Selective Regional Lymphadenectomy for Melanoma:
A Mathematical Aid to Clinical Judgment

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THE contribution of regional lymphadenectomy to the overall attack upon primary cancers is under the scrutiny of laboratory experiments and cooperative clinical trials, as well as sophisticated statistical analysis. Actually, there are three instances in which such treatment is likely to remain secure: 1) When clinical evidence of metastatic regional lymphadenopathy exists in the presence of an otherwise operable primary cancer, lymphadenectomy combined with adequate local excision of the primary salvages a portion of the patients so treated. Standard radical mastectomy is a classic example when performed upon a patient with locally operable mammary cancer and ipsilateral axillary lymphadenopathy indicative of metastases. 2) In other instances, such as carcinoma of the colon, resection of regional lymph nodes facilitates, or is essential for, adequate local excision of the primary neoplasm. 3) Palliative lymphadenectomy provides satisfactory control of superficial metastatic disease which has ulcerated, or is likely to do so. Cervical or inguinal lymphadenopathy exemplifies such palliative treatment by virtue of underlying major vessels prone to injury by uncontrolled neoplasm or irradiation therapy.

These sound indications for lymphadenectomy probably constitute a small minority of the instances in which such treatment is undertaken, however. The aspect of regional lymph node dissections of greatest significance, by virtue of both the prevalence of the clinical stage as well as the magnitude of potential good or harm, is the decision for or against regional lymphadenectomy when curative resection of the primary cancer is undertaken in the absence of clinical evidence of regional lymph node metastases or other dissemination. Surgeons are often confused or blindly follow geographical or political trends with respect to the elective, or allegedly "prophylactic," regional lymphadenectomy. The confusion is primarily due to comparison of dissimilar groups and incomplete specification of clinical data in existing series. The case for regular conduct of elective lymphadenectomy is based largely upon two comparisons:

1. The survival rate for patients treated by elective lymphadenectomy (X) exceeds that of those requiring *early* therapeutic lymphadenectomy for clinically detected metastatic lymphadenopathy in follow-up examinations (Y).

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2. The proportion of patients surviving after adequate local excision of the primary and elective regional lymphadenectomy, which yields nodes histologically non-neoplastic (X), is greater than that for patients treated by local excision without lymphadenectomy (Y).

Neither comparison is valid, because the groups bear greatly dissimilar rates of regional lymph node metastases, a characteristic known to markedly alter survival for most cancers. The majority of patients undergoing elective lymphadenectomy (IX) have no nodal metastases upon microscopic study and most never develop metastatic cancer. On the other hand, patients in group IY virtually all have microscopically confirmed neoplastic lymphadenopathy detected nearly simultaneously with the primary cancer, a most adverse determinant of longevity. Continuing, group 2X has been shown to be *free* of an adverse survival determinant (metastases to regional lymph nodes), whereas those treated by adequate local excision without lymphadenectomy regularly include some neoplasms with the biologic capacity to metastasize, but which were not discovered because the lymph nodes were not excised. The reported differences in survival are more closely related to the proportion of nodal metastases than to treatment directed toward regional lymph nodes.

Discounting for the present favorable or unfavorable effects of removal of normal regional lymph nodes, the patients benefited by the regular practice of elective lymphadenectomy are those whose cancers can be controlled by removal of clinically normal, microscopically neoplastic lymph nodes, but who cannot be salvaged by lymphadenectomy performed when the metastases have become palpable. Obviously, poor follow-up examinations and methods weigh in favor of elective lymphadenectomy. Against this yield must be balanced those patients harmed by a program of routine elective lymphadenectomy: patients who will remain free of tumor with adequate local excision alone, but who suffer mortality or significant early or late morbidity from the lymphadenectomy. If neither mortality nor morbidity occurred, such a consideration would not be required.

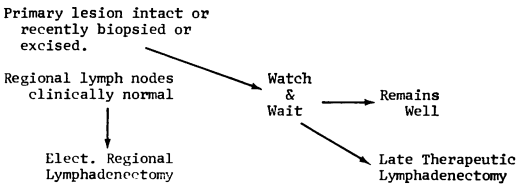

FIG. 1. This schematic representation of *appropriate* comparisons of the value of routine elective lymphadenectomy may be employed retrospectively or prospectively and applies to other neoplasms with superficial, palpable regional lymph nodes as well as malignant melanoma.

An appropriate comparison demands a similar initial clinical status with clinically normal regional lymph nodes as shown in Figure 1. The survival of patients in whom elective lymphadenectomy was employed is then compared with the observed group, with the important proviso that those patients developing clinical metastatic lymphadenopathy undergo a therapeutic lymphadenectomy. If routine elective lymphadenectomy is to be validated, the survival of patients so treated must exceed that of those treated by local excision by a sufficient margin to more than compensate for those harmed by such a practice, not to mention the patients forced to have lymphadenectomy who suffer neither death nor disability but only inconvenience and expense.

Application to Malignant Melanoma

Malignant melanoma arising peripherally upon an extremity with axillary or groin nodes that are normal to palpation provides an excellent and pertinent clinical example. Nearly 50 clinical papers are annu-

TABLE 1. *Collected Published Reports on Melanoma*

Parameter	Site of Primary Melanoma		
	All Sites[1]	Extremities	Lower Extremity
N_x	0.60 386/644 (7,10,16,19,24,26,31,38,41,42)[2]	0.70 146/207 (16,24,31,41)	0.70 113/161 (31,41)
N_y	0.25 123/487 (7,18,24,26,31,35,37,38,41)	0.19 12/62 (41)	0.19 12/62 (41)
N_z	0.004 1/251 (31)	—	—
N_{dm}	0.15 — (24,26,41,42)	0.16 16/101 (24,41)	0.14 9/62 (41)
N_{all}[3]	1.00	1.05	1.03
S_e	0.48 113/233 (4,7,13,14,15,18,20,23,25,26,30,31,39)	0.39 9/23 (4,25,30)	0.44 4/9 (30)
S_d	0.39 105/271 (4,13,14,16,22,27,28,34,38,39)	0.29 31/107 (4,13,16,22,34)	0.29 24/83 (13,22,34)
M_t	—	—	0.015 12/791 (6,11,13,21,29,39,40,41,44)
M_b	—	—	0.33 — (6,13,29,40,43)

[1] Excludes ocular melanoma.
[2] Sources of data in references.
[3] Exceeds 1.0 in extremities due to data derived in part from different series and small number of patients in some cells (e.g., N_y extremities).

ally published on this subject in the English language; yet the data referable to solution of the problem posed in the introductory paragraphs is seldom found. On the other hand, precise data abound as to the histologic status of dissected regional lymph nodes and the effect upon survival thereof. This information is, unfortunately, not clinically procurable in an individual patient until the lymphadenectomy, for better or worse, has been performed. The comparison illustrated in Figure 1 can be attempted from data derived from published reports by means of a simple mathematical expression designed to contrast the proportion of patients harmed and helped by a practice of regular elective lymphadenectomy. The following symbols indicate the proportions of a population with primary operable melanoma with clinically normal regional lymph nodes in terms of 5-year results:

The N and S factors refer to patients whose primary melanoma has been adequately excised,

N_x = those remaining well without regional metastatic lymphadenopathy

N_y = those developing operable metastatic regional lymphadenopathy without disseminated melanoma during follow-up

N_z = those developing unresectable metastatic regional lymphadenopathy without disseminated melanoma during follow-up

N_{dm} = those developing disseminated melanoma without clinical progression through the stage of regional node metastases

M_t = operative mortality (hospital deaths) for patients undergoing elective regional lymphadenectomy

M_b = early and late morbidity resulting from elective regional lymphadenectomy (e.g. 60-day hospitalization, permanent dependent edema, and miscellaneous significant complications common to other major operations)

f = weighting factor relating morbidity to mortality; arbitrarily defined as 0.1 (ten serious complications = one death)

S_e = survival rate for patients subjected to elective regional lymphadenectomy with microscopic lymph node metastases

S_d = survival rate for patients requiring late therapeutic lymphadenectomy (i.e. those patients still salvageable when their clinically normal regional lymph nodes have progressed to clinically apparent metastases).

It is apparent that $N_x + N_y + N_z + N_{dm}$ should equal unity and that N_z will approach zero if follow-up examinations are frequent and careful. Table 1 represents a summary of the data base derived from published reports on malignant melanoma. One may then compare the proportions harmed and helped by regular application of elective regional lymphadenectomy for melanoma arising upon the extremities as follows:

Harmed	vs.	*Helped*
$N_x(M_t + fM_b)$		$N_y(S_e - S_d) + N_z(S_e)$
$(0.70)\ (0.015 + 0.1 \times 0.33)$		$(0.22)\ (0.48 - 0.29) + (0.004)\ (0.45)$
$(0.70)\ (0.048)$		$(0.22)\ (0.19) + 0.0018$
0.0336		0.0436
or		or
34/1,000		44/1,000

In this comparison, values of N_y and S_e were interpolated from Table 1 due to the small number of cases comprising these cells for extremities. Thus, 44 patients will be benefited, 34 harmed and 922 unaffected, aside from the discomfort and expense of the operative procedure, among 1,000 patients subjected to elective lymphadenectomy for melanoma. One may recompute net benefit, substituting data most favorable and least favorable to acceptance of elective lymphadenectomy as in Table 2. Upper extremity melanoma, for example, is a clinical situation tending to place elective lymphadenectomy in a somewhat less unfavorable light. Although the number of patients benefited by routine elective axillary lymphadenectomy remains small, those harmed approach zero by virtue of the very low mortality and morbidity attending axillary lymphadenectomy. Sabatier[86] has also suggested that one may calculate such values referable to the individual physician's weighting of morbidity to mortality (f) and excellence of follow-up care (N_z/N_y). Table 3 provides such data whereby one may estimate his own weighting of morbidity and the excellence of his re-examinations in terms of net patients affected per 1,000.

TABLE 2. *Substitution of Extremes of Data*

Situation Referable to Elective Lymphadenectomy	N_x	N_y	N_z	M_t	M_b	f	S_e	S_d	Net Number Patients/1,000 Harmed	Helped
Least favorable	0.70	0.19	0	0.015	0.33	0.2	0.45	0.39	70	
Most favorable	0.60	0.25	0.10	0.0	0	0.01	0.48	0.29		96

TABLE 3. *Variations in Adequacy of Follow-up and f Weighting*

N_x/N_y Decreasing quality of follow-up ↓	f Values: Increasing Significance of Morbidity →			
	0	*0.01*	*0.10*	*0,20*
0	+25	+23	+ 4	−18
0.01	+26	+24	+ 5	−17
0.10	+35	+33	+14	− 8
0.20	+45	+43	+24	+ 2

+ = net helped; − = net harmed.

$$\frac{\text{Net Patients Helped}}{1{,}000} = \frac{N_x}{N_y} \times 99 - 214f + 25.4.$$

Available data does not permit analysis in terms of man-years but one may compute direct fiscal costs of regular application of regional lymphadenectomy, assuming a $2,000 hospital bill per operation and a surgeon's fee of $600. If the net benefit is to ten patients, as in the first calculation, the expense per patient benefited is $260,000. At the extreme interpretation of data favorable to elective lymphadenectomy (Table 2) the figure becomes $27,083 per patient benefited.

While these data indicate that the conviction with which one can apply elective regional lymphadenectomy to melanoma is far less than that suggested in most surgical series, it may well be that certain patients can be identified who will more likely benefit from the operation than the population tested. We have previously expressed this concept as the specification of sound clinical judgment in this situation.[33] Figure 2 uses estimates of operative mortality and morbidity and of the likelihood of regional metastases occurring now or in the future to determine indications for elective lymphadenectomy. Some patients have such favorable lesions that lymphadenectomy is not indicated no matter how satisfactory an operative candidate the patient may be. Other patients represent such substantial operative risks that lymphadenectomy is withheld even though the tumor is such that nodal metastases are very likely.

Analysis of Selected Patients

To better define these areas, a selected personal series of patients was studied who qualified as presenting with 1) the melanoma intact, or having been recently biopsied or excised, 2) clinically normal regional lymph nodes, and 3) no evidence of disseminated melanoma. This study was expressly undertaken to see if some factors thought to be related to prognosis in melanoma could be used to predict likelihood of regional node metastases, and thereby warrant elective lymphadenectomy in some patients while sparing those very unlikely to need such treatment. Certain demo-

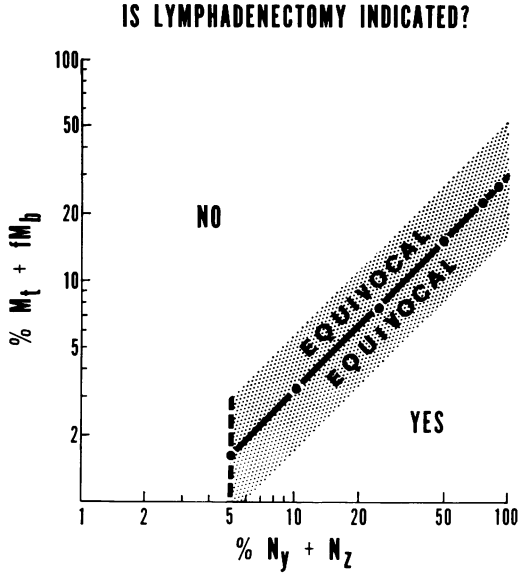

FIG. 2. Application of the comparative mathematical representation schematically, in terms of operative risk (% $M_t + fM_b$) and likelihood of eventual regional lymph node metastases (% $N_x + N_y$), demarcates the points at which those harmed equal those helped by routine elective lymphadenectomy and an appropriate "gray" zone of equivocation. The fallacy in the diagram is that objective measurements of operative risk and prediction of lymph node metastases (*vide infra*) leaves much to be desired at present.

graphic data and pathologic characteristics of the primary melanoma known prior to the moment when the decision for or against lymphadenectomy is made were selected for analysis. These include the patient's age and sex and presence of coexisting illness, and the greatest diameter, depth of invasion, and cellular aggressiveness of the primary tumor. Table 4 indicates that multivariate analysis of variance among three groups of patients (N = 20) revealed no significant capacity of any characteristic, or a combination thereof, to predict regional lymph node outcome. Unfortunately, there were too few patients who had elective regional lymphadenectomy yield microscopically neoplastic lymph nodes for analysis. When such patients can be analyzed and the entire group enlarged, it *may* be that depth of invasion will prove helpful for prediction of lymph node metastases.

These same characteristics were, however, effective in predicting the likelihood of control of melanoma. Table 5 provides discriminant function coefficients useful in calculating a prognostic figure when the same method of representation is chosen. Values which are increasingly positive indicate a favorable prognosis and negative ones an unfavorable outlook. The confidence with which such an outcome may be expected increases as the discriminant score approaches positive or negative unity. In extreme cases, the score may even exceed ±1.0. Table 6 substitutes data derived from a recent patient, indicating a relatively poor prognosis. While our data have not allowed confident prediction as to lymph node status, the capacity to estimate prognosis can be applied to the problem, albeit less directly. For example, patients with net discriminant scores of +0.30 are quite likely to do well and definitely should not, in our opinion, be subjected to elective lymphadenectomy. Those surgeons unconvinced by the preceding data and still affianced to "prophylactic" lymphadenectomy for melanoma could then somewhat more profitably confine their efforts to those patients with favorable scores less than +0.30 and those with negative scores. It may as well be argued that those with very poor prognoses, as indicated by scores lower than −0.40 are singularly unlikely to have their illness controlled by such a procedure and that they also might be excluded from the operative candidates.

TABLE 4. *Multivariate Analysis of Variance Prediction Status Regional Lymph Nodes*

Group 1: Regional lymph nodes clinically normal throughout follow-up
Group 2: Elective regional lymphadenectomy; nodes histologically normal
Group 3: Late therapeutic regional lymphadenectomy

Characteristic	Null Hypotheses: Groups 1, 2, & 3 Are Similar	Null Hypotheses: Groups 1 & 3 Are Similar
Age	$p < 0.155$	$p < 0.334$
Sex	$p < 0.809$	$p < 0.873$
Co-morbidity	$p < 0.146$	$p < 0.146$
Greatest diameter	$p < 0.780$	$p < 0.843$
Depth of invasion	$p < 0.194$	$p < 0.107$
Cellular aggressiveness	$p < 0.953$	$p < 0.829$

Null hypotheses accepted at the 5% level; i.e., the Groups are not significantly different with respect to the characteristics evaluated.

Multivariate analysis of variance among the following three modes of therapy were also conducted:

1) adequate local excision,
2) adequate local excision plus elective regional lymphadenectomy,
3) adequate local excision plus isolated arteriovenous chemotherapeutic perfusion.

There was absolutely no difference in the proportion of favorable results (survival without melanoma) among the three technics ($p < 0.981$). Patients were not randomly assigned to treatment groups, but therapeutic prejudices of the two sur-

TABLE 5. *Discriminant Function Analysis for Prediction of Prognosis*

Characteristic	Representation	Raw Discriminant Function Coefficient
Age	0–99 years	0.0056
Sex	Male = 1, Female = 0	−0.7701
Co-morbidity	0 → 4+ severity	0.4806
Greatest diameter	Measured in mm.	−0.0122
Depth of invasion	0 → 4+ deeper	−0.2227
Cellular aggressiveness	0 → 4+ aggressive	−0.3553
Constant term		1.1563

Null hypothesis: The representation of predictive criteria is the same among patients obtaining favorable and unfavorable results. $p < 0.0181$. Null hypothesis is rejected.

geons most frequently involved insured comparability of these groups.

Discussion

This method of comparison of treatment regimens was instigated by clinical experience confirming a statement made first, to the authors' knowledge, by Ackerman [1] and Wilson [47] to the effect that the period of lymph node arrest for some cancers is exceedingly brief. Butcher [5] and Spratt [40] contributed to the development of some of the mathematic expressions useful in defining the same problem: When is elective lymphadenectomy truly warranted?

Although many other investigators [2, 17, 22, 39, 44] have come close to repudiating elective lymph node dissections for melanoma, none had both the data and the method to accomplish same. The slight benefit accruing from expenditure of so many man-hours and dollars demonstrated in this report should preclude the procedure's frequent use. The small number of patients seemingly benefited by elective lymphadenectomy, let alone those harmed, is surprising. Indeed, recent editorial opinion also appears to favor watchful waiting in lieu of routine elective lymphadenectomy[3, 12] These opinions are also supported by recent reports from Australia. Sandeman found better survival among melanoma patients whose regional lymph nodes were observed than among a group of patients with melanoma undergoing elective lymph node dissections.[33] McLeod and associates found only slight benefit to those undergoing elective lymphadenectomy when compared to those whose regional nodes were observed.[24] Furthermore, McLeod did not consider the potential harm arising from lymphadenectomy. It appears that the specious credentials supporting routine elective lymphadenectomy do not withstand prospective or proper retrospective analysis.[45]

Although not documented in Table 1 because of space limitations, there was a most impressive similarity among data collected from reports by surgeons, chemotherapists and radiation therapists and from sources as widely divergent as Sweden, North America and Australia. Interestingly, more than half of the data were derived from reports advocating routine elective lymphadenectomy. The similarity is supportive of our inability to differentiate among three different regimens, given adequate local excision of the primary melanoma. It appears that some factor common to the melanoma itself, and ill-defined as "biologic behavior," is far more responsible for outcome than adjunctive treatments, given adequate local excision of the primary lesion.

One may contend that serial section of resected lymph nodes would result in more microscopically neoplastic lymph nodes

and thereby increase S_e, favoring lymphadenectomy. However, patients with metastatic melanoma in regional lymph nodes discovered only by serial section survive as do those with no demonstrable metastases at all.[18, 20] Melanoma so detected may be an implant incapable of biologic autonomy and destined for death or innocuous entrapment. Pickren has described similar results referable to mammary cancer.[32] The survival rate of patients with clinically normal, histologically neoplastic lymph nodes exceeds that of those who require therapeutic lymphadenectomy simultaneous with treatment of the primary at 5 years, but does not at 10 years. The data considered here concern 5-year survivals, and it is manifestly better to be free of cancer for more than 5 years rather than less. However, the adverse prognostic significance of conventionally demonstrable lymph node metastases is undeniable.

In-transit metastases were not included among complications of elective discontinuous lymphadenectomy although they may occur in as high as one-fourth of patients in whom regional chemotherapy is not employed.[43] Conversely, it may be that in-transit metastatic melanoma can be confined to an extremity only by lymphadenectomy, and without dissection the melanoma disseminates and effects death of the host sooner than if mechanically confined to the extremity for some considerable portion of the total illness. In view of the inability to specify whether in-transit disease is favorable or unfavorable in terms of survival, it has been ignored in the comparative formula. Patients with entrapment metastases also frequently survive for 5 years, only to die before 10 years elapse.

The appreciable salvage rate resulting from late therapeutic lymphadenectomy (S_d) reflects the elimination, over a period of months to years, of those patients which particularly virulent melanoma which disseminates with or without groin metastases. Those remaining harbor a clinically less rapidly progressive lesion with regional lymph nodal metastases without dissemination, a relatively favorable situation in several neoplasms.

TABLE 6. *Sample Prediction of Prognosis for New Patient Entering Series (Table 5)*

Characteristic	Raw Discriminant Function Coefficient	×	New Patient's Rating	= Product
Age	0.0056		25 (yrs.)	+0.140
Sex	−0.7701		0 (fem.)	+0.000
Co-morbidity	0.4806		0	+0.000
Diameter	−0.0122		5 (mm.)	−0.061
Depth	−0.2227		2	−0.445
Cell Aggres'ness	−0.3553		3	−1.066
Constant Term	—		—	+1.156
Net discriminant score indicates poor prognosis:				−0.276

The authors still hope to identify factors associated with lymph node metastases and develop a scoring system, similar to that described for overall prognosis, to objectively determine relative need for elective lymphadenectomy. Multiple attempts, of which Cochran's [8] report is a better example, have been made to ascertain such parameters with conflicting results upon non-discriminant analysis. Continuing analysis of the personal series may place this in better perspective, particularly with reference to the possible significance of depth of invasion of the primary melanoma.

These considerations are applicable to any cancer with primary lymphatic drainage to a superficial, palpable lymph node group. Such comparisons may contribute to clarification of the existing confusion regarding the role of axillary lymphadenectomy in primary operable mammary cancer. Unfortunately, data on late therapeutic axillary dissection, or completion mastectomy, are too scant to attempt assessment at this time.

Ordinarily, one may expect 20% of regional lymph nodes normal upon palpation to harbor metastatic melanoma if dissection is carried out. That elective lymphadenectomy bears such slight net benefit is little short of amazing in view of such an error in clinical assessment. However, the figure for "false negatives" is similar in most series [19] and lymphography presently gives no promise of materially improving accuracy.[9, 46] From our own experience, biopsy sampling of a single node, such as at the time of femoral cannulation for perfusion, has also not been helpful. The 20% error group represents an opportunity to refine the population for which elective lymphadenectomy must be considered by transferring properly some patients to the early therapeutic dissection category. Unfortunately, the means to accomplish such an end are not at hand.

We intend to add patient data to the base upon which the predictive characteristics have been constructed and tested, hoping to refine and better define our capacity to determine more precisely which patients need, and which do not need, elective lymphadenectomy.

Taking this favorably staged group as a whole, elective lymphadenectomy has little to recommend it. These expressions and refinements are the essence of sound clinical judgment, the most highly prized surgical trait. Traditionally, even the master clinicians have had difficulty defining the ingredients, much less their proportions, of sound clinical judgment. "Some have it, a few acquire it, but most never know it." This time-honored dictum should no longer apply when surgeons begin to specify and objectively assess the factors which heretofore have withstood comparison, analysis, and formal instruction.

Methods such as those applied to melanoma will allow both the intelligent dissection and coherent instruction of clinical judgment. To insure proper use of such methods, one must continue to increase objectivity in assessment of operative risk, insure comparability of groups and more clearly define the outcome criterion.

Summary

A simple mathematical analysis of comparable patients harmed and helped by routine practice of elective regional lymphadenectomy for melanoma indicates such slight net benefits as to preclude its extensive use. Although analysis of several patient and primary tumor characteristics did not allow confident prediction of lymph node outcome, overall prognosis could be anticipated by a system of discriminant scores. Utilization of such scores may facilitate selective lymphadenectomy and add another dimension to specification and instruction of sound clinical judgment.

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Discussion

Dr. Gumport (New York): It has been a pleasure to hear Dr. Polk's presentation of a mathematical approach to ascertain the value of elective lymph node dissections for melanoma. This has long been a source of controversy. For the third time in 20 years our service is engaged in reviewing cases which now total approximately 800. This work is not yet complete. However, a few salient points appear as true today as when the study was initiated with Dr. Herbert Willy Meyer in 1950.

Lymph node dissections certainly should not be done routinely. They should be done selectively, in addition to being elective. They are not for everyone.