

Currently, the results lead us to continue the multidiscipline approach. Combination chemotherapy and radiation therapy offers safe and effective palliation. It does not adversely affect surgical morbidity or mortality. We believe that it does enhance the quality of life of these patients and perhaps with further follow-up study will demonstrate an improvement in long-term survival.

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DISCUSSION

DR. J. BRADLEY AUST (San Antonio, Texas): I am indebted to Dr. Condon for sending me a copy of his paper before this meeting. He adequately catalogues the trials and tribulations of dealing with this difficult group of patients. They are truly far advanced, but he has assumed that they can be treated surgically.

When I think about carcinoma of the esophagus, I divide patients into essentially three groups: (1) those with Stage I or Stage II disease who are potentially curable and should have a curative type of procedure; (2) those with such far advanced disease that they cannot be resected and continuity restored for successful swallowing; and (3) a vast group in between which are Stage III and IV disease, a very frustrating group, and these are the patients Dr. Condon is addressing.

Those in the first group may be helped by a radical esophagectomy such as the "Skinner" procedure, and attempt made for cure, but in Dr. Condon's group of patients it is clear that palliation was the goal, and I would not argue with Dr. Condon's philosophy that in his group of patients palliation must be the major goal of therapy.

How do you measure palliation? This is a good question. It should be balanced against operative mortality, and from my viewpoint, local recurrence, which is *prima facie* evidence of inadequate surgical resection. If we add these up in his series, the operative mortality and the local recurrence vary somewhat depending on how early deaths are counted, between about 20 and 25% of the patients. Balanced against a 2-year survival rate of 35% with an ability to swallow the major goal of therapy, I would view that he has benefited this group of patients.

The one question that I have is related to the use of the Karnofsky scale, which I think is admirable and should be used more often, but I wonder if perhaps he should add to the denominator those patients who died at surgery, so that one can compare the Karnofsky averages in patients who are treated with other forms of therapy, such as laser, to restore the swallowing mechanism.

DR. JOHN L. CAMERON (Baltimore, Maryland): I would like to confine my comments and questions primarily to the paper of Dr. Condon, although I believe they are also pertinent to those patients in Dr. Wolfe's presentation who had adenocarcinoma of the esophagus.

I believe the important issue in Dr. Condon's paper on adenocarcinoma of the esophagus is the pathogenesis.

Adenocarcinoma of the esophagus is clearly increasing in prevalence in university hospitals. Whether that is secondary to a change in referral patterns or recognition or whether there is a true increased incidence of the lesion is not clear, but I believe it is obvious that we are seeing more and more adenocarcinomas of the esophagus. This point is emphasized by Dr. Wolfe's presentation in which almost 50% of his patients had adenocarcinoma. If you look at series presented 15 and 20 years ago, the percentages of lesions that were squamous and adenocarcinoma were greatly different.

There is increasing circumstantial evidence that suggests that in virtually all patients with adenocarcinoma of the esophagus, the lesions arise from Barrett's mucosa. I would like to present briefly some of the circumstantial evidence for this that we have accumulated.

In the last 6 years we have seen 54 patients with adenocarcinoma at the gastroesophageal junction. When we examined the specimens in the routine fashion, just as in Dr. Condon's paper, approximately 25% were associated with Barrett's mucosa. However, when the specimens were totally embedded and serially sectioned, we found Barrett's mucosa in 35 of the 54 patients or an incidence of about 65%. Now, 30 of those 35 patients with clearly identifiable Barrett's mucosa were white males, and virtually all of them were heavy smokers or heavy drinkers, and most of them were both.

Dr. Condon did not comment on that in his presentation, but I would like him to tell us whether his patients were virtually all white males, heavy drinkers, and heavy smokers. That goes without saying in a V.A. population, but in his university hospital, I would like to hear the distribution.

If we take the other 19 patients in whom we could not find Barrett's mucosa, the question is: are these stomach cancers that are growing up or are they cancers that arose in Barrett's mucosa and the Barrett's mucosa has just been replaced?

Fifteen of the 19 patients were white males and virtually all were cigarette smokers and heavy drinkers, so it looks very similar to the Barrett's group.

If we look at adenocarcinoma of the body of the stomach, we have to go back over twice the time period as we did for adenocarcinoma at the GE junction because in our institution and, I am sure, in all of yours, this lesion is decreasing in prevalence unlike adenocarcinoma at the GE junction. Of 63 patients with adenocarcinoma of the body of the stomach,

only 18, or 29%, were white males. Therefore, the 19 patients with adenocarcinomas at their GE junction more closely resemble the Barrett's patients.

Our survival curve for the first 32 patients is very similar to those of both Dr. Condon's and Dr. Wolfe's, the 2-year survival rate being 35% and the 5-year survival rate being 15%. It is not a completely hopeless disease, currently treated primarily surgically. However, it is one that if there is a premalignant lesion, I believe that perhaps we should spend a lot of time looking for it and policing it so that we can either intervene before the disease develops or at a very early stage.

I would like to emphasize one of the points made by Dr. Condon. Our two longest survivors, one out 7 years and one out 5 years, both had positive proximal margins, so presumably they still have tumor in and at the anastomosis. Neither of these patients has any evidence, however, of recurrent disease; therefore, I believe more than the operation we do, it is the biological activity that determines the subsequent course.

I would like to close and ask Dr. Condon a few questions. (1) Did they totally embed their specimens, and do they think that the incidence of Barrett's mucosa is, in fact, only about 25%? (2) If Barrett's mucosa is indeed premalignant, how hard should we look for it? Should every patient with symptoms of gastroesophageal reflux be endoscoped? I recognize that in our series as in Dr. Condon's, 40% of patients who develop Barrett's cancer never have symptoms of reflux; therefore, we are not going to be able to pick those patients up early, but how about the 60% who do have symptoms of reflux? Should all patients have endoscopy and biopsy for Barrett's mucosa? (3) If you find Barrett's mucosa in a patient, how should it be surveyed? How often should the patient be endoscoped? Should the patient be followed by barium swallows, endoscopy, cytology, and how frequently?

We have not routinely done blunt transhiatal esophagectomies in patients with Barrett's mucosa, although we have in recent years for patients with squamous cell adenocarcinoma primarily because in most patients with Barrett's cancers, the tumor extends down below the cardia, and you have to resect the stomach. Therefore, you are left with a shortened gastric tube, and I wonder if perhaps the shorter graft doesn't account for the significant leak rate that Dr. Condon had and whether or not he believes subsequently that transhiatal esophagectomy should not be the means of therapy for this lesion.

DR. HARRY B. GREGORIE, JR. (Charleston, South Carolina): Carcinoma of the esophagus imposes a death sentence at 6 months in the vast majority of people from the time of diagnosis. At this time, in my mind, there is no good or dependable treatment.

We all wish to avoid adding misery to those who are already miserable or to the hopeless. I wish to commend the authors for their efforts in this difficult situation and field for a very good study and for excellent early results.

I would make a plea for caution in accepting short-term achievements. Two years is a short term. Other studies have shown exciting and good results at the 2-year mark, but at the 5-year mark all patients are dead.

In the light of contrast, I have had the opportunity to look at 50 patients wherein there was Stage I-III disease and an opportunity for long-term follow-up. I present this information hopefully to shed light on that which may offer hope for a few.

(Slide) In this group of 50 patients, 40 had squamous lesions and 10 had adenocarcinoma. Of the patients who are alive, there are nine of the 50 or 18% with average survival of 6.6 years, five with squamous lesions and four with adenocarcinoma. The five patients with squamous lesions received preoperative radiation therapy. One patient was judged to be in extremely early stages of disease, a 45-year-old woman brought in with rectal bleeding eventually due to hemorrhoids, and, like too many, she had endoscopic manipulation of every orifice with a serendipitous discovery of a carcinoma of the esophagus at a very early stage, and we did esophagectomy without preoperative treatment.

In the long term there were 11 patients (22%), all of whom lived over 5 years, and in this group, the average survival time was 13.8 years. In this group there were 11 squamous lesions and no adenocarcinoma. All 11 patients with squamous lesions received preoperative radiation varying from 2500-4500 rads.

(Slide) In this group there was no chemotherapy. There were no positive nodes. There were no undifferentiated or small carcinoma, and no close margins. All patients received thorough esophagectomy with substitution by stomach or colon brought to the neck or into the upper chest.

(Slide) Esophagectomy of this nature, I believe, may be indicated for palliation as we must overcome dysphagia. Clearly it is indicated for early lesions. Residual carcinoma after chemotherapy or radiation in a node negative situation would also call for esophagectomy in my judgment.

The big question, and one that I hope perhaps there will be better answers to, is what is to be done with the patient having radiation therapy and chemotherapy with no microscopic residue? I personally would not wish to submit to esophagectomy in that setting. However, how do we measure this? To the best of my understanding, it can only be measured now by endoscopy, computed tomography (CT) scanning, and perhaps nuclear magnetic resonance.

I would ask the authors if they might comment on that, and again I would congratulate them on an excellent study and hope that we shall hear from them in the future in a longer-term situation.

DR. EDWARD PARKER (Charleston, South Carolina): I want to comment on these two papers, the first very briefly, just to say that our experience with radiation therapy in adenocarcinoma has not been as discouraging as Dr. Condon's. We believe it can have real value, especially before operation. The report of Dr. Wolfe was likewise intensely interesting, and my remarks will be more pertinent to his series.

First of all, in our studies of primary carcinoma of the esophagus, we have excluded cases considered primary in the stomach and invading the lower esophagus, because we believe this is a different disease. It has always been remarkable to me that carcinoma of the pyloric end of the stomach does not invade the duodenum and squamous cell carcinoma of the terminal esophagus does not invade the stomach, but carcinoma of the fundus of the stomach does invade the esophagus.

The primary carcinoma of the esophagus that we have seen is practically all squamous except for an infrequent adenocarcinoma. We conducted a similar type of study beginning in May 1980, extending for 4 years. During that time we were using a protocol consisting of mitomycin C along with 5-FU and concomitant radiation therapy, 3000 rads in 3.5 weeks, followed by resection in patients in whom there was no contraindication to the triple mode.

During the 4 years we saw 129 patients. In some patients, chemotherapy, radiotherapy, or resection, any two or all three, were contraindicated, and one member of the staff elected not to follow the protocol in 40 patients.

Our results to date follow: among patients having chemotherapy alone or radiation therapy alone, there are none surviving. Among six patients having resection alone, there is one 6-year survivor. A second patient survived 5 years, but he died of recurrence in the sixth year. Among 13 patients having chemoradiation therapy (without resection), there is one 4-year survivor.

There were only 21 patients (among 89 entered into the protocol) who had the triple therapy. Among these 21 patients, there have been three 4-year survivors, one 5-year survivor (death due to a stroke), and two 6-year survivors: a total of seven survivors for 4 years or longer.

In conjunction with our previous experience, much of it with Dr. Gregorie and many other colleagues dating from 1940, it has been our observation that adjunctive antineoplastic therapy, either radiation alone, as we used it preliminary to resection for many years before 1980, and radiation and chemotherapy as we used it from 1980-1984, has been associated with a lower operative mortality rate than treatment by resection alone. Also, we have noted improved 2- and 5-year survival rates. From 1967-1975, the 2- and 5-year survival rates for resection alone were 13 and 5%, respectively. For radiation followed by resection, the 2- and 5-year survival rates were 20 and 10%, respectively. However, we added the chemotherapy in 1980 because our results were not improving as they had been before.

However, that is not the end. With preoperative radiation therapy, there has been no tumor in the surgical specimen in 13% of our patients. With preoperative radiation and chemotherapy, there has been no residual tumor in 35% of our patients.

We need a tumor marker to avoid operation in those patients in whom the primary tumor has been eradicated and in whom the ability to swallow has also been restored. We also need an effective treatment for so-called micrometastases because if the esophagus has been resected, the majority of our patients die of distant metastasis and not of local recurrence.

If carcinoma in any way is related to infectious disease, such as bacterial

or viral as demonstrated by Dr. Rous at the Rockefeller Institute in 1922 and possibly by Dr. James Hardy only yesterday, it is possible that successful antigenic or antibody therapy, or a combination or even prevention by vaccination, may some day become an actuality.

I wish to commend both Dr. Condon and Dr. Wolfe and their colleagues for their intensive studies in both of these devastating diseases.

DR. THOMAS DANIEL (Charlottesville, Virginia): I would like to congratulate Dr. Wolfe and his colleagues on their fine study and also thank Dr. Wolfe for allowing me to review the manuscript.

The dramatic clinical tumor response that the Duke protocol is capable of achieving in many patients and the report of no operative deaths in these sick patients represents a significant achievement for the combined therapy approach in and of itself.

I have three questions that arise when we compare and contrast our ongoing study at the University of Virginia with that reported by Dr. Wolfe.

(Slide) I have limited my discussion to squamous cell tumors. We have not had very encouraging results even in the short-term phase for adenocarcinoma. As you can see, our protocol is similar in the amount of radiation used and in the use of cisplatin. In place of VP-16 we have used 5-FU and mitomycin C based on encouraging results with these drugs and cisplatin in squamous cell carcinomas of the anus and of the head and neck areas. We have had the same dramatic clinical response as described this morning. In addition, over half of our esophageal specimens have shown no tumor present compared with 34% in the big series. We have, however, encountered in 38% of our patients clinically significant nondilatable strictures that developed after radiation and chemotherapy, which themselves were an argument for proceeding with surgical resection.

My first question, therefore, is: what factors could have led to no significant preoperative strictures in Dr. Wolfe's series? Does this relate to the presence or absence of full thickness disease, to differences in the delivery of therapy, or perhaps to the concomitant use of steroids? Although we have had no operative deaths, we have, nevertheless, observed significant postoperative pulmonary problems, and I wonder if our manner of delivering radiation therapy plays a role.

We change from anterior-posterior portals to oblique portals to deliver the last 1500 rads. This protects the spinal cord, but irradiates significant posterior lung parenchyma. Dr. Wolfe, you had only two postoperative pulmonary problems. Was all your radiation delivered in the anterior-posterior plane?

My last question concerns the indication of a transhiatal esophagectomy.

(Slide) The seven sequential cases in our study have all been done using the transhiatal technique. We have been surprised and pleased with the ease that the proximal and midthoracic lesions can be removed in spite of previous chemotherapy and radiation therapy. We have had no tracheobronchial injuries or significant hemorrhages and note that patients tolerate this operation better than similarly treated patients who have thoracotomy. Dr. Wolfe, have you recently revised your indications for performing transhiatal procedures in these pretreated patients?

DR. WILLIAM D. JOHNSTON (Nashville, Tennessee): I rise to ask one question of both Dr. Condon and Dr. Wolfe and to give my answer to that question if it were asked of me. Both of you have used different operative approaches for different areas of involvement. My question is: where have you put your anastomosis?

Over the last 6 years I have worked with Dr. Lucian Davis in Nashville, and we have used a combined approach and have different surgical approaches for resection. Most often we use a vertical midline abdominal incision and a left neck incision. We also use a right thoracotomy for mid- and upper-esophageal cancers but we have always put the anastomosis in the neck. I have become convinced that I am going to try to always put the anastomosis in the neck where it has a better chance to heal and if it does not, a leak has not been fatal in our experience. Also, the four late strictures we have had have been safely dilated with maintenance of satisfactory swallowing. I am more cautious about dilating an intrathoracic stricture, and as we all know, a leak in the chest has a higher incidence of mortality.

Another point about the approach in the neck. We used to use the right side when we did a right thoracotomy because the patient would be more favorably positioned. We have changed to always using the left neck, even when we have the patient turned up a little bit for the right thoracotomy. There are two reasons for this. I believe the approach is a little easier on the left side. We never bother the sternum or the clavicle (except for substernal gastric bypass). There is enough room to mobilize and do a good anastomosis in the neck. The anastomosis is easier than doing it in the chest. There is excellent exposure, and the recurrent laryngeal nerve is less prone to injury during the neck approach on the left side simply because there is a longer distance between the two points of fixation in the left compared with the right side. Also, if the recurrent laryngeal nerve is resected or damaged in the process of resection, it is almost always on the left side because that is where the recurrent laryngeal nerve is lower in the chest. You should resect the recurrent laryngeal nerve if needed to resect the tumor adequately because we can handle unilateral vocal cord paralysis well with Teflon injections, and these patients are quite pleased with their voice.

DR. JAMES L. MAHONEY (Closing discussion): I will now attempt to address some of the issues that have been brought up by the discussants. Dr. Aust inquired about the Karnofsky rating of those patients with adenocarcinoma who did not have this type of resection. Unfortunately, I cannot answer that accurately because our series only includes those patients treated on the General Surgery Services and is not a complete review of our institutions' experience with treatment of adenocarcinoma of the esophagus. In the future it would be worthwhile to use the Karnofsky performance scale to evaluate those patients who are treated with methods other than surgical treatment.

Concerning Dr. Cameron's comments, we have not specifically assessed our patients in regards to their smoking and drinking. However, even excluding the VA patients, our patients probably do have a high incidence of excessive drinking, more so than smoking.

We have not totally embedded our specimens, and the incidence of Barrett's esophagus may be higher than our 25% incidence if that technique is carried out.

In reference to patients with reflux symptoms and endoscopically diagnosed Barrett's esophagus, we would recommend a protocol of endoscopic observation and biopsy every 6 months. If progressive dysplasia develops on serial biopsies of the Barrett's mucosa, we would recommend esophagectomy before demonstration of obvious carcinoma.

In response to Dr. Cameron's comments about the gastric resection, we agree that in resecting a portion of the stomach we may cause a greater incidence of anastomotic leak. However, by placing the anastomosis in the neck, we believe that the leak rate has a low morbidity, and leakage of the cervical anastomosis rarely requires operative drainage.

Dr. Gregorie asked how far one should go in determining residual tumor after adjuvant therapy. We would recommend resection of the esophagus and complete pathologic examination. I do not believe that biopsies can ensure against residual tumor in a patient treated with adjuvant therapy for adenocarcinoma of the esophagus.

Dr. Johnson, our anastomosis is placed in the neck. Because of this, as I stated, the leak rate is not associated with a significant morbidity and also these patients do not have symptoms of reflux esophagitis, which often occurs with esophagogastric anastomoses within the chest. In particular, we use the left side of the neck, and our approach is posterior to the sternocleidomastoid muscle. With this posterior approach we have not had any injury to the recurrent laryngeal nerve, which can occur with an approach anterior to the sternocleidomastoid muscle.

Finally, I would like to thank Dr. Mansberger, Dr. Sawyers and the Association for the privilege of discussing this paper.

DR. WALTER G. WOLFE (Closing discussion): Let me, too, thank the discussants for their comments and interest.

In regard to Dr. Cameron's remarks, I would agree that adenocarcinoma seems to be on the increase, at least in the EG junction. I was surprised that there were these many patients with adenocarcinoma in our group. One of these patients had Barrett's esophagus, and that patient was reconstructed with the jejunum because he had had previous gastric surgery and had had reflux surgery.

All our patients are smokers. I believe there is a high correlation between smoking and alcohol intake. It is certainly prevalent among patients with cell carcinoma. It is unusual to see any of these patients who are not smokers, and during that preoperative regimen therapy there is a tremendous effort made to reconstitute nutrition, and also to stop smoking and improve the patient's overall condition.

Only two patients, whom initially I believed were nonsurgical candidates staged at the end of the study, went back into surgery, and nobody who went through the protocol at the end was found to be a nonsurgical candidate: therefore, I believe the clinical evaluation initially is fairly accurate and holds up well.

I cannot agree that more than 2 years is short term for talking about survival, but I do not believe it is short term to talk about palliation as your introductory remarks about the 6-month survival of this disease indicates, and we believe that the palliation is significant. We believe it is significant because the initial chemotherapy debulks the tumor. Radiation therapists do not like to use the word "sensitizer," but these drugs are sensitizers, and they change the influence of radiation to this tumor. I am certainly convinced of that. The catabolic effect of the disease is arrested. The patient has an interest in eating and drinking, and consequently, there is good improvement within the first month of therapy. The bad point is the last dose of chemotherapy and the end of radiation. The patient will, consequently, take 3-4 weeks to recover his white count and to come around to where he believes he is ready to tolerate a major operative procedure.

With regard to the patient with a negative swallow on endoscopy, the problem is we do not know if the specimen is negative until it is out of the patient. We have done biopsies on patients, and many times the biopsy results come back negative, but usually when you scope these patients and restage their disease, there is abnormality in the esophagus. It is not entirely back to normal.

I believe the comments by Dr. Parker with regard to how we choose, and understand this disease are important. Even though the esophageal response is excellent, esophagectomy is going to be necessary.

I believe things are changing with carcinoma of the esophagus. Dr. Parker, you have got a great series, and I am certainly happy that you updated this. I like the fact that you also have somewhere around 30% of your specimens sterile. It speaks well for this therapy, both as a palliative procedure to eliminate surgery for patients who clearly are not good candidates and do not need it as well as hopefully improved survival. The therapy controls local disease. That is the key thing. I believe you

need to look at this therapy as controlling a local disease, and that is the key.

One of the things, Dr. Daniel, is that these patients that come to operation are not as sick after 3 or 4 months of extensive therapy. I believe that changes your results. You eliminate many patients we used to operate on because they could not swallow. They have palliation. Consequently, you do not find yourself in a situation of operating on patients where you know the morbidity and mortality and risk is high. As I have said before, good patients make good surgeons, and if you get these patients in good condition, the results are going to be good.

Pulmonary insufficiency, I believe, is related to smoking in our situation, and, in general, I still believe that and I do not believe it is related to either the cisplatinum and/or radiation therapy.

With regard to transhiatal esophagectomy, I do not care for the procedure. I believe it has a place in high lesions, high middle third, and low cervical lesions where taking the stomach above the azgos vein is not going to give you sufficient margin and you must go to the neck. Consequently, in that group of patients, we have used transhiatal esophagectomy and it has worked well. I have also used it in patients with poor pulmonary function where avoiding a thoracotomy is going to lower the risk; therefore, I believe in those two areas there is a role for it. I will not get into the further controversy about transhiatal esophagectomy.

Leaks are bad. I do not care if they are in the neck or wherever, and they should be avoided. On the right side, we usually use a stapler with the anastomosis high above the azgos vein. It is my impression that patients swallow better with that segment of the esophagus. Other surgeons who do transhiatal esophagectomy and bring the stomach to the neck say that is not a point, but in general, when patients return for follow-up, those patients who have that segment of esophagus below the constrictors seem to swallow better.

On the left side, I usually sew the anastomosis in a single layer using silk, and I have found that to be very satisfactory.

I believe dilatation of the esophagus is always a serious matter. I do not believe there is a problem dilating upper-third anastomoses.

In our patients who have had head and neck surgery, seven patients had either laryngectomy and/or radical neck. I believe it is difficult to take the stomach and the neck in that setting, especially on top of radiation to the neck, and so I still believe that for middle-third lesions, the anastomosis can be done high in the inlet, and I like the Lewis approach, which is an esophagogastrectomy and esophagectomy through the right chest.

I thank the discussants again, and I thank the Association.