The High-Low Amputation Ratio: A Deeper Insight into Diabetic Foot Care?

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The purpose of this study was to propose and evaluate a high to low (Hi-Lo) amputation ratio as a potential additional quality measure giving further insight into high-risk foot surveillance beyond foot screening examinations. As part of the Dartmouth Atlas of Health Care project, a secondary analysis was performed on Medicare administrative data. Amputation rates were adjusted for age, gender, and race. This included 37,808 minor (foot-level) amputations and 44,599 major amputations from 1996 to 1997. We also calculated the longitudinal national trends in the Hi-Lo ratio with data from the Centers for Disease Control and Prevention from 1992 to 2002. The adjusted mean Hi-Lo ratio was 1.35 (standard deviation, 0.42). The lowest ratio was 0.56, and the highest ratio was 3.43. The correlation coefficient for the Hi-Lo ratio with major amputation rate was 0.48 ($P < .0001$; $R^2 = 0.23$). Similar correlations were found for the highest and lowest percentiles for major and minor rates. The Centers for Disease Control and Prevention data of the Hi-Lo ratio using the crude and age-adjusted rates suggest stable trends in the ratio over a decade. The Hi-Lo measure demonstrates face validity, yet only a small proportion of the variance is described by local propensity to perform major amputation or by major amputation rates alone. The United States has relied on a foot screening measure alone, perhaps explaining why major amputation rates have not substantively declined. If we are to reduce the amputation burden, we should begin with a straightforward measure that can be implemented at most any center (The Journal of Foot & Ankle Surgery 45(6):375–379, 2006)

Key words: diabetes, diabetic foot, amputation, quality improvement

One of the most feared complications of diabetes is amputation (1–4). This fear is warranted, because diabetes is the major underlying cause for most amputations in Western countries (1). Furthermore, a diabetes-related amputation markedly worsens quality of life and increases the risk of further amputations (5–7). Most ominously, the mortality rate after amputation is about 40% at 1 year and 80% at 5 years (3, 8). A disproportionate share of these adverse outcomes occurs in patients who undergo so-called "high-level" or major amputations above the foot (9, 10). Therefore, a general goal of any treatment scheme would be to perform as distal an amputation as possible. This has the potential benefits of reducing the size and weight of any prosthetic device, improving general functional capacity, and reducing energy requirements of walking (11).

Despite better understanding of the causes of diabetes-related amputations and proven prevention modalities, lower extremity complications from diabetes remain very prevalent (12). Equally disturbing is that this apparent treatment of last resort is highly variable in performance. Wrobel et al found that patients with diabetes were 9 times more likely to have a major amputation based on the local practice styles of where they live after they accounted for people's age, sex, and race (13). The variation was not highly associated with local propensity to perform major amputation ($R^2 = 0.31$). The degree of variation was 2 times higher than most of the previously studied general surgical procedures with these same methods and data sets (14–17). A subsequent study reported a similar degree of variation observed in the Department of Veterans Affairs (VA), where the major amputation rate varied 7.6 fold over 10 centers (18). Previous authors have attributed regional variation in medical care to population characteristics, ca-

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pacity of local health care systems, and the practice style of local physicians (15).

This public health burden persists despite several national and international directives, and guideline initiatives implemented over the last decade in an attempt to help reduce amputation rates (19–27). In 2004, the Agency for Health Care Research and Quality put forth the preventive quality indicator of discharges of lower extremity amputation to serve not as a measure of hospital quality, but rather as one measure of outpatient care (28). The total amputation rate, however, may not be the best measure for gauging the success of these programs. We do not yet have a clearly defined benchmark or quality measure for determining the appropriateness of diabetic limb salvage care.

With the belief that lower levels of amputation are generally a better functional outcome than higher levels, we propose the high to low (Hi-Lo) amputation ratio as an additional outcome measure that can give facilities further insight into their local quality of diabetes foot care efforts. We examined the utility and face validity of the proposed measure through its discrimination of amputation profile in the tenth and 90th percentile of hospital referral regions in the Medicare population and a 10-year trend of data made available from the Centers for Disease Control and Prevention (CDC) (12, 13).

Methods

The methods for this study have been previously described (13) and are part of ongoing work with the Dartmouth Atlas of Health Care project (16). Numerators were calculated from hospital discharges using diabetes code and the highest-level nontraumatic amputation in persons enrolled in Medicare from 1996 to 1997. Major amputations were defined as transtibial or transfemoral. Minor amputations were defined as toe, ray resection, transmetatarsal, and Chopart's amputations. Denominators for persons with diabetes were estimated by multiplying the regional prevalence of diabetes by the regional Medicare population (13). This included 37,808 minor amputations and 44,599 major amputations.

The unit of analysis was the hospital referral region (HRR), which represented health care markets for their respective tertiary medical centers. Individual regions were created by the zip codes where a plurality of patients sought care. Previous authors studied 11 surgical procedures and found 90% of enrollees resided in the same HRR as the surgical center (14). An indirect method was used to adjust rates for gender, race, and age. HRRs with rates based on 10 or fewer procedures were dropped from the analysis to avoid unstable estimates of regional variation. We found 52,285 minor amputations in our analysis of 1996 to 1997 part A data. A separate analysis of 1997 part B data found 53,705 minor amputations (Geiss L, personal communication, 2001). It appears that the majority of minor amputations missed in part A data are performed on persons without diabetes. This is supported in our analyses, because 35 HRRs had to be dropped and 80 HRRs were found to have rates >25% below the national average for minor amputation in persons without diabetes. There are a number of limitations in using part B Medicare data for minor amputation in persons with diabetes. Claims are limited to one diagnostic field, and thus yield low sensitivity for the diabetes diagnosis because minor amputations are performed for competing reasons (that is, gangrene, osteomyelitis, septic arthritis, etc). We also calculated the national trends in the Hi-Lo ratio with the CDC data from 1992 to 2002 (11).

Statistical analysis consisted of the calculation of the extremal ratio, where the highest rate HRR was divided by the lowest rate HRR. The Hi-Lo amputation ratio was computed for each of the 306 hospital referral regions by dividing the major amputation rate by the minor amputation rate. The Pearson correlation coefficient was used to quantify correlation between major amputation and Hi-Lo amputation ratio.

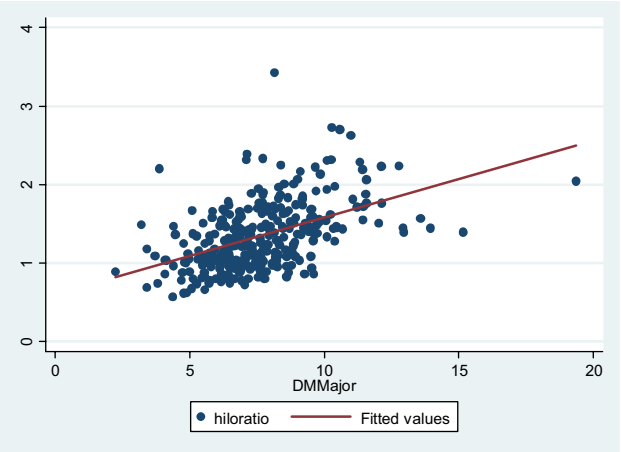
Results

Calculated using rates and adjusted for age, gender, and race, the Hi-Lo amputation ratio was 1.35, with a standard deviation of 0.42 (crude rate = 1.18 calculated using counts). The lowest ratio was 0.56 and the highest ratio was 3.43, yielding an extremal ratio of 6.1. The Pearson correlation coefficient for the Hi-Lo amputation ratio with major amputation rate was 0.48 ($P < .0001$; $R^2 = 0.23$) (Fig 1). For the top tenth percentile centers, the Pearson correlation coefficient for the Hi-Lo ratio with major amputation rate was −0.27 ($P < .0001$), and the minor amputation rate was 0.36 ($P < .0001$). For the lowest 90th percentile centers, the Pearson correlation coefficient for the Hi-Lo ratio with major amputation rate was 0.33 ($P < .0001$), and the minor amputation rate was −0.30 ($P < .0001$). Figure 1 (scatter plot of Hi-Lo ratio) suggests a linear relationship.

The CDC data from the 1992 to 2002 calculation of the Hi-Lo ratio using the crude and age-adjusted rates suggest stable trends in the ratio (Figs 2 and 3).

Discussion

Providing the right care to the right people, at the right time, in the right amount, is the marching order for those aspiring to optimize the quality of care. Many quality improvement experts recommend improving the process of high-risk foot care through use of stratified foot risk examinations (29). The International Working Group on the



DM Major = high-level diabetes-related amputation
Hiloratio = High-low amputation ratio
The correlation coefficient for the Hi-Lo ratio with major amputation rate was 0.48 (p=0.00001; R^2 =0.23).

FIGURE 1 Scatter plot of major amputation with Hi-Lo amputation ratio. DM Major, high-level diabetes-related amputation; Hiloratio, high-low amputation ratio. The correlation coefficient for the Hi-Lo ratio with major amputation rate was 0.48 (P = .00001; R^2 = 0.23).

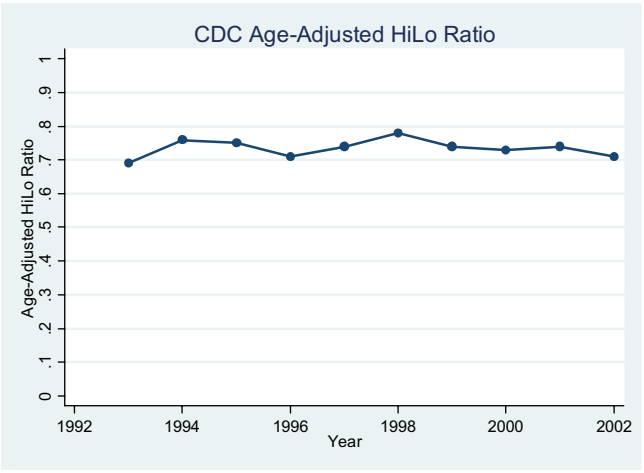


FIGURE 2 CDC-adjusted Hi-Lo ratio from 1992–2002.

Diabetic Foot risk classification system has been shown to have predictive validity over 2.5 years (30). Using this approach, a recent prospective cohort study demonstrated a 47% reduction in amputations, a 38% reduction in hospital admissions, and a 70% reduction in skilled nursing facility admissions observed over a 24-month period (31). However, despite this knowledge, patient-reported foot examinations remain stable (12). It is with this urgency that we propose the Hi-Lo ratio as an additional quality measure. Results from this measure can give centers additional insight into the quality of their foot care programs. It could be used to examine local coordination strategies, referral path-

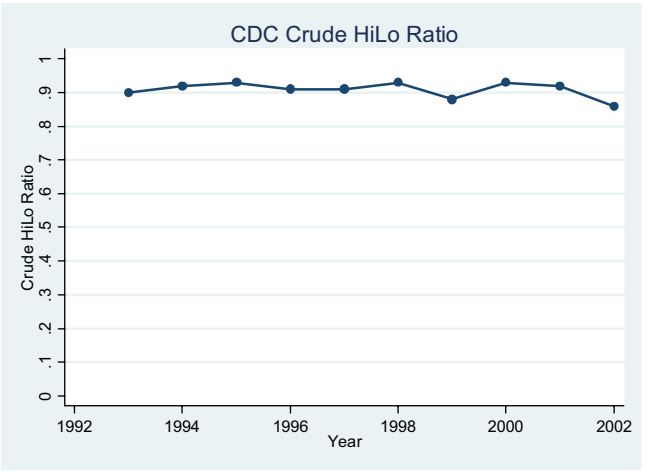


FIGURE 3 CDC crude Hi-Lo ratio from 1992 to 2002.

ways, and organization of care at the front line and front office (18, 32, 33).

Although in the United States there are large variations in the provision of amputation and trends in this procedure are essentially stable, in closed systems of care, amputation rates have been decreasing (34). Within the VA, law and policy are explicit in their establishment of facility foot care programs with annual reports to Congress. These policies mandate the establishment of multidisciplinary foot care teams and a designated facility level coordinator (35). Although the policies do not mandate a specific organizational framework, they direct facility managers to identify veterans at risk for lower limb complications, provide preventive care, track high-risk foot care across the continuum of outpatient, inpatient, and rehabilitative care, and provide education, footwear, and social support. Furthermore, the VA directive is supported by nationally issued foot care guidelines for risk stratification (36) and quarterly and cumulative performance measurements on facility and network foot screening and referral of high-risk patients to foot specialists. When looking at the VA's decreasing rate of major amputations, there has been a steady reduction since the introduction of various organizational initiatives: prevention of amputation directive (1993), foot care performance measures (1996), electronic medical record (2000), practice guidelines (2004), or amputation registry (2004), and high-risk foot registry (2005). The VA has also used the Hi-Lo ratio as a method to measure outcomes. The Central Oversight Committee suggests that centers with higher-than-average Hi-Lo ratios look at their system of care to determine if trends can be identified and strategies developed to address causes of higher-than-average ratios. Specifically, it allows systems to examine each component of its program including: 1) identification of potential patients at risk; 2) foot risk score screening methods for patients at risk, 3) referral systems within the institution for patients with ei-

ther current conditions or high-risk scores (this includes interfaculty referral from remote sites); 4) treatment algorithms and care maps for patients at high risk or with current wounds and ulcers; and 5) that the right specialists (vascular surgeon, orthopedic surgery, podiatric surgeon) are readily available so the right care can be delivered at the right time. In addition to these issues, communication between providers, both interfacility and intrafacility should be examined to ensure that care is compassionate, safe, effective, efficient, and interdisciplinary.

There are several surmountable limitations to using the Hi-Lo ratio as an additional outcome measure. At the facility level, there is little downside because the metric is a ratio; therefore, errors in the numerator and denominator would likely cancel each other out. However, for facility comparisons, caution must be used. The same methods would need to be used for calculating rates of amputation across centers conforming to uniform guidelines for presenting age-standardized rates. When used in isolation or for punitive purposes, there could be several limitations to the Hi-Lo measure versus stratified foot examinations. Previous authors have described using process measures over outcome measures because of problems with risk adjustment and comparing small rates of events (29). We acknowledge these difficulties and recommend this measure as a method to point out high variation care. It would permit further exploration into why a center might experience adverse outcomes. For example, a referral center receiving sicker patients too late in their disease process might be able to work with referral sources or be accounted for in the analysis. This illustrates the importance of uniform denominator calculation if one decides to make detailed comparisons. This measure will also permit further insight into care across the continuum of disease. Conformance with yearly foot examinations only permits insight into the screening process. The Hi-Lo measure would allow further exploration into high-risk surveillance and limb salvage care (18, 32, 33). Ideally, prospective clinical data would be used to calculate the numerator. Currently using administrative data for hospitalization may not reflect rates per person if the patient is hospitalized more than once for the same condition. Administrative amputation data are known to have other limitations (37). Prior research suggests individuals undergoing lower extremity amputation have a substantial risk for reamputation at 1 year (1, 3). We cannot identify these as the same individuals. Ascertainment bias may exist for the numerator. In 1985, sensitivity for the diabetes diagnosis in Medicare claims data was found to be 84%, ranging from 88% to 100% (38).

When the Hi-Lo measure is applied to the CDC data, the 10-year trends appear rather stable. The variation of the Hi-Lo ratio in the Medicare data is pertinent because the degree of variation is consistent with our previous work investigating major amputation rates (39). The mean Medicare ratio is higher possibly because of an older population, different methods of analysis, differences in gender ratio, and the previously mentioned limitations of studying minor amputations using inpatient administrative data only from 1996 to 1997.

The Hi-Lo measure demonstrates face validity because there is a statistically significant correlation with major amputations (0.48; $P < .0001$). Yet, major amputations only describe 23% of the variance in the Hi-Lo ratio, suggesting there is more to be gained by using this metric over major amputation rates alone. Our previous work demonstrated that local propensity to perform major amputation described little variance ($R^2 = 0.31$) in major amputation for persons with diabetes (13). These two findings suggest that the Hi-Lo metric conveys more information than either of these 2 rates alone or in combination.

Aside from the previously described and not described nontrivial issues that need to be addressed in calculation of the Hi-Lo ratio, we still believe it to be an important step in giving further insight into local high-risk foot surveillance and limb salvage efforts. As it has been described, foot screenings alone do not result in lower amputation rates (40). In the United States, we have only relied on this measure (12). Perhaps this is one of the reasons why we have not seen major amputation rates drop substantially. It may be the measurement culture within the semiclosed system of the VA that has produced sustained reductions in major amputations. Their strategies included use of a directive, practice guidelines, uniform electronic medical record, reminders, performance and outcome measures, and an "at-risk" registry (18). If we are to begin to see a sustained reduction in major amputations, we should begin with a simple measure that can be implemented at almost any center.

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