risk and efficiency of the method.

Scientific publications

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ANALYSIS OF THE INDICATIONS, EFFECTIVENESS AND COSTS OF TOTAL KNEE ARTHROPLASTY

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Introduction

Osteoarthritis is the most common locomotor system disease affecting human beings, also accounting for the highest economic and social costs, especially in most developed societies.

The anatomic region most affected by osteoarthritis in the locomotor system is the knee. In Catalonia, knee osteoarthritis occurs in 9.9% of the population aged between 18 and 75, and this rate rises to 31.1% among the population aged over 65.

Advanced-stage knee osteoarthritis is treated with total knee arthroplasty (TKA). For this reason, it is becoming increasingly important to evaluate the effectiveness, indications and costs of this kind of treatment.

Objective

1. to describe the prognosis of advanced-stage knee osteoarthritis.
2. to determine the appropriate guidelines and the priority criteria for TKA
3. to establish and validate an evaluation protocol which may be used in the hospitals of our country.
4. to state the effectiveness of short-term TKA (1year)
5. to evaluate the prognosis factors related to the achievement of better or worse outcomes
6. to establish the surgery cost in order to analyse the cost-benefit relation
7. to determine the effectiveness of long-term TKA (15 years at the most) in our environment

Methods

Three main studies have been carried out in order to meet these aims:

Study 1. Prospective study of all patients who were attended at external consulting rooms in Vall d'Hebron Orthopedics Hospital with TKA indication in 1999; n = 250.

Study 2. Prospective study of all patients who were operated on TKA in our hospital during 1999; n=250.

Study 3. Retrospective study of all patients who had a total knee replacement in our hospital between 1986 and 1997; n=1.500.

The following measuring instruments were used to develop these 3 studies:

- A "specific" measuring instrument to evaluate pain, knee function and knee physical examination: knee rating scale of the American Knee Society
- A "generic" measurement instrument to evaluate the patient's self-perceived health: Nottingham Health Profile (NHP)
- Protocol for collection of demographic and diagnosis data, co-morbidity, surgery sheet data, clinical evolution, stay and complications
- Radiographic analysis of knee osteoarthrosis and the knee with TKA
- Procedure costs questionnaire

Results and Implications

The most important conclusions regarding clinical implications obtained from a detailed analysis of the different studies outcomes are the following: :

1. If the worst clinical evolution outcomes in patients suffering knee osteoarthritis waiting for surgery are to be found in women aged between 66 and 70, with a Kellgren radiographic score over grade III and a score under 50 points in the knee rating scale of the American Knee Society, our opinion is, –without considering sociological factors- that these patients have to be given surgical priority. .
2. The importance of specific and generic measuring instruments when controlling waiting lists and outcomes in this kind of surgery has to be pointed out. Considering the good results obtained in our research work, we suggest the knee rating scale of the American Knee Society as a specific measuring instrument and the Nottingham Health Profile as a generic measuring instrument.
3. In this study, acute infection is the unique factor associated to the worst outcomes one year after the surgery. For this reason, in this kind of surgery, it is essential to underline the importance of antibiotic prophylaxis and to maximise aseptic measures in the surgical area and in hospitalisation units.
4. If the TKA cost is similar to the non-surgical knee osteoarthritis cost considering life expectancy, it can be affirmed that surgical treatment with TKA is more useful since it solves short, medium, and even long-term, medical and social problems regarding knee osteoarthritis.
5. The TKA prognosis factors which provide worst long-term outcomes are infections, prior osteotomy and a wrong placement of implants. For this reason, nowadays it is not advisable to force tibial osteotomy indications and maximise technical precision when placing implants
6. Best outcomes are obtained with superficial TKA, especially using most-advanced implants.
7. Worst outcomes are obtained in young patients. For this reason, it is important to prolong TKA indication to the maximum extent.

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THE COM99 STUDY: A CLUSTER-RANDOMIZED TRIAL OF AN INTERVENTION TO IMPROVE COMPLIANCE WITH MEDICATION

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Introduction

Adherence to blood pressure medications is an important factor in achieving adequate blood pressure control. COM99 is a clinical trial whose objective is to estimate the efficacy of an intervention to improve adherence and BP control.

Methods

Cluster randomised-trial. Forty two physicians from hospitals and primary care centers were randomly allocated to the intervention or control groups (I or C). Patients (>49 years) had non-controlled essential systolic and/or diastolic hypertension and high or very high cardiovascular risk according to the 1999 WHO-ISH risk stratification. A multilevel intervention was implemented in the I group. Adherence was measured electronically in each patient for 6 months with the eDEM system (AARDEX®). BP readings were obtained in each visit with a validated semiautomatic sphygmomanometer (OMRON 705-CP). Two hundred patients had 24 hours ambulatory BP measurements (ABPM) taken at baseline and after 6 months (Spacelabs 90207 device). The trial was actively monitored to perform quality data assurance as well as external auditing.

Results

Six hundred one patients have been recruited and data from 461 patients that have completed 6 months of follow-up are presented. There were 239 patients in the C group and 222 in the I group. Patients (C and I) were comparable (% , average, or median), and neither clinical nor statistically significant differences were observed for male sex (56,5 and 48%), age (66 and 66), number of drugs (2 and 2), IMC (30 y 31), creatinine (1,25 and 1,15 mg/100), tobacco use (12 and 13%), DM (55 and 58%), and risk factors (1,8 and 1,8). Physicians were also comparable for age, sex, and training. Baseline SBP and DBP were 160/87(C) and 160/87 (I). After six months of follow up, 38% of patients in the I group had their SBP controlled (<140mmHg) compared with only 22% in the control group ($p<0,05$). There were no differences in DBP control (75 and 75%). There was available information on adherence measurements for 540 patients and there were not statistically significant differences on adherence to drugs (mean adherence 90% vs. 91%).

Implications

Preliminary data show that the intervention is effective in reducing systolic blood pressure in patients at high cardiovascular risk. However, no differences between groups were found in adherence measurements. Electronic measurements of adherence might have positively influenced adherence in both groups and this would explain the high adherence levels found at 6 months of follow-up in the patients analyzed so far.

Scientific publications

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OUTCOMES OF SECOND EYE CATARACT SURGERY. A RANDOMIZED CONTROLLED TRIAL.

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Objective

The persistent increase of the demand and rate of cataract surgery has led to a debate about the benefits of surgery in the second eye. Previous studies have observed some benefits, specially in patient-reported visual disability and stereopsis. The purpose of this study was to assess the benefits of cataract surgery in both eyes (intervention group) compared to surgery in one eye only (control group).

Methods

A two-arm randomized controlled trial has been performed on patients from the ophthalmology departments of two teaching hospitals. Inclusion criteria were bilateral cataracts and indication of first eye cataract surgery (visual acuity of 0,3 logMAR or worse in both eyes). Patients with severe ocular comorbidity were excluded. The main outcomes were: binocular logMAR visual acuity, binocular log contrast sensitivity, log stereopsis (depth perception) and patient-reported visual disability (Visual Function Index VF-14). The VF-14 is a questionnaire that measures the degree of difficulty of the patient in carrying out 14 activities potentially related to vision (e.g. reading small print, watching TV). A secondary outcome was patient-reported health status measured by Short Form SF-12. An analysis was performed by comparing the 4 to 6 months postoperative visits between groups: after the second eye for the intervention group and after the first eye for the control group. The change related to the baseline (no surgery) was also compared.

Results

Of 296 patients included in the study, 148 were randomized to the intervention group and 148 to the control group, having similar baseline characteristics. Data of the postoperative visit was available for 139 patients of the intervention group and 135 patients of the control group. The clinical outcomes presented statistically significant differences between groups for visual acuity and stereopsis: the intervention group presented a better LogMAR visual acuity (difference of 0,07, 95%CI from 0,03 to 0,12), a higher proportion of cases with a good visual acuity ($\leq 0,1$ logMar): 46,0% vs 26,7%, and a lower proportion of cases with a low visual acuity ($>0,3$ logMar): 2,2% vs 14,8% ($p < 0,001$). Log stereopsis was 0,62 log sec arc (95%CI from 0,45 to 0,79) better in the intervention group, and no patients of the intervention group presented no measurable stereopsis or 3.000 sec arc, while 18,5% of the control group did. No significant differences were found for contrast sensitivity: difference of 0,04, 95%CI from -0,002 to 0,087. Patient-reported visual disability (VF-14) was 8,2 points better for the intervention group (95%CI from 4,4 to 12,4). Patient-reported health status (SF-12) was similar between groups for the physical dimension: mean of 47,5 for the intervention group vs 46,2, but the difference was statistically significant for the mental dimension, being better for the intervention group: 52,5 vs 51,2 points.

Implications

This study suggests that there is benefit related to second eye surgery in bilateral cases with indication for surgery in both eyes, mainly for perceived visual function and stereopsis, being marginal for visual acuity. It is also important to consider the role shown for both eyes surgery in reducing the occurrence of bad outcomes of surgery in one eye only and increasing the proportion of good outcomes. For this reason, the decision of operating the second eye should be specially supported in stereopsis and patient-reported visual disability, as well as visual acuity, and based on the outcomes of first eye surgery.

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EVALUATION OF PREVENTIVE INTERVENTIONS TO DECREASE THE INCIDENCE OF CARDIOVASCULAR DISEASES IN PRIMARY CARE, CONSIDERING THE AVAILABLE SCIENTIFIC EVIDENCE ON EFFECTIVENESS, SAFETY, COST-EFFECTIVENESS AND PATIENT'S BASAL RISK. THE RISK PROJECT.

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Introduction

Cardiovascular diseases are the first cause of death and hospitalization and one of the most common problems in primary care. Guidelines for clinical practice from different scientific societies have recommended the identification of the absolute risk or probability that a patient suffers an acute coronary event in presence of risk factors in order to take therapeutic decisions.

Multivariate equations or risk tables derived from the NorthAmerican longitudinal study of Framingham (FRA) have traditionally been used to quantify coronary risk. However, comparisons of FRA with the Seven Countries Study and other posterior European studies, suggested that FRA equations overestimate risk in European populations where ischaemic heart disease mortality is lower than in NorthAmerica.

The objective of the RISC Project is to validate the FRA equations in our population.

Methods

FRA multivariate equations were applied to the individual risk factor of the MONICA-Catalonia cohort study carried out in 1986-88, including 2.571 subjects aged 25 to 64 years (50.3% women) followed-up for ten years. This allowed to estimate the individual risk of presenting an acute coronary event fatal or non-fatal in the next ten years and the expected number of coronary events in the MON cohort according to FRA risk. MON multivariate functions were calculated separately using the same FRA Cox models and variable definitions. The risk factors considered were: age, smoking, systolic blood pressure, total/HDL cholesterol, left ventricular hypertrophy and diabetes. The end-points considered were fatal or non-fatal acute myocardial infarction, unstable angina, ischaemic heart disease and sudden deaths. The coronary event observed/expected relationship was compared by FRA, by the recent European SCORE study and to the average incidence for the same period of the MON population register. The distribution of the coronary risk in our population by FRA and own equations was compared. Statistical analysis was carried out with the SPSS-9® package.

Results

60 coronary events were observed in ten years. The expected number was 54 (O/E = 1.1) (MON register), 25 (O/E = 0.80) coronary deaths (SCORE), while 210 (O/E = 0.29) were expected by FRA.

The median (P50) risk or probability of presenting a coronary event in the following ten years among the MON population was 10% in men and 2,3% in women by FRA, and 1,7% and 0,4% respectively by own equations. 20% of men and 2,4% of women presented a coronary risk greater than 20% by FRA and only 1,2% (men) and 0,1% (women) by MON. The ratio of median risks calculated by both equations was 3,6 for men and 4,3 for women. The sensitivity and specificity of FRA versus MON equations vary by age and risk level. The largest contribution to coronary risk in Catalan men is made by smoking.

Implications

These results imply that the use of FRA risk equations in our population is inadequate and might imply an over pharmacological treatment

Scientific publications

Conroy RM, Pyörälä K, Fitzgerald AP, Sans S, Menotti A, DeBacker G et al . Estimation of ten-year risk of fatal cardiovascular disease in Europe: the SCORE project. Eur Heart J 2003; 24: 987-1003.

DeBacquer G, Ambrosioni E, Borch-Johnsen K, Brotons C, Cifkova R, Dallongeville J, Ebrahim S, Faergeman O, Graham I, Mancia G, Manger Cats V, Orth-Gomér K, Perk J, Pyörälä K, Rodicio JL, Sans S, Sansoy V, Sechtem U, Silber S, Thomsen T, Wood D. European guidelines on cardiovascular disease prevention in clinical practice Full text: Third Joint Task Force of European and other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of eight societies and by invited experts). *Eur J Cardiovasc Prev Rehab* 2003; 10 (suppl 1): S1-S78.

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COST-EFFECTIVENESS OF ANTIDEPRESSANT PHARMACOTHERAPY IN PRIMARY CARE. A RANDOMISED STUDY THAT COMPARES THE EFFECTIVENESS AND COST-EFFECTIVENESS OF FLUOXETINE WITH IMIPRAMINE IN PRIMARY HEALTH CARE

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Introduction

Most of the treatments for depressive disorders are prescribed at a primary care setting (PCS). Previous research are not conclusive about comparative effectiveness of antidepressant pharmacotherapy for different depressive disorders. There are only a few cost-effectiveness studies conducted under common clinical conditions. The following is a cost-effectiveness study comparing imipramine (IMI) and fluoxetine (FLU) for treating depressive disorders in a PCS.

Methods

Participating primary care physicians offered participation to all patients that should be prescribed an antidepressant treatment for a depressive disorder. All patients should sign the informed consent. Patients taking an antidepressant medication during the previous 60 days were excluded from the study. After inclusion, patients were randomised to either IMI or FLU therapy. Physicians decided all treatment patterns following their clinical criteria (dosage, visits, referrals). Patients were evaluated at baseline and after three and six months by a mental health professional, blind to antidepressant prescription, using the SCID-I diagnostic interview, the MADRS and HDRS clinical scales and the EuroQOL quality of life scale.

Results

103 subjects were included (53 to the FLU group and 50 to the IMI one). There were no significant statistical differences between groups in sociodemographic and clinical variables. Ninety four (91,3%) patients had at least a follow-up evaluation. Drop-outs were similar between groups. At 30-day follow-up, mean dosis was 20,7 mg/day (sd= 4,6) for the FLU group and 58,3 mg/day (sd= 30,3) for the IMI. Depressive symptoms improved during the 6-month follow-up. When comparing subjects by diagnostic group, we found that subjects with major depression (MD) treated with IMI improved more at 30 days ($p < 0,05$). Clinical differences between FLU and IMI groups decreased at the 90- and 180-day evaluation and were not statistically significant. Subjects who had a depressive disorder that did not meet DSM-IV MD or dysthymic disorder criteria and took FLU had a greater improvement at 30-day follow-up than patients taking IMI. FLU was associated with higher total costs throughout every evaluation.

Implications

Patients with depressive disorders treated in primary care show clinical improvement; 2) IMI seems to be a better cost-effective alternative for treating MD than FLU; 3) FLU seems to be a more effective treatment for subjects who have a depressive disorder that does not meet DSM-IV MD or dysthymic disorder than IMI, but associated costs are higher; 4) IMI dosis prescribed by primary care doctors were low (50-75 mg) but effective; 5) Most of the patients with a depressive disorder treated with an antidepressant medication did not meet DSM-IV MD or dysthymic disorder criteria

Scientific publications

Gabarrón E, Vidal JM, Haro JM, Boix I, Jover A, Arenas M. Prevalencia y detección de los trastornos depresivos en atención primaria. *Atención Primaria* 2002; 29: 329-336.

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DEFINITION OF INDICATIONS AND SUITABILITY CRITERIA FOR SURGICAL INTERVENTIONS VIABLE FOR MAJOR AMBULATORY SURGERY IN CATALONIA

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Objective

The increasing demand for surgical intervention in the western world has forced health care systems to adapt to changes in demography, morbidity and technology, at the same time maintaining the standards of quality and equity of the system. Alternative health care systems such as Major Ambulatory Surgery (MAS) have been introduced to meet this challenge, and represent a change in the health care process rather than the introduction of new surgical techniques. The aim of MAS is to maintain safety and efficacy levels while improving the cost effectiveness of certain surgical interventions of selected patients. The object of this study is to examine the extent and typology of MAS and conventional surgery activity over the period 1994–1998 in several hospitals in Catalonia, as well as evaluating the resources used, the clinical effectiveness, and the safety and satisfaction of patients who underwent surgery during the period 1999–2000.

Methods

A combined retrospective (1994–1998) and prospective (1999–2000) observational study was carried out describing the processes and results of the 15 most common MAS procedures at 21 hospitals of the Network of Public Hospitals (XHUP) of Catalonia. Information on MAS and conventional surgery for the 15 selected procedures performed at the 21 participating hospitals during the period 1994–98 was collected during the retrospective phase, along with the characteristics of each participating hospital and the indications for MAS each hospital established. In the prospective phase, indicators of effectiveness, safety and satisfaction were registered in a sample of the main procedures used by MAS (post-operative complications and patient satisfaction were obtained via a telephone interview). Each hospital consecutively registered all interventions corresponding to the 15 selected procedures until they reached the sample size established by each centre (corresponding to the activity in 1998). During the study a predominance of cataract procedures was observed and in order to obtain significant data on the other procedures it was decided to reduce the cataract sample, selecting 1 in 3. The sample size measured was of 2.500 interventions.

Results

MAS has become well established in Catalonia in the last few years, with a Substitution Index of 18% in 1994 and 41% in 1998, and with 23.000 interventions estimated for the year 2.000 in the 15 procedures studied. The majority of interventions using MAS in Catalonia are for cataracts (46%) followed by carpal tunnel, inguinal hernia and varicose veins (about 7% each). Mean time of hospitalization for MAS was 5 hours (97 minutes preoperative stay, 48 minutes duration of surgery and 151 minutes postoperative stay). Length of hospitalization varied according to procedure and also according to the hospital. Most patients who undergo MAS are not severe cases, 90% are ASA I-II. Likewise, MAS is a safe process with a very low incidence of complications (1,4%), the majority of which were hospitalized. Postoperative complications occurred in 35% of cases and were mostly minor: headache (14%), pain (11%), and nausea or vomiting (9%). Patients consulted some health care service after hospital discharge in 10% of cases. Finally, patient satisfaction with MAS was considered to be high, with an average score of 77%.

Implications

MAS appears to be a health care alternative of similar safety and effectiveness as conventional surgery for selected patients without severe conditions, and one that optimizes length of hospitalization which will affect efficiency and management of waiting lists.

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KNOWLEDGE AND COMPLIANCE WITH ANTIHYPERTENSIVE THERAPY IN PRIMARY HEALTH-CARE: RESULTS OF A RANDOMISED TRIAL. RUNNING HEAD: COMPLIANCE WITH ANTIHYPERTENSIVE THERAPY

Prime Investigator: Ester Amado Guirado

Co-primer investigator: Enriqueta Pujol

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Introduction

Hypertension is a risk factor that is diagnosed, evaluated and followed up almost exclusively by primary health care services, and is one of the most frequent reasons for consultation

Main objective

To evaluate the effectiveness of a nurse-led educational intervention in patients with hypertension in the improvement of:

- awareness of disease, the importance of a healthy lifestyle and anti-hypertensive medication
- compliance with medication and recommendations for a healthy lifestyle
- follow-up of hypertension

Methods

Design

Multi-centred, prospective study, patient randomisation by primary healthcare centre, and follow-up of one year.

Setting

36 urban primary healthcare centres; 18 as intervention group (IG) and 18 as control (CG).

Participants

Patients aged <80 years with hypertension (n=996; 515 in IG and 481 in CG) being treated with anti-hypertensive drugs on an outpatient basis. 487 participants were necessary in each group. Patients with severe mental and sensory disorders or major physical impairment were excluded.

Mesures

Each patient filled in one questionnaire at baseline and four during follow-up

Measurements

Questionnaire on knowledge and awareness of the disease and medication; compliance with treatment; follow-up recommendations for healthy lifestyle; systolic (BPS) and diastolic (BPD) blood pressure and body mass index (BMI) measurements at each visit.

Intervention

3-stage education program

Nurses receive training in the use of anti-hypertensive drugs (focusing on side effects and interactions)

Patients are given a written health care report at each visit

Patients receive verbal and written healthcare information and a leaflet.

Results

Follow-up was 87,4% (871/996) at which disease awareness increased by 24,9% in IG and 17,5% in CG ($p < 0,001$) and of medication by 9,6% in IG and 6,3 % in CG ($p = 0,03$). Compliance with medication, as measured by the Morisky-Green test, increased by 8,6% in IG and by 8,1% in CG ($p = \text{NS}$). There were no differences in compliance with the other measuring instruments used. BPD in IG decreased by a mean of 1,38 mmHg (95%CI: -2,14 to -0,62). Mean anti-hypertensive drug intake and BMI increased in the CH group.

Implications

Instruction intervention had a considerable impact on the awareness of the disease and its treatment. Compliance was less affected as were the levels of blood pressure and the consumption of anti-hypertensive drugs. The nurse's role is to educate patients with regard to medication, diet and healthy lifestyles, especially those who consult the health centre less frequently.

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TABLE SUMMARY. SCIENTIFIC ACTIVITY INVOLVED IN EACH PROJECT

Projects	Papers	Congress/courses communications	Others Papers
01/14/98	Secondary prevention of myocardial infarction and health related quality of life. Premise study	2 (Med Clin; Farm Pract)	
01/44/98	Evaluation of preventive interventions to decrease the incidence of cardiovascular diseases in primary care, considering the available scientific evidence on effectiveness, safety, cost-effectiveness and patient's basal risk. The risk project.	3 (Eur Heart; Eur J Cardiov Prev Rehab; Rev Esp Salud Pública)	6
02/24/98	The com99 study: a cluster-randomized trial of an intervention to improve compliance with medication: preliminary results.	1 (Med Clin)	1
02/51/98	Knowledge and compliance with antihypertensive therapy in primary health-care: results of a randomised trial. Running head: compliance with antihypertensive therapy		
05/05/98	Efficacy and efficiency in percutaneous treatment of hepatic tumors by radiofrequency	3 (Hepatology; Gastroenterol Hepatol)	20
07/20/98	Epidemiology of bacterial resistance in the area of baix llobregat	9 (Formación Médica Continuada en Atención Primaria; Arch Intern Med; AATRM; Am J Med; Eur J Clin Microbiol Infect Dis; Scand J Clinical Infect Dis; An Int Med; Lancet)	3
07/50/98	Analysis of factors determining the appearance of bacterial resistances to antibiotics in girona province. Modeling and prediction using time-series models.	4 (Intern J. Antimicrob agents; Gac Sanit; J Mod Appll Stat Meth; J Hosp Infect)	6
08/02/98	Home hospitalization of exacerbated copd patients a randomized controlled trial of clinical efficacy and costs of services for chronically ill patients		7
09/28/98	Variations in the use of resources for stroke care: impact on costs and outcomes. (Accivas study).	1 (Cerebrovascular Diseases)	1
10/31/98	Outcomes of second eye cataract surgery. A randomized controlled trial.		
11/43/98	Analysis of the pre-hospital and in-hospital care of cancer patients. Identification of deficiencies in the coordination of the various levels of care in oncological diseases		
12/15/98	Management of heart failure: coordination between hospital and primary care.	2 (Rev Esp cardiolo; Aten primaria)	1
13/48/98	Definition of indications and suitability criteria for surgical interventions viable for major ambulatory surgery in catalonia.		6
15/47/98	Cost-effectiveness of antidepressant pharmacotherapy in primary care. A randomised study that compares the effectiveness and cost-effectiveness of fluoxetine with imipramine in primary health care.	1 (Aten Primaria)	
16/17/98	Prospective study of the risk of nosocomial hepatitis c infection	1 (Prog Obst Ginecol)	
18/09/98	Analysis and classification of hospital emergencies by means of the ambulatory patient groups (apg)	4 (Med Clin; Gac Sanit; Papeles Médicos; Supl Annals de Medicina)	1
18/25/98	Determination of the criteria for quality in emergency health care services: indicators	3 (AATRM; Annals de Medicina)	6
19/06/98	Variability in health care practice and outcomes of trauma care in road traffic injury cases in catalonia, spain. A multicenter study.		10
20/19/98	Analysis of the indications, effectiveness and costs of total knee arthroplasty		



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