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## Editorials

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## Editorials

### Heart Valve Surgery at Henry Ford Hospital from a Perspective of Thirty-Two Years

This issue of the Henry Ford Hospital Medical Journal contains eight papers on the subject of the porcine bio-prosthetic heart valve. It is now 32 years since the first heart valve operation, a mitral commissurotomy, was performed at Henry Ford Hospital. The operation was carried out in spite of the rather vigorous opposition of the chief of cardiology. When 12 cases of mitral commissurotomy with three deaths were reported to the Detroit Academy of Medicine, a discussant who had done some rapid calculation said that he could not say anything favorable about an operation which had a 25% mortality rate. He was not impressed with the rebuttal argument that the valves of those who had not survived were hopelessly deformed and the problem was more that of insufficiency than stenosis. Nothing but replacement with new valves would have been curative.

Mitral commissurotomy rapidly became a respectable operation in the early 1950s. It was never called "blind surgery" by those who did it but rather a procedure under "digital vision." Modifications of the technique of Dr. Charles P. Bailey and his associates became available, but undoubtedly the improvement in results was due more to the accumulation of surgical experience. At Henry Ford Hospital, troublesome bleeding around the commissurotomy knife was eliminated by Dr. Edward Munnell's development of a six-fingered glove, the knife passing through the sixth finger to which a ligature could be applied. During the early operations, the pressure changes in the left auricle were displayed and recorded by the Hathaway impedance gauging system. The presence of unsuspected significant mitral insufficiency, so evident to the surgeon's finger, could be graphically recorded.

It was hoped that a similar operation would be able to separate the fused cusps in aortic stenosis. Since it was obviously impractical to approach the aortic valve with a finger through the wall of the left ventricle, Bailey developed a transaortic operation, with the forefinger passing through a cloth tunnel sutured to an opening in the aorta. Although I tried this operation several times, I never had good results. Mainly, I was impressed with the rigidity of the fibrosed and calcified valves. More consistent results were obtained with the Bailey aortic dilator, an instrument passed into the valve via the left ventricle. By vigorously squeezing the handle to expand the

mechanism in the valve and by listening for the cracking of the calcified tissue, one could be sure that the valve had been opened to some extent.

Before the pump-oxygenator became available, brief "open heart" operations were done under hypothermia or simply by means of caval occlusion. There was ample time to make three cuts in the pulmonary valve, but the same technique applied to the aortic valve was not successful. The remark was often heard that "We need a new valve."

A pump-oxygenator of the DeWall-Lillehei bubble type was first used at Henry Ford Hospital in April, 1956. First priority was given to operations on children with congenital heart disease, especially those with ventricular septal defects, because many were threatened with irreversible pulmonary hypertension. But before long, open operations for mitral and aortic stenosis began to replace the closed procedures. In 1958, there were 118 mitral commissurotomies, and all but two were by the "old-fashioned" closed technique. In 1964, of 88 operations, 55-60% were done under direct vision. When the problem with the valves was mainly stenotic, these operations were nearly all successful. But until prosthetic replacement became available, there was no real solution to the problem of mitral insufficiency.

With the adequate operating time provided by extracorporeal circulation, it was at least possible to perform a more cosmetic repair of the stenosed or leaking aortic valve. A few cases of insufficiency were corrected by suturing the cusps to make a bicuspid valve. Commissures (if present) could be cut under direct vision, and calcified plaques could be removed. We even used a high speed dental drill for decalcification! During a three-year period from 1962 to 1965, the drill was used in 75 operations for calcific aortic stenosis. In 56, the valve leaflets were debrided, and in 19 operations the calcified aortic annulus was prepared to receive a prosthesis.

The first caged ball valve was placed in the aortic position by Dr. Dwight Harken in 1960. The lucite poppet in his prosthesis was noisy, and there was more interest in the Starr-Edwards valve, which had a silicone rubber ball (1962). The obvious disadvantage of the spherical poppet was that it tended to obstruct the flow of blood. The



Smeloff-Cutter valve in the mitral position produced less obstruction, since, in systole, half of the poppet was back in the auricle. Numerous valves with disc poppets soon appeared on the market, but they all carried the same danger of thrombosis and embolism as the ball valves.

In 1950, Drs. Aram, Munnell, and I performed some animal experiments in the surgical laboratory at Henry Ford Hospital on aortic valve homografts. Since we had no heart-lung apparatus that would allow us to place the grafts in the subcoronary position, we inserted them in the descending aorta. The cusps deteriorated rapidly unless aortic insufficiency was produced in the recipient animal by the destruction of one cusp. The grafted valve continued to function until the host's valve became competent by adaptation of the two undamaged cusps. There was a surprising amount of interest in our work abroad, especially in England and New Zealand. American prosthetic valves were prohibitively costly in those

countries, while human homografts were reasonably available. The result of this situation was the early work of Duran and Ross in England and of Barratt-Boyes in New Zealand, now of Australia.

No homograft was ever used in a human being at Henry Ford Hospital. But in 1971, Dr. Julio C. Davila began to use grafts from a lowly animal, the pig, to replace aortic and mitral valves. Dr. Donald J. Magilligan's article on the "Natural History of the Porcine Bioprosthetic Heart Valve" describes the developments of this decade at Henry Ford Hospital. Experience with these "gluteraldehyde-stabilized porcine xenografts" or "porcine bioprosthetic heart valves" constitutes the basis of the lead articles in this issue of our Journal.

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## A Challenge to Physicians: The Obligation and Ultimate Reward

We live in intensely troubled times. Widespread social dislocations, economic disarray, and nuclear destruction threaten to disrupt our lives. These anxieties, and the intermittent rewards and joys, if not experienced directly, come through unrelenting communications of one sort or another. Whether the individual mission be a labor of economic survival, the pursuit of creative work, or the search for identity, we cannot escape transmitted words and images issuing from a host of authorities, assumed experts, analysts, and interpreters. The mounting problems are more than matched by a legion of answers, and the field of medicine is no exception. Public controversies about the objectives, structure, control, service distribution, and financing in medicine create dilemmas of purpose and direction for many physicians.

In my reflections on these controversies, two recently published articles keep coming to mind. Though of different themes, both have substantial implications for the practice of medicine. The first article is by Harry Schwartz, published in *Newsweek* (1), with a later version in *The New York Times* (2). The second is the Sounding Board communication of Rashi Fein in the *New England Journal of Medicine* (3). Schwartz addresses the ever-growing, already staggering costs of medical care, and he foretells some punishing debates on the principles of how we will (not whether we should) ration its services. For physicians, no less than for the nation at large, this is a profoundly disturbing scenario by a university writer-in-residence. Juxtaposed in my mind is Fein's timely appeal

for more humanism in the language of medicine and, ultimately, in the actions of medicine. In a profession so infiltrated by the jargon of the business world, who can take issue with this appeal from a scholar of medical and health affairs?

Apart from the messages themselves, the fact that they have not come from within our own profession indicates perhaps either a timidity by physicians or a preoccupation with the pressing affairs of today. For another controversial issue, one of horrendous implications and affecting all humanity, physicians have been aroused and responsive, as witnessed by the widely acclaimed efforts of Physicians For Social Responsibility and the recently published book, *The Final Epidemic — Physicians and Scientists on Nuclear War* (4). Why have these socially concerned physicians not spoken out for the issues identified by Schwartz and Fein, both so vital to the integrity of the medical profession and our national welfare? One might ask, also, why it is that the existing agencies within organized medicine have not similarly responded? Answers may be found in an understanding of the diversity which characterizes the centers of philosophic and policy formulations with the medical world.

First, it should be acknowledged that physicians are addressing the cost issue by voluntary restraints in practice, by policies and procedures adopted by hospital staffs, local medical societies, specialty groups and national associations, and by principles and goals pro-



vided by the Institute of Medicine (National Academy of Sciences). But these sincere efforts have been blunted by countervailing forces, both economic and political, beyond the domain of the medical care "industry". Although commonly so characterized, the medical profession is not, in fact, organized. It is an assortment of specialty "cartels", loosely aligned through various colleges and councils that exist primarily and understandably to define areas of responsibility and for accrediting and educational purposes. Quite properly, the American Medical Association "has officially reaffirmed that national representation of the medical profession is its most prominent function." Yet it is compromised, since nearly one-half of the nation's physicians, many of whom hold more progressive views, are not members of the AMA. Our medical schools and research establishments, with superb resources generated by governmental largesse and generous philanthropic support of the last several decades, are not in a mood for containment. One result, quite unintentional, is an upward push on already costly health services. Nor is it likely that universities and community hospitals, for reasons of prestige and politics, will significantly reduce the upward trend by moderating their acquisition of the latest sophisticated services. Despite its ambivalence about physician needs and its need to protect hospital interests, the American Hospital Association has nonetheless sponsored cost-containment procedures. These measures have had but limited success.

Whatever the approach to the issue of cost containment, the physician as the primary provider bears a great responsibility. Are we so involved in our businesses and in our various professional organizations that a union of concerned physicians cannot emerge and boldly take up Schwartz's editorial challenges? Do we have too much to lose in a society dominated by an economic *raison d'être*? Must the whole social order change before medicine changes?

Forty years ago Roscoe Pound, then Dean of the Harvard Law School, defined professionalism as a "pursuit of a common calling as a learned art and as a public service — nonetheless a public service because it may incidentally

be a means of livelihood" (5). Today's physician, whatever his or her environment, should constantly strive for that goal. The economic burden of American medicine is at the limit of tolerance, and time is running out for the prevailing order. More aggressive countermeasures are being generated by those who hold the purse strings. The need for physicians is clear — to seek collectively an overall reordering of values and goals and to do so with the same passion and persuasion as the Physicians for Social Responsibility seek nuclear disarmament. If physicians take this initiative, they could establish a new base of professionalism. They could reawaken the awareness that our primary obligation as physicians is to heal, comfort, and prevent, not to do business. No one said it better than Sir William Osler in his 1903 address, *The Master-Word in Medicine* (6):

"More than any other, the practitioner of medicine may illustrate the second great lesson, that we are here not to get all we can out of life for ourselves, but to try to make the lives of others happier. This is the essence of the oft-repeated admonition of Christ: 'He that findeth his life shall lose it, and he that loseth his life for my sake shall find it'; on which hard saying, if the children of this generation would lay hold, there would be less misery and discontent in the world. It is not possible for anyone to have better opportunities to live this lesson than you will enjoy. The practice of medicine is an art, not a trade; a calling, not a business; a calling in which your heart will be exercised equally with your head."

The challenge is there. Will we meet it and, in so doing, find our ultimate reward?

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## The Beta Blocker Heart Attack Trial: At Last, An Effective Medical Therapy to Prevent Death from Coronary Heart Disease

In the last two decades major advances have occurred in our understanding and treatment of coronary heart disease, in particular for those individuals who have experienced acute myocardial infarction. Most recently, it has been demonstrated that beta adrenergic blocking agents can lower the mortality rate after such an event (1,2). Before the mid-twentieth century, this disease was merely a subject of interest to the morbid anatomist. Now, the expansion of our scientific knowledge has culminated in identifying an important therapeutic intervention.

The first advances came when antiarrhythmic therapy and electronic pacemakers and defibrillators were used in the setting of the new coronary care units. These developments focused the attention of the medical community on acute myocardial infarction with an intensity that would have made James Herrick, the first to describe an acute "heart attack", smile with pride (3). This focusing of clinical research on acute myocardial infarction, largely due to the development of the coronary care unit, cannot be underestimated. It permitted us to describe the patient with acute myocardial infarction more intensely and provided a framework within which medical and surgical interventions could be evaluated. The initial emphasis was on the recognition and treatment of cardiac arrhythmias that occurred in the early phase of acute myocardial infarction.

The coronary care unit also became the starting point in the study of the natural history of patients experiencing an acute myocardial infarction. These patients provide us with an important glimpse of the vast problems of individuals in our society suffering from coronary heart disease. As our knowledge expanded, we realized that patients with acute myocardial infarction represent a heterogeneous group, many of whom are at low risk of having recurrent infarction and death. Others are at an increased risk, with a high mortality rate in the first six months after the event. On the average, however, the one-year mortality rate of patients experiencing acute myocardial infarction is 5-6%, and the two-year mortality rate is under 10%. In order to make use of the technological and pharmacological developments that have occurred in the last two decades, we must understand the natural history of individuals with acute myocardial

infarction as we reflect on new therapeutic interventions. The risks of the intervention must be measured against the risk of the disease itself.

A number of secondary interventions have been proposed in the last two decades for the long-term treatment of patients following myocardial infarction. Our understanding of these interventions has not been simple, and many questions still remain. Clinical investigation has been hampered by our continued ignorance of the mechanism of ischemia, infarction, and the progression of coronary arterial disease. The Coronary Drug Project (4-6) tested a number of medications, including estrogens, clofibrate, thyroid hormone, and niacin, but to no avail. The early thrust was on anticoagulant therapy and, more recently, on antiplatelet agents, based on the assumption that coronary thrombosis represented a major mechanism of acute myocardial infarction. The significance of thrombotic events in acute myocardial infarctions still is not fully understood. Whether it is a primary event or secondary to coronary arterial narrowing and stasis associated with left ventricular asynergy is still not entirely clear. Trials with anticoagulant therapy, and more recently with aspirin (7), have provided less than clear answers. Although the Aspirin Myocardial Infarction Study (7), carried out by the National Heart, Lung, and Blood Institute, demonstrated that aspirin was ineffective, the persantin-aspirin trial (8), which has been reorganized, is still investigating the effect of aspirin and persantin in post-myocardial infarction patients. The use of sulfinpyrazone (9) has been so badly clouded by poor experimental design that we probably will never know whether or not this drug is effective. At least at present, the data do not indicate significant effectiveness for any of these agents.

Beginning about 15 years ago, beta adrenergic blocking agents began to be tested in post-myocardial infarction patients. These early studies gave promise without proof; but as a result the Beta Blocker Heart Attack Trial (BHAT) (1), which studied propranolol, and a number of trials with similar agents were carried out in Europe (2). These studies all indicate that a significant decrease in mortality, between 26% and 36%, can be achieved with these agents. By and large, these trials have been designed to test the effectiveness of the drug in the latter

phase of acute myocardial infarction, beginning one to three weeks after the event. These agents not only have demonstrated a decrease in total mortality, but they have also been shown to reduce the recurrence of myocardial infarction. In the long term, the 26% decrease in mortality over a two-year follow-up period indicates that the administration of these drugs will result in the survival of two to three individuals out of 100 treated. Preliminary analysis indicates that the impact of these drugs is uniform in all clinical subgroups. The relative effect is the same, but the impact on the total mortality rate is greater in those at high risk. Those with multiple infarction, those with complicated in-hospital courses, those individuals who are older — all have a higher mortality rate; therefore, the 26% decrease in mortality achieved by beta blockade results in greater numbers of individuals being saved.

Nevertheless, the results of these trials indicate with a clarity rarely observed in medical research that beta blocking agents should be administered to all individuals after acute myocardial infarction excluding those for whom they are contraindicated, such as patients with chronic lung disease, bradycardia, hypotension, or severe congestive heart failure.

How long to continue therapy remains unanswered. The BHAT results indicate that a positive effect was observed throughout the three years of follow-up. Whether or not long-term administration may be associated with adverse effects is not known. Preliminary data suggest that these agents may have an adverse effect on triglycerides and high density lipid cholesterol, although this effect on

long-term mortality in coronary heart disease is not clear. At present, it appears that the drug therapy should be continued for at least three years after an acute myocardial infarction.

The remarkable achievement of the beta adrenergic blocking story is a culmination of many years of research in the coronary care units and basic research laboratories around the world. This research has led to our better understanding of acute myocardial infarction. Nevertheless, it is important to realize that only a small fraction of patients survive to reach the hospital and that 60% of the deaths in coronary heart disease are sudden and occur long before the individual reaches the coronary care unit. The identification of the patient with acute myocardial infarction is the first step in interdicting the sudden death process. The administration of beta blockers to patients after a myocardial infarction reduces not only total mortality but also the risk of sudden cardiac death.

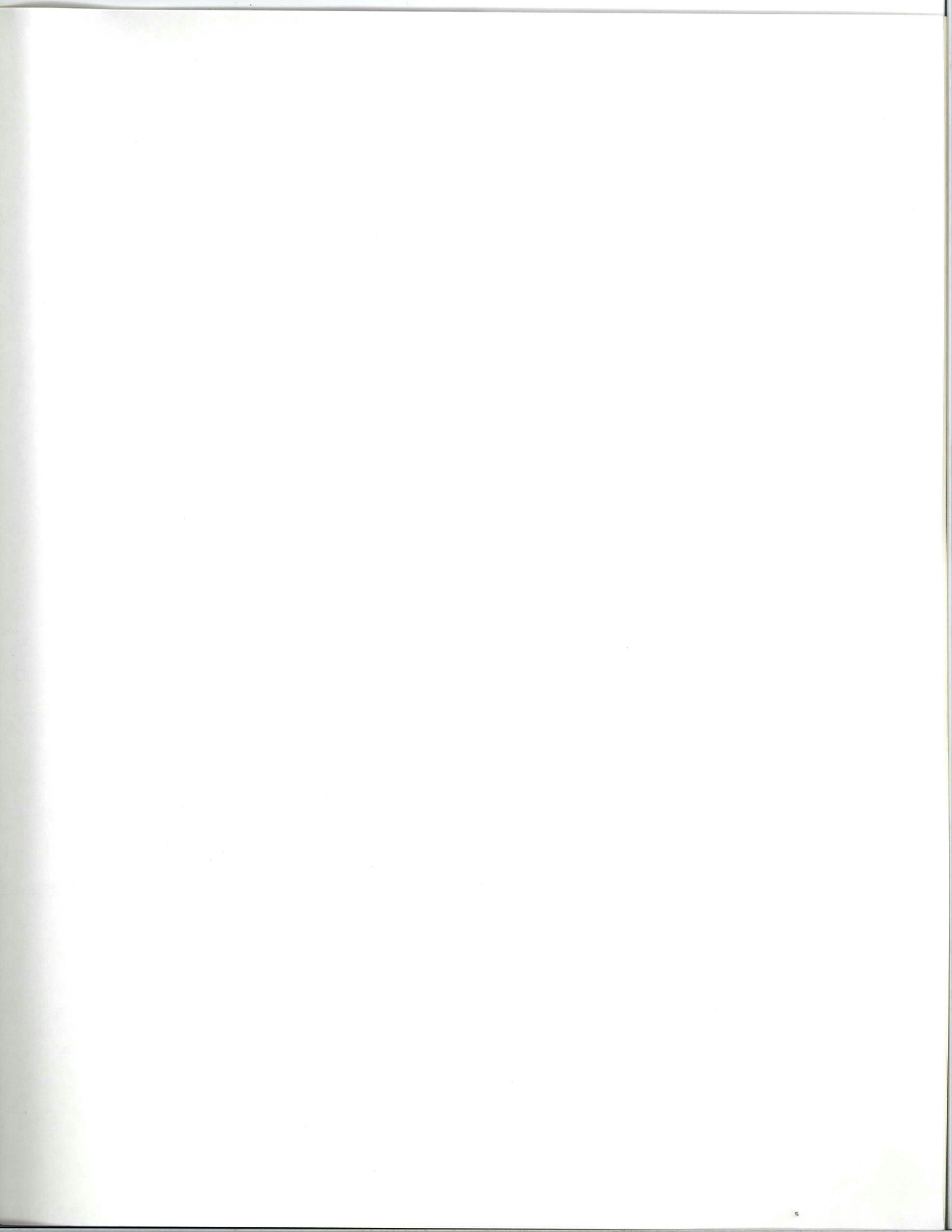
These recent successes are clouded by the realization that our knowledge about the development and progression of coronary heart disease remains catastrophically limited. Hopefully, in the future, we will be able to prevent this disease successfully. For the present, however, we have an opportunity to offer our patients who have experienced a recent myocardial infarction an effective means of preventing recurrent cardiac events.

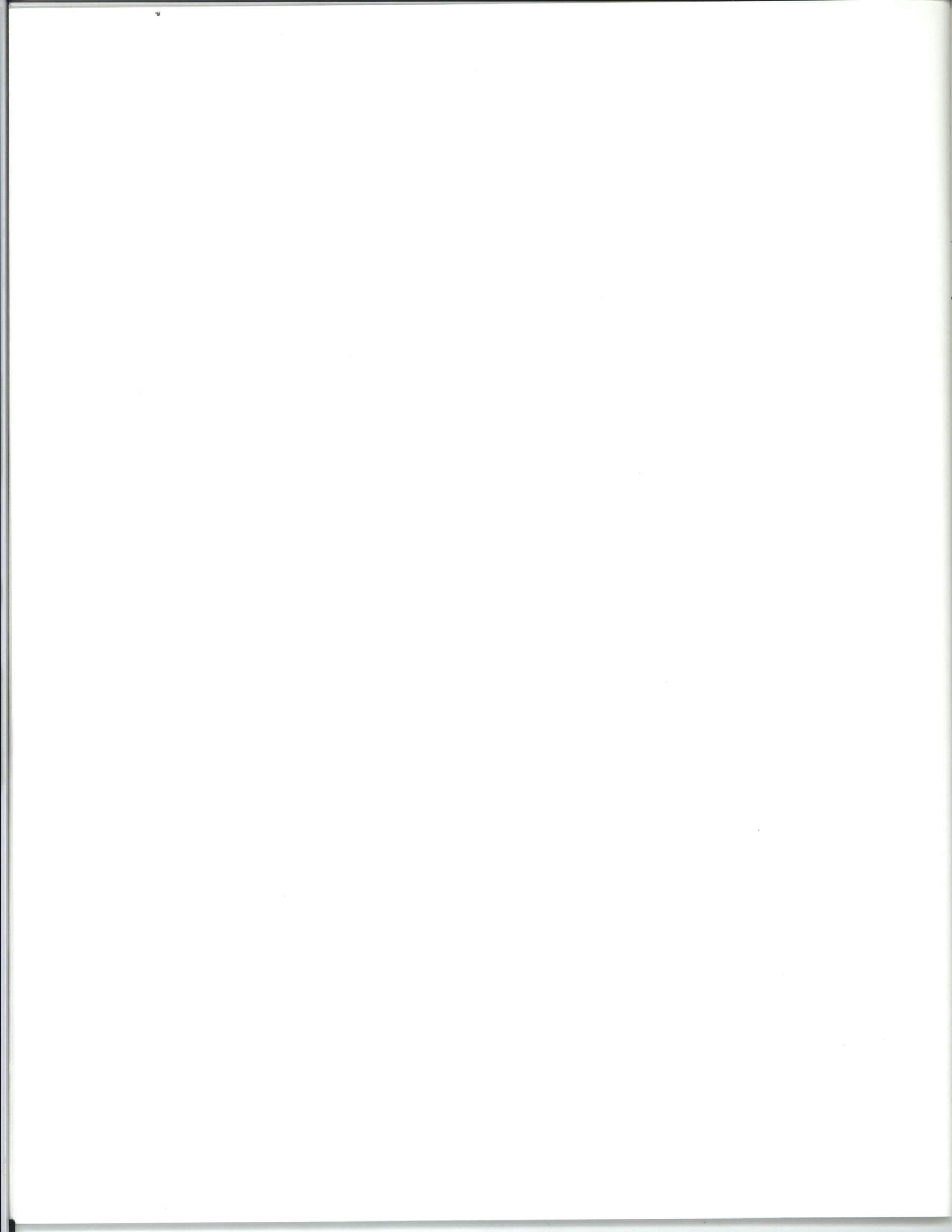
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**Observations Suggesting a Possible Link  
Between Gammacarboxyglutamic Acid and  
Porcine Bioprosthetic Valve Calcification** 152

*Joseph A. Helpert, MA  
Stephen J. McGee, MS  
Jeanne M. Riddle, PhD*

## SPECIAL ARTICLE

**The Surgeon and the Patient with Cancer:  
The Development of Surgical Oncology** 156

*Angelos A. Kambouris, MD*

## CLINICAL ARTICLES

**Preliminary Report: Effects of Tetracycline  
on Fecal Bile Acid Pool Composition  
in a Human** 160

*Jerome R. Waldbaum, MD  
William T. Beher, PhD  
Robert J. Priest, MD  
Sofia Stradnieks*

**Medical Grand Rounds: Open and Closed  
Loop Insulin Delivery Systems in Diabetes:  
Current Status** 163

*F. John Service, MD, PhD*

**Clinical Note: Use of Clonidine to Detoxify  
Opiate-Addicted Patients** 168

*Dennis L. Caffrey, MD  
Tai P. Yoo, MD*

## EDITORIALS

**Heart Valve Surgery at Henry Ford Hospital  
from a Perspective of 32 Years** 170

*Conrad R. Lam, MD*

**A Challenge to Physicians: The Obligation  
and Ultimate Reward** 171

*Richmond W. Smith, Jr, MD*

**The Beta Blocker Heart Attack Trial: An  
Effective Medical Therapy to Prevent Death  
from Coronary Heart Disease** 173

*Sidney Goldstein, MD*

Vol 30, No 3 — HENRY FORD HOSPITAL MEDICAL JOURNAL — 1982