

**An Assessment Study of the Effect of
Cost and Dose on the Hemodialysis Treatment in Colombia**

by
Victor H. Nunez

ISBN: 1-58112-077-X

DISSERTATION.COM



1999

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published by

Dissertation.com
1999 • USA

ISBN: 1-58112-077-X

www.dissertation.com/library/112077xa.htm

NORTH CENTRAL UNIVERSITY

**AN ASSESSMENT STUDY OF THE EFFECT OF COST
AND DOSE ON THE HEMODIALYSIS TREATMENT
IN COLOMBIA**

A Dissertation submitted to
the graduate faculty of the College of Business and Management
In candidacy for the degree of

DOCTOR OF PHILOSOPHY

By

VICTOR HUGO NUNEZ

Prescott, Arizona
June 1999

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DISSERTATION ABSTRACT

Name : Victor H. Nunez Degree : Doctor of Philosophy
Major Field : Business & Management Awarded: June 19, 1999
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Location : Prescott, Arizona

Title of Dissertation: AN ASSESSMENT STUDY OF THE EFFECT OF COST
AND DOSE ON THE HEMODIALYSIS TREATMENT IN
COLOMBIA

Scope of Study: This dissertation investigates the effect of cost and dose on the hemodialysis treatment modality. This modality of dialysis is an alternative to renal transplantation for people diagnosed with end-stage renal disease. The mortality rate is used as a quality indicator of the hemodialysis treatment by assessing the quality of service in Colombia and comparing it with the quality of service in the United States.

Findings and Conclusions: The hypothesis testing used in this research shows that there is a significant difference between the delivered dose of hemodialysis in Colombia and the United States. The mortality rate for patients in hemodialysis in Colombia for a comparable age group (45-64) is higher than that of the United States. This is attributed in great part to the effect of the hemodialysis dose on the treatment. A simple linear regression shows a strong negative relationship between mortality rate and dose. Cost also has an impact on the quality of service of the hemodialysis therapy. Nevertheless, a direct relationship between cost and mortality rate could not be established. Factors such as patient's vascular access and dialyzer flow rates are not evaluated in this investigation.

Chair's Approval: Judith L Forbes Date 7/13/99

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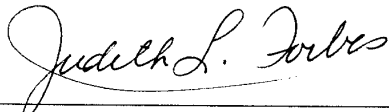
APPROVAL

We the undersigned, certify we have read this dissertation and approve it as adequate in scope and quality for the degree of Doctor of Philosophy.

Learner: Victor H. Nunez

Title of Dissertation: AN ASSESSMENT STUDY OF THE EFFECT OF COST AND DOSE ON THE HEMODIALYSIS TREATMENT IN COLOMBIA.

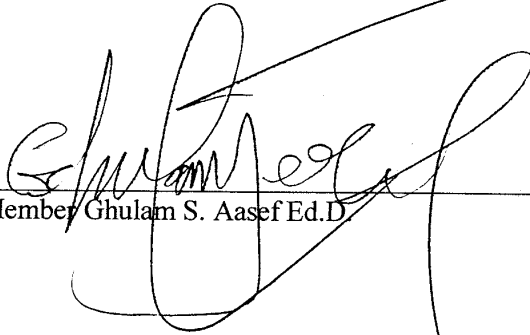
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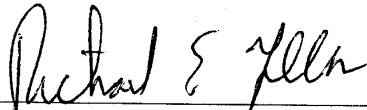
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ACKNOWLEDGMENTS

I express my sincere appreciation to all those who have contributed in one way or another to this dissertation. I first must acknowledge Dr. William Restrepo and Dr. Jorge Coronado. I owe most of what I know about hemodialysis treatment management to these two friends. I also appreciate the support and motivation I have received from the Colombian Society of Nephrology. I greatly appreciate the support, guidance and advice of Dr. Alfonso Otero. His constant involvement in this project greatly enhanced the final dissertation. Last, but not least, I thank my wife, Rosa, and my daughters, Claudia and Veronica. Too often, they paid a price when I had to meet important deadlines. I greatly appreciate their love and patience, without which I could never have written this dissertation.

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Chapter 1

Overview

Introduction

Patients in dialysis treatment overseas, especially in South America, have not received the medical attention that they deserve. Colombia has a high rate of population with kidney diseases. Every year many people die from kidney malfunctioning. However, the reaction to this disease by the government and the medical community is slow. This research explores the major variables influencing this situation by making a comparison with the same variables in the U.S.A.

Statement of the problem

This dissertation addresses the factors that influence the differences in quality of dialysis service in the United States and Colombia. Considered in this research, is the influence of variables such as cost and dose in the quality of treatment of hemodialysis patients. Other variables of interest are culture, regulations, medical staff training, environment, technology and diet but they are beyond the scope of this study.

An assessment was made in establishing these differences, and how the differences in the quality of hemodialysis service between the two countries may be related to the variables in question. Recommendations of this study are presented to the policymakers to support implementation of corrective action that may eliminate these differences and thus improve the quality of hemodialysis treatments in Colombia.

Definition of Dialysis

Dialysis is a treatment used on those patients that suffer from chronic renal diseases, which arise when the kidneys are unable to function adequately. There are two methods of dialysis - hemodialysis and peritoneal dialysis. Hemodialysis filters blood through a device made of an artificial membrane. Peritoneal dialysis uses the peritoneal membrane, a thin lining in the abdomen, as the filter [BMA Handbook, 1993].

The process of dialysis consists of the movement of a solute across a semipermeable membrane in a direction and rate consistent with concentration gradients. Any solute which has a higher concentration in the blood than the dialysate (solution used in the dialysis treatment) flows “down” its concentration gradient and so leaves the blood [Netter 1987]. In other words, the toxic substances are removed from the bloodstream with the dialysis, because kidneys are not able to do their filtration function effectively.

There are two methods for measuring the hemodialysis dose. One of these is Kt/V while the other one is URR. Kt/V is a measurement of the amount of plasma cleared of urea divided by the urea distribution volume. URR is the urea reduction ratio [Daugirdas, 1994].

Importance of this Research

This research is important because, according to the data collected, the quality of hemodialysis treatment in Colombia is inferior to that of the U.S.A. This study analyzes the effect of dose and cost on the quality of the dialysis treatment in both countries.

This research shows that the effectiveness of hemodialysis treatment of Colombia is inferior to that of the United States. Changes in Colombia are recommended at the end of this study for improving the quality level of the hemodialysis treatment. A reduction in the mortality rate of patients in hemodialysis treatment is considered a quality improvement. It is assumed that by researching and assessing the influence of cost and dose on the mortality rate, the quality of service of this treatment might be improved.

The recommendations from this study might be used by the policy makers, hospitals, clinics, and medical staff and possibly by the Colombian government. The information obtained from the research would be beneficial to the Colombian hemodialysis population.

Literature Review

This research assesses the effect of factors such as culture, regulation, cost, medical staff training, dose, diet, environment and technology on the quality of dialysis treatment in Colombia and the U.S.A. The literature was reviewed to find out how much had been done in improving the hemodialysis treatment in the U.S.A. by the government, the renal community and private agencies. A similar review was done for Colombia.

There is an on-going discussion in the renal community about how to monitor the treatment of hemodialysis and peritoneal dialysis in the United States [American Journal Kidney Diseases, 1994]. The pattern of acute renal failure in third-world countries including Colombia, Brazil, Argentine is changing but at a lower pace than that in developed countries such as the USA [Quality Journal Medical, 1989]. Therefore,

learning what variables contribute to this slow trend would be interesting and beneficial.

The choice of a dialysis treatment depends on many factors, both medical and non-medical. A full and rational treatment requires easy access to a transplantation program and to all dialysis modalities, extracorporeal or peritoneal. Currently, hemodialysis (HD) is used almost exclusively in clinics, peritoneal dialysis (PD) being preferred for home treatment [Nephrol Dial Transplant, 1996].

The Medicare end-stage renal diseases (ESRD) program costs more than \$2 billion a year in the U.S. Costs per treatment vary significantly across hemodialysis facilities, yet the relationship of these cost differentials to case mix and outcome is uncertain. Results showed that patients receiving care in hospitals and clinics received a more costly routine dialysis treatment, as well as more intensive nursing care during the treatment process, than did patients at home [Clinical Nurse Results, 1992].

Data from the Michigan Kidney Registry and the US Renal Data System (USRDS) show that the number of patients receiving treatment for end-stage renal disease (ESRD) increased sevenfold following the introduction of Medicare coverage for ESRD in 1973. Initial selection criteria for acceptance into the ESRD program included age less than 65 years and absence of systematic diseases such as diabetes. Renal transplantation is an alternative to dialysis when the cost of this treatment is too high. In the U.S., the End- Stage Renal Disease Program is underfunded and over regulated [American Journal Disease, 1992].

Although the government is working in improving the mortality rate in the USA, there is no consensus between payers, providers, and patients as to what the objectives

of the End-Stage Renal Disease Program are or should be. However, an integrated health care delivery system would benefit the renal disease patient [American Journal Kidney Disease, 1992].

The differences established among the major variables of the United States and Colombia (variables such as culture, regulation, cost, dose, diet, regulations, medical staff training and environment) that influence the quality of hemodialysis service were evaluated.

Methodology

A combination of qualitative and quantitative techniques is used in this research. Interviews were conducted to learn more about the patients' background and the kidney diseases, while quantitative data was collected through a survey questionnaire. This is the most suitable methodology for this study because it will deal with a narrow population with similar characteristics. The population consists of patients between 40 and 70 years of age, who have been diagnosed with end-stage renal disease, and are under hemodialysis treatment in the United States and Colombia.

Qualitative methods are used to explore the influence of physiological, economic and psychological factors in persons under hemodialysis treatment. Mail surveys were employed to gather data from patients; however, historical research is also used in this investigation to interpret the past in searching for facts.

Quantitative methods are used to prove or disprove the hypothesis that factors such as cost and dose impact the quality of service of the dialysis industry in

Colombia and the United States. Contacting selected clinics in the United States and renal units in Colombia, data was obtained using a questionnaire.

Dose and cost are the independent variables of interest in this research, while the mortality rate is the dependent variable. Data were collected and analyzed to describe the effect that dose, cost, or both have over the mortality rate. Part of the information of this study was gathered through the sales representatives of Fresenius Medical Care, in each of the above nations. Another means of collecting data were through contacts with health organizations. In Colombia, the National Institute of Health, the Institute of Social Security and the Colombian Society of Nephrology were contacted. In the United States, the National Kidney Foundation, the American Society of Nephrology, the National Institute of Diabetes and Digestive and Kidney Diseases, and others were contacted.

A simple questionnaire was utilized for data collection. This questionnaire was translated into Spanish to facilitate its use in Colombia. The data collected in Colombia are compared to the data collected in the U.S.A. The purpose was to establish and recognize differences between cost and dose in the quality of hemodialysis service of Colombia and U.S.A., quantify the differences, and evaluate whether the differences influence the mortality rate of Colombia.

Reducing the differences in treatment between Colombia and the United States may enhance the quality of service of hemodialysis in Colombia. Recommendations of this research may contribute to upgrade the quality of service for persons in hemodialysis treatment in Colombia and other third world nations.

The National Kidney Foundation, Inc. recommends for further research that

observational data should be collected on the relationship between the frequency of measurement of hemodialysis adequacy and patient outcomes and costs of care.

Chapter 2

Literature Review

This research evaluates the influence of factors such as culture, regulation, cost, medical staff training, dose, diet, environment and technology on the quality of hemodialysis treatment. Because of economic conditions, the pattern of acute renal failure in third-world countries (Colombia, Brazil, Argentine) is changing but at a slower pace compared with that in developed countries such as the U.S.A. [Quality Journal Medical, 1989)].

The main modalities available for the treatment of end-stage renal disease (ESRD) include hemodialysis, peritoneal dialysis and kidney transplantation. However, the choice of a dialysis treatment depends on many factors, both medical and non-medical. During the course of the renal disease, patients may select to change from one modality to another, which is from peritoneal dialysis to hemodialysis.

A full and rational treatment requires easy access to a transplantation program and to all dialysis modalities, extracorporeal or peritoneal. Currently, hemodialysis (HD) is used almost exclusively in clinics, peritoneal dialysis (PD) being preferred for home treatment [Nephrol Dial Transplant, 1996].

In 1972, the Congress approved the Medicare end-stage renal diseases (ESRD) program. This law came into effect in July of 1973. Since then, the program has spent million of dollars per year in ESRD therapies. Costs per treatment vary significantly across hemodialysis facilities, yet the relationship of these cost differentials to case mix and outcome is uncertain. Result showed that patients receiving care in the hospitals

and clinics received a more costly routine dialysis treatment as well as more intensive nursing care during the treatment process than did patients at home [Clinical Nurse Results, 1992].

Data from the US Renal Data System [USRDS, 1998] show that the number of patients receiving treatment for end-stage renal disease (ESRD) increased approximately to 250, 000 compared to an estimated 11,000 patients in 1973. This year followed the introduction of the Medicare program.

Initial selection criteria for acceptance into the ESRD program included age less than 65 years and absence of systematic diseases such as diabetes. Renal transplantation is an alternative to dialysis when the cost of this treatment is too high [American Journal Disease, 1992].

Cost

Hemodialysis is more costly to society than peritoneal dialysis. This is attributed to current governmental policies that promote hemodialysis over peritoneal dialysis [Ford-John, Mark, 1996]. The government promotes hemodialysis over peritoneal dialysis because the former can be used with any adult patient without restrictions such as weight, mental or physical condition. In addition, the government has a better control over the treatments done in clinics and peritoneal dialysis is a treatment usually done in house. This frequency of use makes the hemodialysis treatment more costly.

The rate of diffusion of technology and regulations also play an important role in the dialysis industry because they slow and restrict the rate of entry for new firms.

Ozminkowski, Hassol, Firkusny, and colleagues, in estimating increases in outpatient dialysis costs resulting from scientific and technological advancement raise

some concerns. These researchers highlighted the intervention of governmental assistance programs such as Medicare in financing the dialysis treatments and encouraging technology:

The Medicare program's base payment rate for outpatient dialysis services has never been adjusted for the effects of inflation, productivity changes, or scientific and technological advancement on the costs of treating patients with end-stage renal disease. In recognition of this, Congress asked the Prospective Payment Assessment Commission to annually recommend an adjustment to Medicare's base payment rate to dialysis facilities. One component of this adjustment addresses the cost-increasing effects of technological change--the scientific and technological advances (S&TA) component. The S&TA component is intended to encourage dialysis facilities to adopt technologies that, when applied appropriately, enhance the quality of patient care, even though they may also increase costs. The S&TA estimates also allow for differences in the incremental costs of technological change that are based on the varying advice of experts in the dialysis industry [1995].

The Medicare program funding and financial assistance has an impact on the level of patient care, especially because cost-containment on this program by the government affects the quality of the dialysis treatment. These financial restrictions have a repercussion on the mortality and morbidity rate of patients on dialysis in the U.S.A.

Hull discussed the impact of reimbursement regulations on patient management:

The Medicare End-Stage Renal Disease (ESRD) Program has saved the lives of thousands of patients with chronic renal failure; however, the absolute cost of the program has steadily increased since its inception in 1972 and quickly exceeded all budget estimates, although the actual cost per patient has increased only 0.69%, which is less than half the inflation rate. Cost-containment efforts have resulted in progressive reductions in reimbursement provided by Medicare to both physicians and dialysis centers. The reimbursement amount per dialysis treatment--the largest component of ESRD expenditures--has actually decreased from \$138 in 1974 to approximately \$54 in 1991 when measured in constant dollars. It is likely that these reimbursement restrictions have negatively impacted the level of patient care; both mortality and morbidity rates in patients receiving chronic dialysis are increasing in the United States [1992].

Likewise, Hornberger compares the effectiveness of hemodialysis prescription and cost-effectiveness that will improve the morbidity and mortality rate of patients under

dialysis treatment. Hornberger's article listed clinical guidelines:

Case-mix adjusted mortality rates for patients undergoing hemodialysis for ESRD increased during the 1980s, despite the introduction of advanced dialysis technologies. Variations in dialysis practices suggest that excess mortality may be caused by inadequate uremic-toxin clearances. Cost-effectiveness analysis was used to assess whether attempts to improve uremic-toxin clearance are cost-effective, assuming that these therapies are clinically effective. Options considered in the model were delivered fractional urea clearance (Kt/V), dialysis-treatment duration, type of dialyzer membrane, dialysate, and ultrafiltration. These calculations indicate that, if higher levels of Kt/V prove clinically effective, they are also cost-effective [1993].

Hart and Redding discussed the advantage of home medical care from a physician's perspective as a cost saving alternative to clinic and hospital care. He emphasized, the home environment as a patient care benefit over the hospital:

As medical costs increase, alternatives to hospitalization for medical care must be sought. Patient care provided through outpatient clinics and home settings offers such alternatives. Intravenous antibiotics, fluids, blood, total parenteral nutrition, chemotherapy, and pain management as well as dialysis may now be given in the comfort of the patient's home. Overall, home services may save 30% to 50% in costs compared with costs for the same service provided in the hospital. The major saving comes from removing the charge for the hospital room [1994].

Mills and Andrew discuss the factors that affect the technical efficiency of freestanding, independent dialysis facilities. The type of ownership, quality measures, organizational controls and market competition affect these facilities. Although for-profit and not-for-profit dialysis facilities appeared different in their production inputs and outputs, no support emerge across methodologies that either type of ownership determined better technical efficiencies. Similarly, market competition and organization control did not show any impact on technical efficiency. However, quality measures such as the increased reuse of hemodialyser had greater technical efficiency [1995].

Similarly, Griffith and Colleagues all strive to compare the efficiency of dialysis treatment by for-profit versus not-for-profit freestanding renal dialysis facilities:

A study was conducted to determine whether for-profit and not-for-profit freestanding renal dialysis facilities differ with respect to efficiency in the production of dialysis treatments. For-profit sole proprietorships, for-profit partnerships and for-profit corporations each produced significantly more dialysis treatments per month than not-for-profits, adjusting for quantities of resource inputs and case-mix characteristics.

They concluded that:

For-profit facilities appear to be more efficient producers of dialysis treatments than not-for-profits. Further study should address whether other factors such as differences in severity of disease or in quality of care are responsible for these observations [1994].

Likewise, Patterson compared the efficiency and efficacy of organizations and their impact on healthcare costs. In addition, he assessed the health maintenance organizations that are in business for profit versus the ones that are in business for nonprofit:

HMOs have emerged as an integral part of the attempt to mitigate and control growing healthcare costs. The conversion of nonprofit HMOs to for-profit status has focused attention on the growing role of the for-profit sector in healthcare and rekindled the debate regarding the propriety of for-profit enterprise in what has historically been a nonprofit bastion. Most have focused on hospitals, nursing homes, kidney dialysis centers, and hospital chains. These findings may be used by state or federal authorities to support policies for regulatory oversight of FP managed care organizations; by managed care organizations to adjust competitive market strategies; and by employers and consumers in the evaluation of their purchasing decisions regarding cost, quality, and access to care [1997].

Messana described barriers such as cost containment in achieving quality care from an administrative perspective of the ESRD program, and the balance between cost of treatment and quality patient care:

The achievement of quality care is the goal of all health care providers. Today's environment of health care reform and cost containment provide added challenges to achieve the balance between costs and quality. The End-Stage Renal Disease Program has faced cost-containment restraints more stringently than any other Medicare provider. Twenty years of fixed reimbursement coupled with periodic reductions have placed barriers in the attempt to achieve quality patient care. The administrators of these programs have been faced with slicing the reimbursement

pie differently in reaction to changes in the costs incurred by the facility and by the erosion of reimbursement by inflation alone. Patients who are dialyzed properly and adequately provide a longer and more consistent source of revenue for the facility. The end-stage renal disease industry as a whole needs to establish guidelines for the care received within the facility. Only through a systematic linkage of cost and quality measurements can the program hope to provide quality patient care [1994].

Medical Staff Training/Education

Just a few articles have been written regarding medical staff training and patient education. Hayslip and Suttle reviewed pre-ESRD patient education in improving the quality of patient satisfaction and slowing the advancement of renal disease:

The education of patients with renal disease focuses on the inevitability of reaching end-stage renal disease (ESRD) and requiring renal replacement therapy. Established education programs begin the process during the late stages of renal disease progression or after the patient reaches ESRD. Early education for the pre-ESRD patient has the potential to improve the quality of patient satisfaction, delay the onset of dialytic treatment, and increase cost-effectiveness. Despite more than 20 years experience in the treatment of ESRD patients, there are relatively few reports in the literature about early education or pre-ESRD education. Early patient education is an essential component that can contribute significantly to slowing the progression of renal disease [1995].

Medical staff training is key in improving dialysis service. Perras and Mattern presented “A practical approach to TQI.” They believe:

Total quality improvement (TQI) is a refreshing new approach to leadership that can be applied to a dialysis setting. The team approach to prospective data analysis is used for problem solution and reevaluation. Adapting theory to daily practical application can be successfully done using time, energy, and full senior management commitment. Staff education and involvement are essential to successful program implementation. Evaluation tools are easily adapted to analyze common dialysis problems. The initial time invested in education and data collection can be great but results in a streamlined process [1994].

Adequate training should be provided to the medical staff responsible for dialysis treatment in order to avoid complications. As Rocco, Bleyer and Burkart pointed out in their research, the utilization of inpatient and outpatient resources helps the management