A Critical Evaluation of Critical Pathways in Head and Neck Cancer

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Background: Critical pathways have been purported to decrease resource utilization in the management of head and neck cancer. Prior reports have documented shorter lengths of stay (LOS) for pathway patients than for historical cohorts.

Objective: To critically evaluate the impact of critical pathways on LOS after laryngectomy.

Design: Length-of-stay trends of 2 concurrent observational cohorts of laryngectomy patients (September 1992 to February 1999) were compared, 1 at each of 2 medical centers. One center instituted a critical pathway for laryngectomy patients in February 1997; the other never used such pathways. In addition, we examined the independent impact of the critical pathway at the pathway institution after controlling for date of laryngectomy (which reflected temporal trends) and other confounding variables.

Results: Both centers experienced reductions in LOS after February 1997, but there was no statistically significant difference between the reductions (1.9 days at the pathway center vs 1.5 days at the nonpathway center; P > .05). Multivariable linear and linear spline regression models demonstrated that the use of critical pathways at the pathway institution had no statistically significant impact on LOS after controlling for the date of laryngectomy.

Conclusions: Pathway implementation has a limited direct impact on LOS in relatively low-volume procedures such as laryngectomy. Although pathways may influence utilization trends, their impact is likely mediated by the development and educational process that accompanies pathway adoption rather than implementation of the pathway itself. The inclusion of temporal trends and contemporary cohorts provides substantial insight into the effectiveness of critical pathways.

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Modern health care delivery has focused on controlling health care costs while preserving quality of care.1-3 One commonly proposed tool, the critical pathway, has been purported to achieve containment and quality management.4-8 Also known as clinical pathways, these timed-care plans are developed by multidisciplinary teams of nurses, physicians, therapists, and pharmacists to manage patients who have specific conditions or who undergo specific procedures. By emphasizing evidence-based interventions and reducing variation in care, critical pathways are believed to lead to high-quality, less costly care.

Several institutions have described experiences with critical pathways in head and neck oncology.9-14 Each center has reported statistically significant associations between the implementation of a critical pathway and shorter lengths of stay (LOS). These reports have compared observational cohorts of critical pathway patients with historical cohorts of prepathway patients and are summarized with the schematic in Figure 1A. However, these before-and-after comparisons are potentially confounded by temporal changes.15,16 For example, managed care and utilization review, which substantially shorten hospital stays,2 have increased dramatically during the last decade. Physicians and nurses have become more educated about the need to minimize hospital stays. Changes in case complexity, associated procedures, and comorbidity may also have oc-
Authors who have studied pathways outside of head and neck oncology have argued that shorter hospital stays cannot be directly attributed to critical pathways alone.\textsuperscript{15-17} Temporal trends may be one of the other factors that explain the observed decreases in LOS. For example, if the actual pattern in LOS is characterized by the monotonically decreasing dotted line of Figure 1B, the observed decreases are clearly due only to temporal trends: the pathway implementation does not alter the trajectory of the curve. On the other hand, if LOS abruptly drops with pathway implementation, as shown in Figure 1C (as is implied by before-and-after comparisons), then the effect is due entirely to the critical pathway, since there are no other temporal trends. It is also possible that both the critical pathway and temporal trends significantly impact LOS, as hypothesized in the curves shown in Figure 1D and E. The purpose of this study was to critically evaluate the independent impact of a critical pathway on LOS after total laryngectomy. We sought to compare LOS trends at a hospital that used pathways with LOS trends at a nonpathway hospital. In addition, at the pathway hospital, we sought to evaluate the impact of the critical pathway after adjusting for temporal trends and relevant clinical variables. Because critical pathways are most pertinent to straightforward, relatively uncomplicated cases, we chose to focus on procedures that would have maximum benefit from a critical pathway. Therefore, we avoided patients with either more complicated procedures or prolonged hospitalizations due to excessive complications.

Figure 1. Explanations for the observed decrease in length of hospital stay (LOS) after head and neck cancer operations. A, Observed effect: average LOS is lower after pathway implementation. B, One explanation: the critical pathway has no impact; rather, the observed effect is due purely to temporal trends. C, Opposite explanation: there are no temporal trends; the observed effect is solely due to the critical pathway. D, Intermediate explanation: LOS is influenced by both the pathway and temporal trends; the pathway causes an incremental drop ($\delta$) in LOS but does not alter the temporal trend ($\beta$). E, Alternative intermediate explanation: LOS is influenced by both the pathway and temporal trends; the pathway quickens the temporal trend $\beta_1$ by slope $\beta_2$.\textsuperscript{15-17}
METHODS

COHORT ASSEMBLY

Yale/New Haven Hospital (YNHH), New Haven, Conn, implemented a critical pathway for total laryngectomy patients in February 1997. Pathway planning, including multidisciplinary discussions, was initiated in autumn 1996. The pathway itself is similar to those previously reported. Briefly, nasogastric tube feedings are started on postoperative day 1. Drains are kept on high-wall suction for 48 hours, then removed starting on postoperative day 3. Patients are discharged on postoperative day 6 before the resumption of an oral diet. Additional details of the pathway are available from the authors.

At the second study institution, the University of Washington Medical Center (UWMC), Seattle, no critical pathway was developed or is planned. Both centers are tertiary care facilities with similarly high head and neck surgical volume.

The inception cohorts at both hospitals were identified in 2 steps. First, financial departmental databases identified patients with International Classification of Diseases, Ninth Revision procedure codes of either 30.3 (complete laryngectomy) or 30.4 (radical laryngectomy) from September 1992 through February 1999. Second, medical records were reviewed to eliminate patients who underwent a total laryngoesophagectomy, laryngopharyngectomy, or glossolaryngectomy or a partial laryngectomy. We included patients with ancillary procedures that were secondary to a total laryngectomy such as neck dissections, flap reconstructions, or percutaneous gastrostomies.

DATA COLLECTION

The general methods of extraction and classification of archival data for patients with cancer have been discussed previously. Clinical data from YNHH records were extracted by an experienced clinical research nurse (A.C.), after confirming interextractor reliability in 20 records with the first author (B.Y.). A coding handbook was prepared to ensure reproducibility of data extraction and to provide guidelines for resolving discrepancies in the medical record and is available from the authors.

Detailed data were collected on YNHH patients. Baseline data (before laryngectomy) included past head and neck cancer treatment, tobacco and alcohol use, TNM stage of the index tumor, symptoms, comorbid disease (Charlson score3), American Society of Anesthesiologists (ASA) rating, laboratory data, and functional status. Treatment data included the date of surgery, ancillary procedures, blood loss, and duration of operation. Outcomes data included LOS and 90-day surgical complication, reoperation, readmission, and mortality rates. The LOS was defined as the interval between the date of laryngectomy and discharge.

Financial data included payer mix and detailed costs of hospitalization (based on the hospital’s cost-based accounting software) for numerous service lines (eg, operating room, intensive care, pharmacy, and others). Limited data were collected for UWMC patients: TNM stage, date of surgery, ancillary procedures, LOS, and total costs of hospitalization.

DATA ANALYSIS

Data from extraction forms were transferred to computer code with double-entry verification. Because critical pathways are not applicable for patients with prolonged hospitalizations due to excessive complications, we excluded patients with LOS of longer than 3 weeks. This excluded 7 patients at YNHH and 2 patients at UWMC. For YNHH patients, bivariate statistical analyses using 2-tailed testing (α = .05), including t tests, χ², parametric and nonparametric correlations, and analysis of variance, were performed with Stata 7.0 (Stata Corp, College Station, Tex). To identify confounding variables for either date of laryngectomy or LOS, we focused the bivariate analyses on the relationships that these 2 variables had with baseline and operative variables. Multivariable analyses were used to determine the independent impact of date of laryngectomy and the critical pathway on LOS for YNHH patients. We used a linear regression to test the model described in Figure 1D and a linear spline regression for the model in Figure 1E. In these models, we included variables that we hypothesized a priori would influence LOS (comorbidity, prior head and neck irradiation, and the use of pedicled or free tissue transfer), even if they were not significant in bivariate analyses. In addition, modeling, we included potentially confounding variables identified through the bivariate analyses. This study was approved by the Human Investigation Committee at Yale University and the Human Subjects Review Committee at the University of Washington.

RESULTS

YNHH (PATHWAY) COHORT

The inception cohort at YNHH included 92 patients (mean age, 63.9 years) with a mean LOS of 11.4 days. A detailed demographic and clinical description of the YNHH cohort is provided in Table 1, along with these variables’ association with LOS. Age, sex, TNM stage, recurrent/persistent laryngeal disease, prior head and neck irradiation, and comorbidity (Charlson and ASA scores) had no statistically significant association with LOS. The operative duration of the laryngectomy had a marginally significant association (P < .08). The use of pedicled or free flaps and increased blood loss were strongly associated with longer LOS (Table 1).

Critical pathway implementation and the date of laryngectomy were associated with shorter LOS in bivariate analyses. Prepathway patients stayed a mean of 11.9 days; pathway patients stayed 10.0 days (P < .03; Table 1). The shorter LOS did not influence surgical complications, reoperation, or readmission rates. The year of laryngectomy strongly correlated with LOS (Spearman ρ = -0.39; P < .001), which is shown graphically in Figure 2.

Cost and payer mix data were unreliable. Observed cost differences did not correlate with differences in LOS, intensive care unit stay, operating room time, or other variables. Inconsistent methods of cost accounting were likely responsible, which highlights the challenges of cost-based analyses. Payer mix could not be analyzed because instabilities in the health insurance industry did not permit consistent categorization of reimbursement mechanisms (eg, strict capitation, preferred providers, and reduced-fee-for-service plans).

COMPARISON WITH UWMC (NONPATHWAY) COHORT

The contemporary “control” cohort at UWMC included 66 patients with a mean LOS of 9.2 days. Although no critical pathway was instituted at UWMC, the date that the laryngectomy was performed (marker for temporal trend unrelated to critical pathway) was also strongly associated statistically with LOS (Spearman ρ = 0.29; P < .02). The relative time trends at YNHH and UWMC are shown in Figure 3. There was no statistically sig-
significant difference between the decreases in LOS at YNHH and UWMC (Table 2).

**MULTIVARIABLE ANALYSES OF YNHH TRENDS**

We used several multivariable approaches to determine whether date of surgery (marker for temporal trend) or critical pathway implementation had greater independent impact on LOS at YNHH. A linear regression model with temporal trend (Figure 1D) determined that only the temporal trend was statistically significant: the LOS decreased by 1.1 days per year (95% confidence interval, 0.5-1.7 d/y), but the incremental impact of the critical pathway was not significantly different from 0 (Table 3). We used a linear spline regression to see if the critical pathway significantly altered the temporal trend (by slope \( \beta_2 \)) (Figure 1E). Again the overall temporal trend \( \beta_1 \) was statistically significant (LOS decreased by 1.0 d/y, 95% confidence interval, -0.5 to -1.6 d/y) (Table 4). However, the contribution of the critical pathway \( \beta_2 \) was again not significantly different from 0.

We tested the robustness of the models by adding potential confounding variables. We used variables that were hypothesized to be confounding a priori (prior irradiation, ASA score, and tissue transfer), those that were discovered in bivariate analyses (blood loss, operative duration) or confirmed to be confounding (tissue transfer), and then all the variables. The inclusion of these variables into the models resulted in minor changes to the magnitude of the coefficients, but did not change the sta-
tistical significance of the findings outlined in Tables 3 and 4. In other words, each model demonstrated that only the temporal trend (date of laryngectomy) had an independent impact on LOS. Critical pathway implementation did not have a statistically significant impact on LOS in any of the models.

In this study of 2 cohorts of patients undergoing laryngectomy from 1992 to 1999, both cohorts experienced similar decreases in LOS, even though only 1 of the 2 hospitals used critical pathways. In the pathway hospital, the implementation of a critical pathway had no statistically significant impact on LOS after controlling for date of laryngectomy.

The strengths of this study are the use of a contemporary cohort and the consideration of ongoing temporal trends. Since we documented the same decreases in LOS after pathway implementation that other institutions have reported,9-14 these additional analyses provide insight into the importance of considering temporal trends and having contemporary controls when drawing comparisons with historical cohorts.

Cohen et al9 first described the use of critical pathways in head and neck cancer in 1997. They reported LOS decreases of 1 to 1.5 days in 2 critical pathways. However, it was not clear that similar procedures were being compared because the proportion of laryngectomies, composite resections of the oral cavity, and other types of resections in each group was not specified. In 1999, Hanna and colleagues16 found that LOS after 3 types of surgical procedures (not head and neck procedures) decreased significantly from 12 days in 30 prepathway patients to 8.8 days in 30 postpathway patients. It was unclear why partial and total laryngectomy were included as one cohort, but the proportion of partial laryngectomy was similar in both groups. Interestingly, the authors commented that “these reductions have resulted from a general atmosphere of cost-consciousness that has led to more efficient academic surgeons and anesthesiologists,” which is essentially captured implicitly by “temporal trend” in the present study.

The University of Pennsylvania reported on the use of pathways in “major head and neck oncologic procedures” in 1999.13 In unadjusted analyses, they found that LOS diminished from 18 days in 87 prepathway patients to 13 days in postpathway patients, with a corresponding decrease in hospital charges from $105,000 to $79,000. The procedures included in the cohort were diverse, including laryngectomies, oral cavity and oropharyngeal resections, maxillectomies, and neck dissections. A subsequent study has shown that these reductions in utilization have been durable.15 Although they concluded that critical pathways were responsible for the decreases, the authors noted that “external regulation has dramatically influenced practice” and that “physicians are changing their practices with or without [pathways].” This is in agreement with the central findings of the present study.

Our results also support the work of Chen et al,14 who reported on a critical pathway for patients undergoing unilateral neck dissection. These investigators compared 3 groups of patients: 96 prepathway patients, 30 pathway patients, and 64 patients who were treated after pathway implementation but not managed on the pathway (“contemporaneous nonpathway group”). All patients were from the M.D. Anderson Cancer Center, Houston, Tex. The authors noted that prepathway patients had a LOS of 4.0 days, but both pathway and contemporaneous nonpathway patients had a LOS of 2.0 days. Similar findings were reported for cost savings. The authors concluded that the critical pathway was responsible for the differences but noted that it may have been the “improved atmosphere of camaraderie” and “the process of thinking about and developing clinical pathways” that were responsible for the improvements.

Contemporary control groups at separate institutions have been used in other disciplines with similar results. Holmboe et al12 studied 32 Connecticut hospitals treating patients admitted for acute myocardial infarction and found no difference in LOS or other primary outcomes between hospitals that used pathways (n=10) and those that did not (n=22). Similarly, Pearson and colleagues10 found that LOS after 3 types of surgical procedures (not head and neck procedures) decreased signifi-
significantly at hospitals that used pathways and at those that did not.

A number of investigators have attempted to determine if critical pathways are effective in randomized clinical trials. Most studies have found no significant decrease in LOS with pathway implementation. The sole study demonstrating that pathways had effectiveness focused on community-acquired pneumonia in Canada.24 In the 9 hospital emergency departments that used the pathway, bed days per patient and admission rates were significantly lower than in the 10 hospitals randomly assigned to conventional management. However, these findings must be interpreted carefully. First, Canadian hospitals have not been subject to the same external pressures as their American counterparts. In fact, even the critical pathway hospitals in this Canadian study had higher utilization rates than what is typically seen in the United States, suggesting that the Canadian hospitals just had more room for “improvement.” Second, pneumonia care is a high-volume procedure, managed by a bewildering number of physicians and allied health professionals, which is not the case with head and neck cancer.

Other randomized studies have demonstrated that quality-improvement techniques have had little effect. The landmark study by Falconer et al23 showed no differences in LOS or charges between 53 patients on a critical pathway for stroke rehabilitation and 68 similar patients who were not on the pathway. The primary difference was that satisfaction rates were worse among patients treated with a critical pathway. Randomized trials that have tested other quality-improvement techniques such as academic detailing and use of opinion leaders have also failed to show significant effects.24-26

An alternative explanation for the YNHH data in Figures 2 and 3 should be discussed. The upturn in LOS at YNHH in academic year 1998 might also suggest that the critical pathway had a strong but temporary effect in 1997. The critical pathway was discontinued in 1999 because the nursing service grew frustrated with the paperwork needed to document persistent variances from the pathway. Therefore, it is possible that nursing dissatisfaction resulted in ineffective use of the pathway in 1998 and that the true impact of the pathway was felt in 1997. We caution against this alternative explanation for several reasons. First, we repeated our analyses using only data through academic year 1997 and found the same results: temporal trends dominated, and the impact of the pathway was not significant (data not shown). Second, the decreases in LOS occurred before pathway implementation and even preceded hospital discussion on developing critical pathways for laryngectomy, supporting our premise that another external factor was more responsible for the decrease. Third, because of small numbers of patients in the organ preservation era, the differences in LOS between 1997 and 1998 were not statistically significant.

We also believe that pathway advocates must consider the frustration experienced by the YNHH nurses. It may be that the YNHH experience highlights the distinction between efficacy (the effect under ideal conditions) and effectiveness (the effect in real-world conditions).27-28 Even if a pathway (or any treatment) is efficacious in theory, difficulties with adherence under real-world conditions may result in an ineffective pathway (or treatment).

Our study has several limitations. First, the comparison is not blinded and randomized. There may be systematic bias in comparing observational practice patterns in Washington and Connecticut, but no such biases are obvious, and prepatherway trends were similar at both institutions.

Second, we were unable to quantify many of the influences on temporal trend, so we relied on the date of laryngectomy. The use of third-party utilization review and level of provider education is difficult to measure, and instabilities in the managed care industry precluded reliable reporting of payer mix. However, given the strong association of date of laryngectomy with LOS, we believe that this variable is a reliable marker for temporal trend.

Third, the use of additional outcomes measures such as cost of care and physician, nurse, and patient satisfaction would have provided additional insights into the analysis. Unfortunately, the cost data were erratic and satisfaction cannot be measured reliably in retrospective fashion. Finally, our observations are relevant only to the relatively low-volume procedures that characterize most head and neck surgery, and are not generalizable to high-volume procedures in other specialties.

We believe our results are generalizable to most head and neck oncology practices, since our basic results are consistent with prior reports in the head and neck literature. However, by including a contemporary control group and considering the impact of temporal trends as well, we have shown that much of the observed decrease in LOS may be explained by variables other than critical pathway implementation. We have used a quantitative approach to measure the concerns that many of these prior studies had already raised.

In conclusion, a direct causal relationship between critical pathway implementation and shorter LOS after head and neck cancer operations is not supported by our findings. At institutions using pathways, pathways may confound temporal trends if they are developed over a period of time. However, because a similar temporal trend was also observed in a nonpathway institution, it is important to recognize that the trends are strongly influenced by other factors as well. These factors, such as managed care penetration, increased utilization review, and provider education, may be more responsible for the observed decreases in LOS after head and neck surgery.

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