Cardioprotection in the ESRD Population: How Do We Get There?

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Cardiovascular mortality for end-stage renal disease (ESRD) patients is about 30 times the risk in the general population. About 30% of ESRD patients have hyperlipidemia. The 1998 National Kidney Foundation Task Force on Cardiovascular Disease recommends implementation of effective measures to prevent and treat cardiovascular disease in this population.

Our intent was to evaluate the extent of use of cardioprotective drugs in ESRD patients through a quality improvement project. Twenty-eight dialysis facilities throughout Ohio volunteered for this project. Data regarding use of angiotensin-converting enzyme inhibitors (ACE-I) and angiotensin receptor blockers (ARB) in heart failure, beta-blockers in myocardial infarction (MI), aspirin in coronary artery disease, and 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins) were collected using chart abstraction for the period March through May 2000. The results were compared to Ohio hospital discharges from July through September 2000. This latter population was comprised of non-ESRD patients. Dialysis facilities were visited and interviews were conducted with staff members. Information was gathered regarding facility infrastructure, quality improvement process, and existing protocols.

27% of ESRD patients with a history of heart failure were on ACE-I, compared to 75.7% of non-ESRD patients. 34.8% of ESRD patients with a previous MI were taking beta-blockers, compared with 68.0% of non-ESRD patients with a prior MI. Aspirin use in ESRD patients with a previous MI was 52.8%, compared to 88% in non-ESRD patients with a prior MI. 17.3% of ESRD patients were on statins. Hyperlipidemia is found in 30% to 50% of ESRD patients.

The use of cardioprotective drugs in the Medicare ESRD patient is lower than in the Medicare non-dialysis counterpart. Reasons for this are related to fragmentation of health care arising from communication and infrastructure issues. Until these issues are addressed and resolved, efforts at initiation of cardioprotective strategies will be slowed.

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Introduction

Cardiovascular disease (CVD) is the major cause of death in patients with end-stage renal disease (ESRD) [1]. Even after controlling for race, gender, age, and the presence of diabetes, patients on hemodialysis (HD) and peritoneal dialysis are 10 to 20 times more likely to die from CVD compared to the general population [2]. ESRD patients, on average, have more hospital admissions per year and longer lengths of stay compared to non-ESRD patients [3]. ESRD patients are seven times more likely to be hospitalized for heart failure, and three times more likely to be hospitalized for myocardial infarction (MI), compared to patients with other chronic health conditions [4].

In the state of Ohio, ESRD affects approximately 12,800 Medicare beneficiaries [5]. About 76% of these patients are on HD [6]. Forty-six percent of the Ohio ESRD population had a hospital stay in 2000, compared with 14.3% of the Ohio Medicare non-ESRD population.

Length of hospital stay was 7.4 days for these ESRD patients compared to 6.0 days for non-ESRD patients. The average payment per admission was 25% higher for ESRD patients than for non-ESRD patients [5]. Cardiovascular diseases constituted the major reason (65%) for all ESRD hospital admissions [5]. One-year mortality for ESRD patients admitted for CVD was 38.6% [5].

Treatment modalities for CVD include the use of medications such as digitalis, diuretics, angiotensin-converting enzyme inhibitors (ACE-I), angiotensin receptor blockers (ARB), beta-blockers, aspirin, and 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins). The question has been raised whether these agents are likewise appropriate for the ESRD population with CVD. The National Kidney Foundation (NKF) Task Force examined the following question: "Should strategies for prevention and treatment of cardiovascular disease in the general population be applied to patients with chronic renal disease?" They concluded that definitive studies to guide clinical care in chronic renal disease patients are lacking. However, the Task Force concluded that, "many of these same strategies could and should be implemented in the care of" these patients [1]. The present study examines the cardiovascular treatment practices in Ohio's Medicare ESRD population and explores the underlying factors contributing to current practice patterns.

Methods

Patients

All 113 HD facilities in Ohio were invited to participate. A total of 28 HD facilities were volunteered by their facility medical directors or administrators. These facilities are scattered throughout the state, incorporating 11 of the 88 counties in Ohio. Of these 28 facilities, there are 25 freestanding and 3 hospital-based facilities. Twenty-two of the facilities were for-profit and six were non-profit.

ESRD data collection

Data were collected regarding the ESRD population using three methods: chart abstraction, focus groups, and facility interviews.

In order to perform the chart abstraction, a case list was obtained from each of the participating dialysis facilities. The following were required in order to be included in the case list: (1) Medicare beneficiary, (2) age > 18 years, (3) HD dependent for > 6 months, and (4) presence of CVD as defined by a history of heart failure, prior MI, hypertension, or coronary artery disease.

A random sample was drawn such that we were 95% confident that the sample proportion for each indicator was within 0.05 of the true proportion. The final sample size included a 20% over-sample to allow for elimination of medical records originally included as part of the eligible population to be sampled. Medical records were eliminated for two reasons: they could not be found, or they did not meet the necessary requirements for inclusion in the project.

Data were collected on the use of ACE-I and ARB in heart failure, beta-blockers with previous MI, aspirin with previous MI, and HMG-CoA reductase inhibitors (statins). Chart abstraction was done on 1,270 charts for the period March through May 2000. Excluded from analysis were patients with documented medical contraindications to the use of ACE-I.

Focus groups were developed to obtain qualitative information regarding the potential for intervention tools. Three issues were addressed: quality improvement projects, preventative practices for CVD management, and mechanisms for exchange of medical information. Invited participants included nurses, dieticians, social workers, and physicians. The responding individuals represented 8 facilities.

On-site dialysis unit interviews were conducted in approximately half the facilities to evaluate communication and infrastructure issues. Questions were asked regarding the roles of the medical director and primary nephrologist, lines of information exchange, emergency care management, and the quality improvement process.

Non-ESRD data collection

Data were also collected by chart abstraction on non-ESRD Medicare beneficiaries. The presence of ESRD was an exclusion criterion in this population. Data were collected on the use of ACE-I and ARB in heart failure, beta-blockers after previous MI, and aspirin after previous MI.

Data were abstracted for this population for the period July through September 2000. The number of charts used for analysis was 1,105 for the non-ESRD MI population and 2,424 for the non-ESRD heart failure population.

Results

Table I compares the demographic information of the ESRD and non-ESRD populations. The ESRD group was comprised of 54% Caucasian patients and 43% African Americans. The non-ESRD group was comprised of 86% Caucasian patients and 10% African Americans with heart failure, while the MI group was comprised of 91% Caucasian patients and 6% African Americans. The gender demographics were comparably split for both ESRD and non-ESRD patients with MI. There were 43% males in the non-ESRD heart failure group. Less than 10% of patients were under 65 years of age in the non-ESRD heart failure and MI groups; 42% of ESRD patients were under 65 years of age.

Figure 1 shows the percent of ESRD heart failure patients that had used an ACE-I. These patients had heart failure, as demonstrated by quantitative (documented ejection fraction of < 40%) or qualitative (documented by statements of prior moderate to severe heart failure) evidence. Twenty-seven percent of ESRD patients meeting these criteria were on an ACE-I, compared to 75.7% of Ohio's Medicare beneficiaries with heart failure. Excluded from both populations were patients that were not on ACE-I for medical reasons, which were clearly documented.

Since some patients with heart failure may have been switched to ARB if ACE-I were contraindicated, additional analyses were conducted to include the use of ARB in both the ESRD and non-ESRD populations. These numbers changed little: 34.8% and 80%, respectively.

TABLE I Demographic comparison of end-stage renal disease (ESRD) and non-ESRD populations.

	ESRD	*Non-ESRD* *Heart failure*	*MI*[a]
Race (%)			
Caucasian	54	86	91
African American	43	10	6
Other	3	4	3
Gender (%)			
Male	52	43	50
Female	48	57	50
Age (%)			
<65 years	42	7	8
65–74 years	31	27	33
75–84 years	23	41	38
85+ years	4	25	20

[a] Note that, due to rounding, the sum of columns may not equal 100%. MI = myocardial infarction.

Thirty-five percent of ESRD patients with a previous MI were using beta-blockers, compared to 68% of non-ESRD patients with a previous MI in whom beta-blockers were used appropriately. These data are shown in Fig. 2.

Figure 3 compares the use of aspirin with previous MI in the ESRD patients with the non-ESRD population. Fifty-three percent of the ESRD patients were on aspirin, versus 88% of their non-ESRD counterparts.

Between 30% and 50% of ESRD patients have hyperlipidemia [1]. We found that only 17% of our Ohio ESRD population was on HMG-CoA reductase inhibitors (statins).

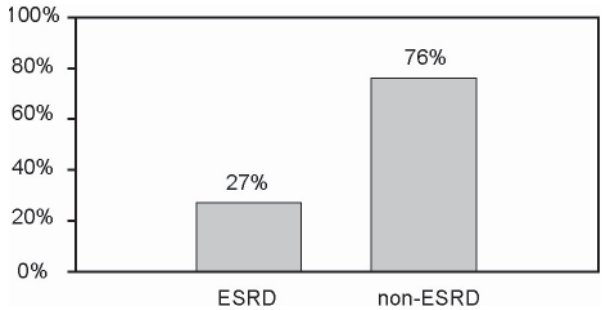

FIGURE 1 Use of angiotensin-converting enzyme inhibitors in patients with heart failure.

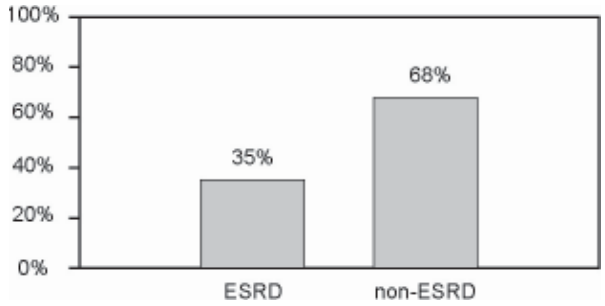

FIGURE 2 Use of beta-blockers in patients with previous myocardial infarction.

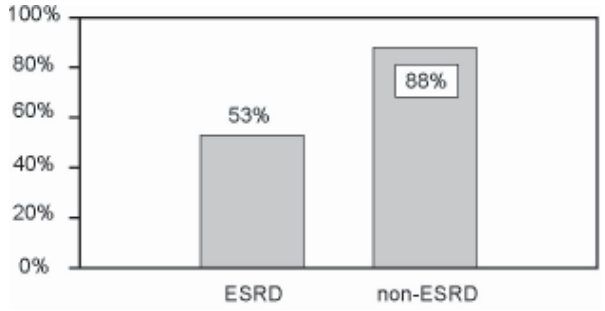

FIGURE 3 Use of aspirin in patients with previous myocardial infarction.

Focus groups

Four focus groups were conducted. The following information is a summary of those discussions. The primary foci of quality improvement projects in this group were management of anemia, adequacy of dialysis, access for dialysis, management of phosphorus, hyperparathyroidism, and prevention of bone disease. The Dialysis Outcomes Quality Initiative (DOQI) guidelines drive the facilities' day-to-day processes. Cardiovascular disease was not one of these foci. There were no preventative guidelines for cardiovascular management.

Communication of medical information by providers from hospital and outpatient visits back to the dialysis facilities was seen as variable by the focus groups. Due to this variability in communication, medication lists and problem lists were not always current and test results were not always available.

Facility interviews

On-site interviews were conducted. Participants commented on the frequent confusion that arises when different aspects of health care are assigned to the different providers. Primary care would be delivered by the family physician in some cases and would be handled by the nephrologist in others. Cardiovascular care could be rendered by the nephrologist under some circumstances and deferred to the cardiologist in other instances. Three different models of facility infrastructure emerged: the Ownership Model, the Group Practice Model, and the Individual Model.

In the Ownership Model, the medical director in concert with a nurse practitioner takes "ownership" of the dialysis patients. All care, including routine annual examinations and urgent visits, is delivered at the dialysis facility. This model addresses both dialytic and non-dialytic needs, including preventative management. Continuity of care was maintained more easily since all records were kept at the facility and could be accessed by both provider and facility staff. Our interviews with the facilities supported this.

In the Group Practice Model, a physician representative from the nephrology group makes monthly rounds. Each month the rounding representative rotates, thereby creating a potential for a breakdown in continuity of care. Additionally, the rounding physician is required to adjust his or her schedule to include the extra responsibility for the month, thereby contributing to a greater potential to have details "slip through the cracks." Components of medical records were kept both at the facility and at the office of the off-site nephrologist.

In the Individual Model, the patient's own nephrologist makes monthly rounds at the dialysis facility and sees the patient in the office. Although continuity of care is maintained, dialysis patients frequently missed office visits because they already spent several hours per week at the facility receiving dialytic care. General care is delivered by either a primary-care provider or the nephrologist. Parts of medical records were kept both at the dialysis facility and at the nephrologist's off-site office.

Discussion

Cardiovascular disease is the major cause of death in the ESRD population [1]. The question has been raised whether currently identified strategies for prevention and treatment of CVD in the general population should be applied to the ESRD population. A report from the NKF Task Force on Cardiovascular Disease [1] evaluated evidence supporting the effectiveness and safety of intervention and treatment of CVD in this population. The Task Force concluded that definitive studies to guide providers are lacking, but that "many of these same strategies could and should be implemented" for the dialysis patient. That recommendation was issued in 1998. Definitive studies to support or challenge this recommendation are still lacking.

An argument could be raised that the focus for use of cardioprotective medications should be the pre-ESRD population, since it might be too late to have much of an impact on the ESRD population. However, disqualification of an entire population from treatment because data are lacking should not be the rationale for strategy, but instead should be the driving force to initiate studies to address this issue.

Admittedly, there are limitations to this project. In addition to the lack of outcome data, this population may have more contraindications to the use of cardioprotective ACE-I, ARB, aspirin, beta-blockers, and statin agents than the non-ESRD population. Issues of potassium levels, bleeding disorders, bradycardia, and myopathy may limit the use of these drugs. Clinical presentations of fluid overload may overlap with heart failure, and objective documentation of ventricular dysfunction may be lacking.

There may be bias due to the selection process. Those facilities that were volunteered by their medical director may represent facilities with more sophisticated quality improvement processes in place. In addition, ours is a descriptive project, and is therefore limited in that associations may be inferred, but causation is not necessarily proven. Most importantly, we do not wish to infer that the non-ESRD population is the gold standard to which the ESRD population should be compared. We agree with the NKF Task Force that data are lacking, and thus we support the initiation of studies to address these issues. Despite the lack of data, the NKF, by consensus, agreed that "many of the same strategies could and should be implemented in the care of patients with chronic renal disease."

Greater than 40% of ESRD patients have diabetes mellitus [7]. The literature supports the use of ACE-I in diabetic patients to reduce the risk of major CVD [8]. Although outcome trials for the ESRD population do not exist, it is unlikely that diabetic patients reaching ESRD had their ACE-I discontinued for lack of supporting data.

Although the identification of these limitations is acknowledged, this project allowed us to understand other potential barriers that limit the use of cardioprotective agents. However, there remains the issue of how to translate recommendations into practice behavior. This must be examined. Is it because providers are not "doing their job," or because there are elements in the system design that interfere with bringing medical innovation to the patient? Further analysis of our results allowed us to focus on two major barriers: communication and infrastructure issues.

How does patient care suffer if communication among health-care providers is flawed? Lack of complete medical history, medication lists, hospital discharge data, and test results limit the provision of appropriate short- and long-term medical care. Recent hypotension or lean weight changes may affect the dialysis prescription. Changes in medication or medication dosages via a hospital admission that are unknown to a dialysis staff member may lead to erroneous conclusions as to the etiology of nausea, blood pressure swings, dizziness, or bleeding. The dialysis facility is frequently seen as the repository of all data for the ESRD patient. Although it is true that information regarding Kt/V_{urea}, urea reduction ratio, dialysis hypotension, and adverse events is housed in the facility, it is not necessarily true that other important information is known to the dialysis staff. Hospital discharge summaries, letters from specialty offices, and results of outpatient tests are frequently not forwarded. Consequently, important management tools may be overlooked and health care for the patient becomes fragmented.

The other barrier, the issue of infrastructure, was evident as our facility interviewees related the lack of a standard "owner" for the dialysis patient. How is ownership a critical issue for this population? An example may be seen in the multiple answers to questions such as "which physician is addressing the hyperlipidemia problem" and "who is going to order the annual mammogram?" Since answers include the primary-care provider, the nephrologist, the endocrinologist, the cardiologist, and the medical director, it soon becomes clear how confusion can occur and how medical care issues can slip through the cracks. "Turf" issues may abound, yet one provider must take charge. We found different models to exist among and within the facilities.

The model that appears to maintain continuity of care is the ownership model. In this model, the medical director serves as the primary provider. An on-site nurse practitioner working with the medical director coordinates patient care, updates problem and medication lists, calls hospitals for discharge summaries and specialists for reports of office visits, and triages the urgent patient problems. The nurse practitioner follows agreed upon guidelines of communication between the medical director and the primary nephrologist. This model appears to overcome several of the barriers noted above. This model would also allow for use of cardiovascular protocols and preventative care protocols to ensure initiation of recommended strategies.

Admittedly, other successful models do exist. In some systems, the nephrologist acts as both specialist and primary-care provider. Other patients retain their original family physician or general internist as their primary provider and

see the nephrologist for dialysis-related issues. In others, a group practice model is used, with a representative from the practice covering the health care of several patients. These models do work, but the potential for communication lapses is greater. When these lapses occur, patient care becomes fragmented.

How should infrastructure and communication issues be resolved? There is no "cookie cutter" design that works best. No one-size-fits-all approach. The answer stems from understanding one's own goals, initiating the process used to achieve them, and critically examining the steps to see how they help or hinder attainment of that goal. These are the steps used in quality improvement. It is now up to the ESRD Networks and the ESRD community to initiate such processes.

The issues of manpower, money, and reimbursement are frequently voiced as barriers to initiating quality improvement efforts. In this age of limited resources, we expect that increased availability of monies is unlikely to occur. Redesign will be critical to implementing change. Initiation of quality efforts usually translates into increased efficiency at a lower cost down the line [9].

Current quality improvement projects usually focus on dialysis issues, such as vascular access and improvement in Kt/V_{urea}. Guidelines or protocols addressing cardiovascular strategies were not seen in our project. Expansion of topics for quality improvement projects that incorporate plan–do–study–act, root cause analysis, and rapid-cycle techniques should be implemented.

In summary, the use of cardioprotective agents in the Ohio ESRD HD population lags behind rates documented in non-ESRD patients. Although many factors can be identified to explain this phenomenon, further analysis suggests that larger communication and infrastructure issues also play a role.

Improvement in cardiovascular mortality rates is likely to rely upon multifaceted interventions. However, until the communication and infrastructure issues are addressed, initiation of preventative strategies will be hampered by the presence of multiple barriers.

Disclaimer

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References

1 Levey AS, Beto JA, Coronado BE, Eknoyan G, Foley RN, Kasiske BL, Klag MJ, Mailloux LU, Manske CL, Meyer KB, Parfrey PS, Pfeffer MA, Wenger NK, Wilson PW, Wright JT Jr. Controlling the epidemic of cardiovascular disease in chronic renal disease: What do we know? What do we need to learn? Where do we go from here? National Kidney Foundation Task Force on Cardiovascular Disease. Am J Kidney Dis. 1998; 32(5):853–906.

2 Foley RN, Parfrey PS, Sarnak MJ. Cardiovascular disease in chronic renal dialysis: Clinical epidemiology of cardiovascular disease in chronic renal disease. Am J Kidney Dis. 1998; 32(5 Suppl 3):S112–19.

3 Becker BN, Coomer RW, Fotiadis C, Evanson J, Shyr Y, Hakim RM. Risk factors for hospitalization in well-dialyzed chronic hemodialysis patients. Am J Nephrol. 1999; 19(5): 565–70.

4 Thamer M, Ray NF, Fehrenbach SN, Richard C, Kimmel PL. Relative risk and economic consequences of inpatient care among patients with renal failure. J Am Soc Nephrol. 1996; 7(5):751–62.

5 Health Care Finance Administration. Medicare 2000 Part A Claims Data. Baltimore, MD: Center for Medicare and Medicaid Services, 2001.

6 2000 Annual Statistical Report for ESRD Networks 9, 10. Indianapolis, IN: The Renal Network, Inc., 2001.

7 US Renal Data System ESRD 2000 Annual Data Report. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2001.

8 Heart Outcomes Prevention Evaluation Study Investigators. Effects of ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus: Results of the HOPE study and MICRO-HOPE substudy. Lancet. 2000; 355(9200):253–9.

9 Berwick DM. As good as it should get: Making health care better in the new millennium. Continuous Improvement. 2001; Aug(6). Accessed from: http://www.ihi.org/resources/ihipublications/ci0801asgoodas.asp