Dysphagia Management and Research in an Acute-Care Military Treatment Facility: The Role of Applied Informatics

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ABSTRACT Purpose: This report describes the development and preliminary analysis of a database for traumatically injured military service members with dysphagia. Methods: A multidimensional database was developed to capture clinical variables related to swallowing. Data were derived from clinical records and instrumental swallow studies, and ranged from demographics, injury characteristics, swallowing biomechanics, medications, and standardized tools (e.g., Glasgow Coma Scale, Penetration-Aspiration Scale). Bayesian Belief Network modeling was used to analyze the data at intermediate points, guide data collection, and predict outcomes. Predictive models were validated with independent data via receiver operating characteristic curves. Results: The first iteration of the model (n = 48) revealed variables that could be collapsed for the second model (n = 96). The ability to predict recovery from dysphagia improved from the second to third models (area under the curve = 0.68 to 0.86). The third model, based on 161 cases, revealed "initial diet restrictions" as first-degree, and "Glasgow Coma Scale, intubation history, and diet change" as second-degree associates for diet restrictions at discharge. Conclusion: This project demonstrates the potential for bioinformatics to advance understanding of dysphagia. This database in concert with Bayesian Belief Network modeling makes it possible to explore predictive relationships between injuries and swallowing function, individual variability in recovery, and appropriate treatment options.

INTRODUCTION

Clinical providers in military treatment facilities (MTFs) face multiple challenges in evidence-based clinical decision-making. First, given the tremendous range of care-related decisions that occur within a single patient's hospital admission, there is relatively limited literature to inform many of those choices. Second, whatever literature is available is likely to be based on civilian sample populations and thus may have limited application to the military population being served. Third, an abundance of clinical data regarding outcomes of various diagnoses and interventions exists, but this information is not readily available in a form that can be analyzed statistically.

Dysphagia, or swallowing dysfunction, is one example of a clinical sequela that has limited research evidence to guide caregivers in MTFs. Internal estimates suggest that up to 20% of military active duty service members (ADSMs) injured during deployment who were admitted to Walter Reed Army Medical Center (WRAMC) and Walter Reed National Military Medical Center (WRNMMC) exhibited dysphagia. Difficulty eating and swallowing can have significant health care implications including aspiration pneumonia, dehydration, malnutrition, and in severe and prolonged cases, death. However, the published literature lacks systematic examination of dysphagia in the ADSM population.

A preliminary analysis of 50 blast-injured ADSMs referred for dysphagia evaluation at WRAMC during the early stages of the conflicts in Iraq and Afghanistan revealed that all demonstrated some aspect of pharyngeal dysphagia.[1] Deficits reportedly included delayed onset of the pharyngeal swallow response, pharyngeal residue, and tracheal aspiration. Reports from civilian populations with traumatic brain injury or spinal cord injury tend to support these results. For example, videofluoroscopic swallowing studies (VFSSs) from 53 patients with dysphagia subsequent to closed-head injuries revealed 81% with delayed or absent swallow response, 50% with abnormal tongue control, and aspiration in greater than one-third of the patients.[2] Records reviewed from 131 patients with spinal cord injury identified the co-occurrence of brain injury, history of spinal surgery, and the presence of a tracheostomy tube to be predictive of dysphagia and tracheal aspiration.[3] These results must be applied with caution by clinicians in MTFs, however, because traumatically injured ADSMs (TI-ADSM) are generally younger and more physically fit than the civilian patients included in these studies, and the mechanisms of injury can differ substantially from those incurred in the civilian population.

To better understand the nature, course, and management of dysphagia in a TI-ADSM population, this project was designed to systematically review and catalog patients referred

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for dysphagia evaluation after sustaining combat-related injuries over the past decade. By organizing this information into a normalized, relational database, clinicians and researchers can answer questions that previously were available only through expert opinion and clinical experience. The purpose of this report is to describe the development and initial examination of the database to illustrate how existing clinical data can be harnessed by clinician–investigators to inform best practice patterns for patient referral, prognosis, and management.

METHODS

Patient Selection

Patients eligible for inclusion were (1) TI-ADSM admitted to a National Capital Regional MTF (WRAMC, National Naval Medical Center [NNMC], and WRNMMC) since the beginning of 2004; (2) referred to the Speech Pathology Clinic for a dysphagia evaluation that was completed during the inpatient hospitalization; and (3) between 18 and 50 years of age. Hospital coders provided lists of potential candidates by querying International Classification of Diseases, 9th Revision, Clinical Modification and "Healthcare Common Procedure Coding System" codes from inpatient records. Candidates' records were screened by research team members to identify and enroll qualifying cases. Once enrolled, patients whose recorded VFSS were available for reanalysis were prioritized for detailed medical record extraction into the database.

Records from patients admitted before August 2012 were exempt from providing informed consent; inpatients recruited thereafter consented and were prospectively enrolled into the study in accordance with the rules and regulations of the WRNMMC Department of Research Programs Institutional Review Board (IRBNet no. 357205).

Database Development

Structure

The WRNMMC Dysphagia Database was constructed in Microsoft Access. Its overall design utilized a normalized relational format to accommodate the longitudinal nature of prolonged hospitalizations. Figure 1 illustrates the basic design of the database with selected variables. Essentially, it is a layered tree-like structure wherein each subject has a unique identifier or primary key as the main trunk. Each patient's hospital admission was assigned a secondary key that linked back to the primary key, and each date with relevant medical information was tagged with a tertiary "encounter" key that linked to the admission identification. Each layer of data included variables that were anticipated to be stable for the duration of time represented at that level, and one or more tables within Microsoft Access were utilized to capture data from each layer. For example, the "Accrual" table corresponded to the first layer described above and included the patient's study identification code, date of birth, sex, race, ethnicity, and height. The second "Admission" layer included

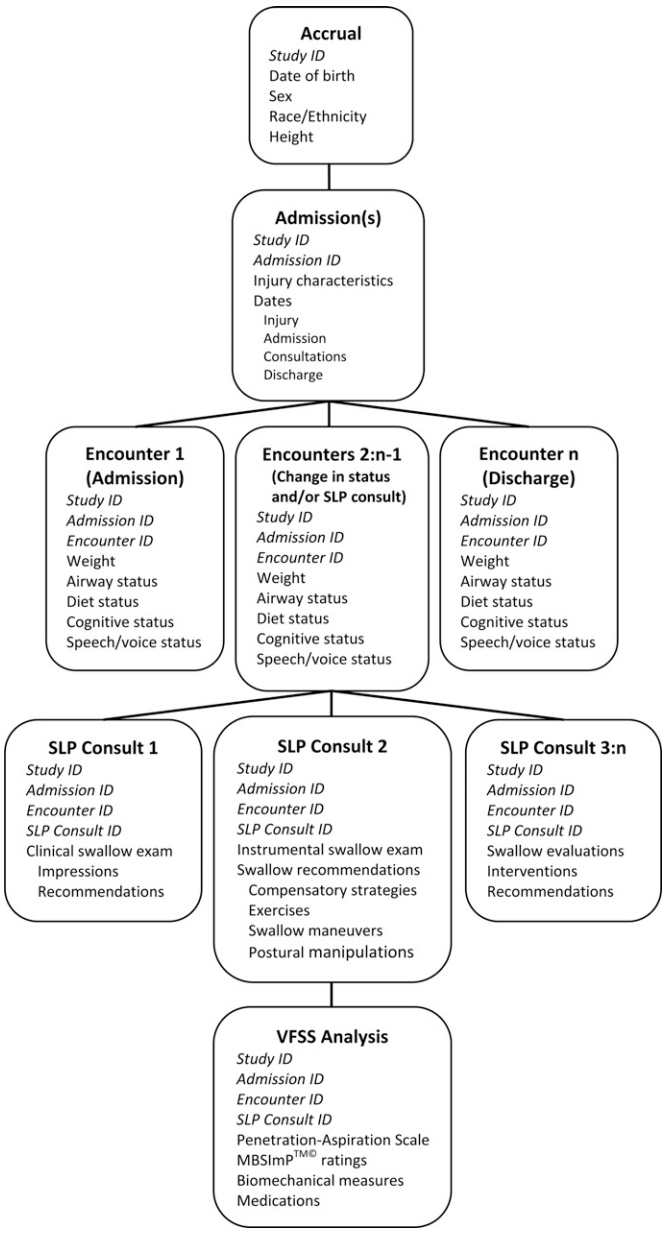

FIGURE 1. General structure and contents of the Dysphagia Database. Each row represents a layer in the tree structure, and each box represents a table; the identification keys linking information between layers are italicized. Note that there may be multiple encounters (1 = admission, *n*[or last] = discharge) other encounters (2 through $n - 1$) were triggered by changes in status or a speech-language pathology (SLP) consult. SLP consults generated an additional layer of data. SLP Consult 1 typically involved a clinical (or "bedside") swallow examination and SLP Consult 2 often included an instrumental (videofluroscopic/VFSS or fiberoptic-endoscopic swallow study. Retrospective analyses (Penetration-Aspiration Scale/PAS, Modified Barium Swallow Impairment Profile/MBSImP, and biomechanical measures) for available archived VFSS recordings were completed, and medications taken on the day of the VFSS were entered; these data were not included in the preliminary models illustrated in this article. Only selected and simplified variables are listed in the figure for clarity; see text or contact authors for more detail.

one table with the nature and severity of injuries sustained as well as dates of injury, admission, key consultations, and discharge. The third "Encounter" layer held information that was likely to change on a daily basis, such as artificial airway status, feeding status or diet orders, cognitive status, speech and voice status, and weight. An encounter was generated for every admission, discharge, and any change in status that was likely to affect dysphagia management. The fourth "Speech-Language Pathology (SLP) Consult" layer comprised several tables specific to each swallow-related encounter. Figure 1 illustrates a typical scenario in which the first SLP consult involves a clinical swallow examination, the second involves an instrumental swallow study, and subsequent consults involve additional evaluations, interventions, or changes in recommendations. Each was linked back to the key for the relevant encounter date. Date (or 1 day) was determined a priori to be the narrowest temporal window of relevance for this study.

The layered tree structure enabled the database to accommodate multiple entries of similar data (e.g., weight, diet status) efficiently while maintaining the ability to collapse data as necessary for specific analyses. Within each table, each column contained one variable and each row indicated a separate patient (in the "Accrual" table), admission (in the "Admission" table), or date of service (in the "Encounter" and "SLP Consult" tables). Thus, a given patient would have a single entry in the Accrual table, typically a single entry in the Admission table (rarely, a patient was redeployed, reinjured, and admitted for a second entry), and perhaps a dozen in the Encounter and SLP Consult tables.

Once the tables were finalized, forms were created within Microsoft Access to facilitate data entry. Forms were organized by topic, and each entry was linked to a single variable within the tables. Customized drop-down response menus provided fixed or binary choices for each question, usually with an option for "other" or "unknown." This necessitated more questions/variables at the data entry stage, but allowed for better management of queries and Bayesian Belief Network (BBN) analysis later. Because the existing electronic health record (EHR) was mostly in narrative form rather than templates, investigators reviewed pages of narrative text to extract relevant variables and enter them into forms.

Variables

The process of determining which variables to include in the database took into account the scope of the database project's goals, current research literature, clinical experience, and patient population demographics. Two research SLPs (AMD, KDB) with combined 25 years of previous medically based clinical experience generated lists of possible variables, organized them into relevant layers and categories with input from statistical collaborators, and beta tested them on an initial set of 10 patient retrospective records. Based on this testing, categories and variables were added, deleted, and modified as appropriate.

Standardized measures, whether available in the EHR or applied retrospectively to data within the medical record, were included in the database whenever possible. For example, nursing notes regularly provided Glasgow Coma Scale (GCS)[4] scores, which offer a relatively universal measurement of cognitive status. Though not a part of the original EHR, an Injury Severity Score was determined for each admission based on injury characteristics described in history and physical notes.

To address questions about predictors for dysphagia symptoms and outcomes, a broad range of medical variables was included in the database. Complete accounting of the mechanism and site(s) of injury can enable investigation of the primary causes of dysphagia as well as the impact of comorbidities on functional outcomes. Details about the timing and results of consult from a variety of potentially relevant disciplines (i.e., neurology, neurosurgery, otolaryngology, audiology, maxillofacial/dental, pulmonology, and gastroenterology) allow for exploration of the course of medical intervention juxtaposed with identification of and recovery from dysphagia. By tracking changes in airway management, nutritional support, and cognitive status, the database offers tremendous capacity to explore dysphagia-specific questions such as the effects of prolonged versus repeated intubations on swallow function as well as more general questions such as average days of intubation or parenteral nutritional support in this population.

Specific to dysphagia, we reviewed archived medical records and SLP notes to assign a score on the swallowing component of the American Speech-Language-Hearing Association's National Outcome Measures System (ASHA NOMS).[5] In addition, the database accommodated detailed information from each swallow-related encounter. Virtually every type of diet modification, direct treatment modality, and compensatory strategy recommended in the course of dysphagia management was captured in variables within the SLP Consult tables.

Additional dysphagia metrics, not included in the preliminary BBN models presented in this article, included Penetration-Aspiration Scale (PAS)[6] scores, the Modified Barium Swallow Impairment Profile (MBSImP),[7] and biomechanical/morphometric analysis.[8] These analyses are being determined retrospectively for individual swallow trials from archived VFSS recordings. Finally, because medications have potential sensory, motor, visceral, and cognitive effects that can impact swallowing,[9] each VFSS Analysis table includes medication information (names, dosages), generated by EHR IT specialists. Before database entry, we coded medications by class (e.g., opioid, antipsychotic, anticonvulsant, and prokinetic) based on pharmacological standards and potentially relevant side effects.

Statistical Analysis

BBN classification was the primary technique used to analyze these data. The analysis is based on Bayes' Theorem that

relates prior probabilities to future probabilities. It effectively links correlated variables based on how they are distributed in a dataset. Recent approaches to BBN modeling utilize machine learning, which permits predictions of outcomes based entirely on data (evidence). This study used a machine learning tool, FasterAnalytics, that learns the structure and joint probability distributions of source study data. It then represents the resulting associations in a hierarchal graphical format. FasterAnalytics allows users to examine cascades of codependent factors that may contribute to a given outcome and to make predictions regarding the potential impact of an intervention on an outcome of interest.[10,11]

BBNs are inherently robust and tolerant of heterogeneous and incomplete data sets, making them powerful tools for analyzing complex clinical data. Several iterations of BBN models were compiled at different stages of database entry. Once the database contained data from nearly 100 patients, a BBN model was trained using 80% of randomly selected cases. The model was tested with the remaining 20%, generating a receiver operating characteristic curve and calculating area under the curve (AUC). Preliminary analyses guided refinement of the dataset and model characteristics for subsequent analyses.

Sample Size Estimation

The BBN analysis will accept and model small sample sizes with large numbers of variables, and the model can continually update as data are added. A power analysis is, therefore, not required for BBN, though ideally the model will eventually stabilize such that it becomes robust even with the addition of future cases.

Sample size estimation was conducted to accommodate traditional statistical procedures, taking into account the availability of records that met eligibility requirements and feasibility for a 2-year period of data retrieval and entry. Results indicated that the desired statistical power could be achieved with a sample of 200 records. For estimates of proportions, a sample of 100 subjects provides a 95% confidence interval (CI) of ±10% and a sample of 200 subjects provides a 95% CI of ±7%. Controlling the probability of a Type I error at $\alpha = 0.05$, a sample of 200 subjects has 80% power to detect a correlation as low as $r = 0.20$. For exploratory regression analyses, approximately 15 to 20 records for each of independent variable are necessary for a multivariate model. Therefore, with 200 records, up to 10 predictor variables can be considered.

RESULTS

Potential candidates between the ages of 18 and 50 admitted to WRAMC between January 2004 and April 2010 were screened, leading to the identification of 455 eligible retrospective cases. In addition, 59 eligible patients admitted to NNMC or WRNMMC between April 2010 and August 2012 were identified. Finally, 43 eligible participants admitted to WRNMMC

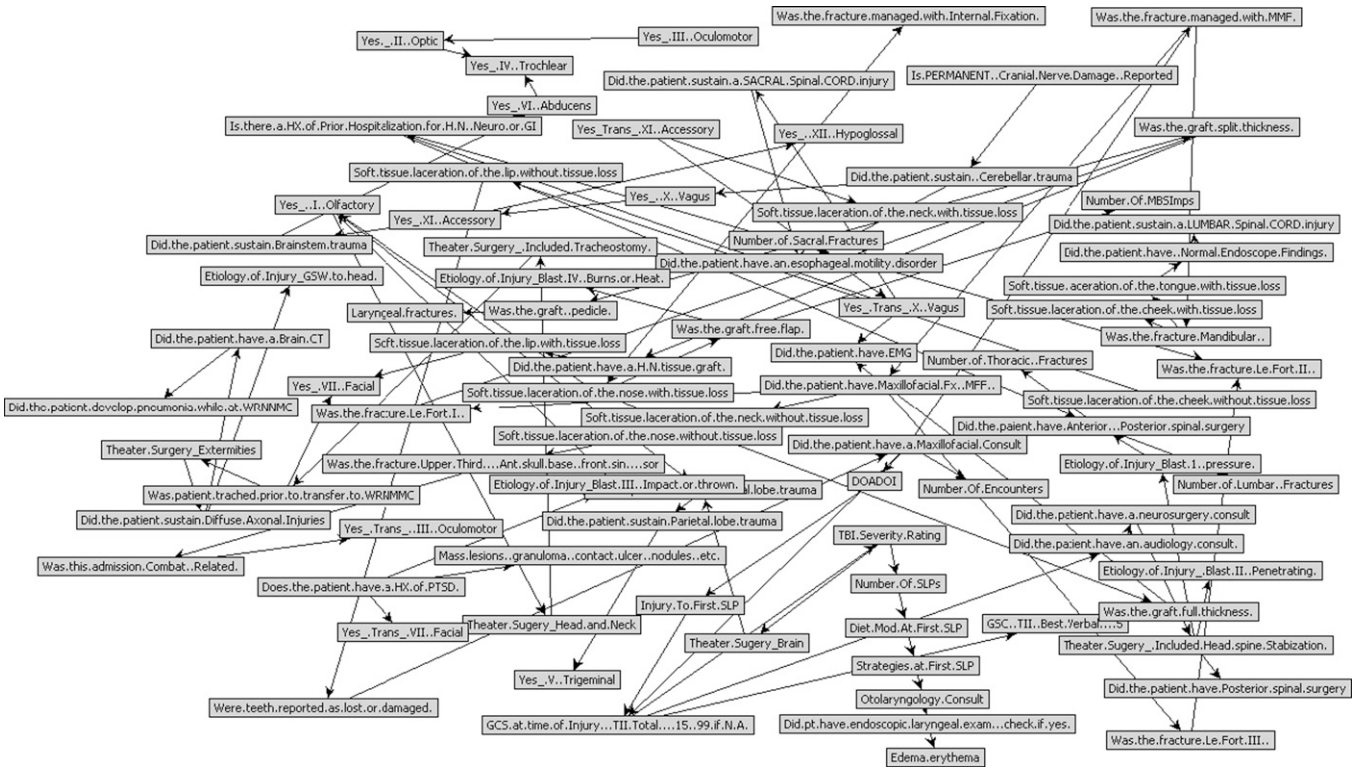

FIGURE 2. Initial Bayesian Belief Network model based on data from 48 patients illustrates association between medical variables at the time of the first swallowing assessment study.

since September 2012 consented to be included. In sum, the pool of potential patients eligible for database entry numbers 557 to date. Separate preliminary BBN analyses were conducted when 48, 96, and 161 cases had been extracted and compiled into the database. The reader is cautioned that these models are not comparable because the structure of the tree and the amount of branch pruning differed markedly as the sample size grew.

The initial model was intended only as an examination of relational associations between variables at the time of the first swallow-related encounter. Figure 2 illustrates this first iteration of 48 cases, which yielded a large and complex tangle of associations that was virtually undecipherable. This was because of the complexity of the patient population, the large number of variables included, and the relatively small sample size.

Although meaningful predictive relationships could not be extrapolated from this model, it was helpful in delineating variables that were inherently related (e.g., "maxillofacial fracture" and "maxillofacial consult"). This guided flattening for the second iteration of the model (Fig. 3), which yielded an AUC of 0.68. The primary outcome variable, selected for both its functionality and objectivity, was a discharge score of 5 to 7 on the ASHA NOMS, indicating that the patient was allowed an unrestricted diet with minimal or no restrictions or cues. The model was trained on 80% of 96 cases and validated with the remaining 20% of the data. Certain factors started to emerge as relationally relevant. Specifically, preadmission intubation, tracheostomy, broken or damaged teeth, and ethnicity were first-degree associates for the primary outcome variable.

At 161 cases, the BBN model became somewhat more refined and interpretable (Fig. 4). It revealed that diet restrictions at the time of the first dysphagia consult was a first degree associate for the primary outcome variable of an unrestricted diet at discharge. Second-degree associates included GCS score, intubation status, and diet change and restrictions based on the first dysphagia evaluation. Model validation at this stage yielded an AUC of 0.86.

DISCUSSION

Clinicians treating unique populations such as TI-ADSMs are often left to determine best practices without appropriate supporting literature, and the prospect of addressing these gaps can be daunting to clinicians and researchers alike. In the case of dysphagia, the lack of existing research regarding this complex consequence of combat-related injuries inspired the development of a comprehensive database rooted in existing clinical records and based on modern informatics principles.

Resources for designing and executing the project included a readily available software platform, experienced clinicians to identify potentially germane variables, guidance from existing literature, and supplemental input from research statisticians regarding optimal database organization. Investigators relied on clinical experience and current literature to interpret preliminary BBN models for refinement of the database. Subsequent analyses were then able to elucidate associations between injury characteristics, medical and surgical

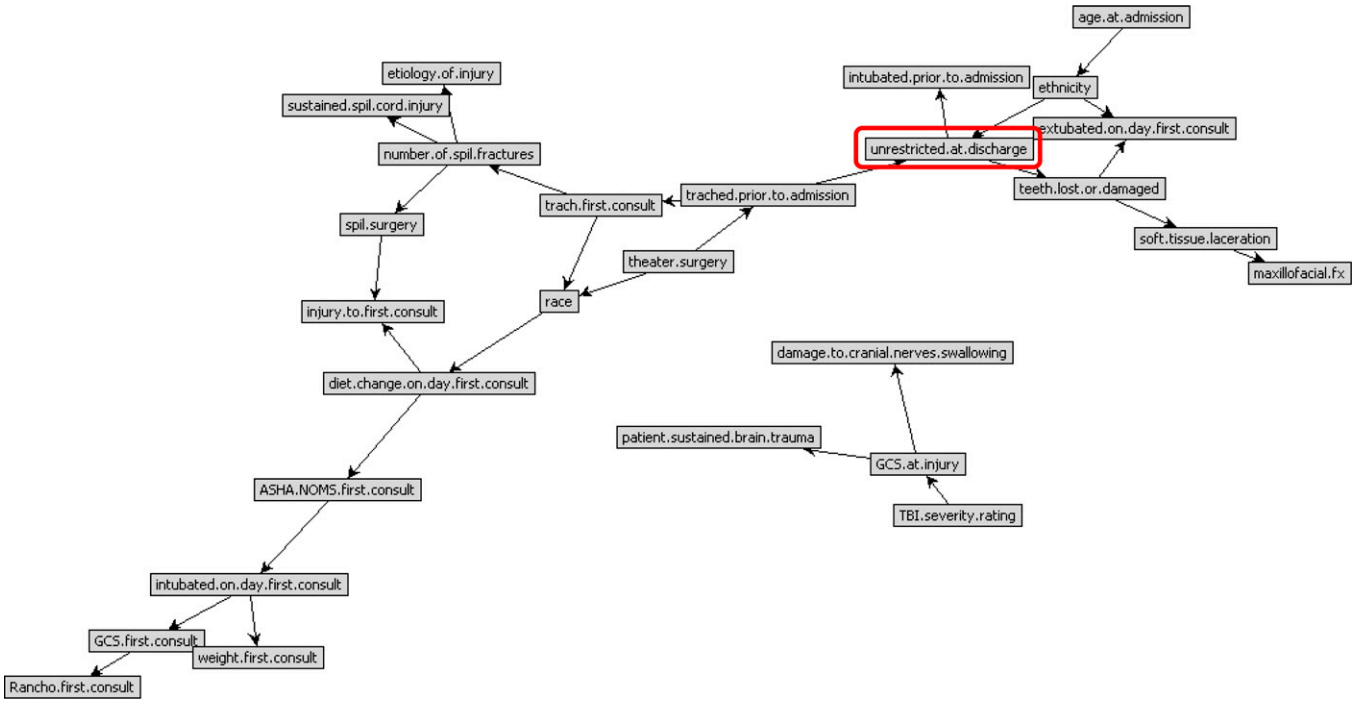

FIGURE 3. Preliminary Bayesian Belief Network model based on 96 cases using a discharge score of 5 or greater on the American Speech-Language-Hearing Association's National Outcome Measures System/ASHA NOMS for swallowing (indicating unrestricted diet) as the outcome variable. Area under the curve/AUC = 0.68 for model validation.

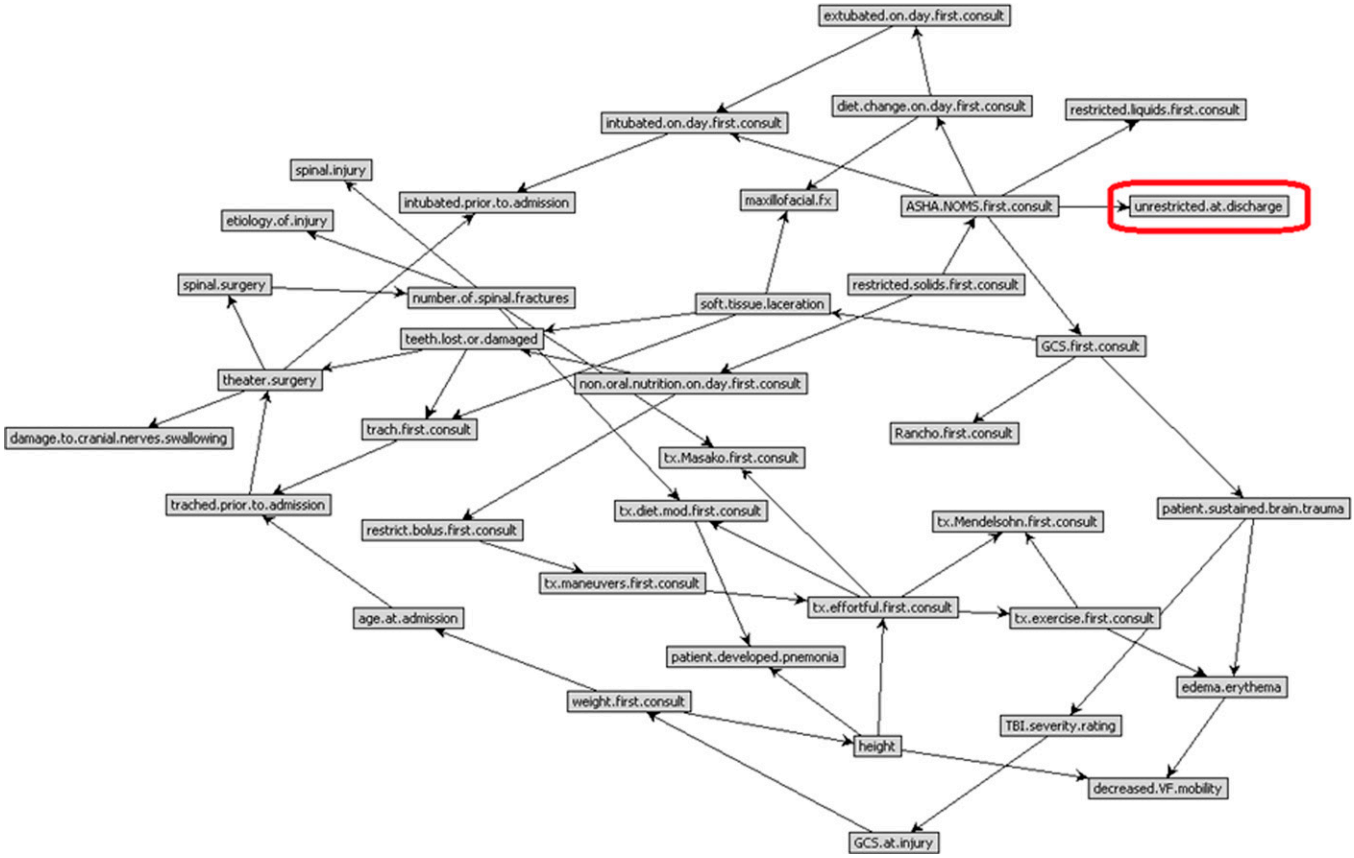

FIGURE 4. Bayesian Belief Network model based on 161 cases using a discharge score of 5 or greater on the American Speech-Languae-Hearing Associaion's National Outcome Measures System/ASHA NOMS for swallowing (indicating unrestricted diet) as the outcome variable. Area under the curve/AUC = 0.858 for model validation.

interventions, recovery benchmarks, and the outcome variable of interest. These relationships will motivate additional lines of inquiry to which traditional statistical methodologies can be applied to test hypotheses for associations revealed within the model.

Dysphagia in the TI-ADSM population typically accompanies serious injuries that require prolonged hospitalization with multidisciplinary care. Analysis of the partially developed BBN model suggests that history of intubation, GCS scores, and dysphagia management recommendations at early stages of rehabilitation are predictive of swallow function at the time of discharge. These results are consistent with those previously reported in other populations.[12–16]

The process of extracting and analyzing data revealed a number of challenges and subsequent opportunities for improvement in clinical workflow and research design. For example, the mostly narrative format of the existing EHR required investigators to read through volumes of records to extract relevant variables. More standardized note templates with predefined fields and responses in EHR would have obvious clinical benefits and could also enable relevant data to be populated directly into the database. In addition, analysis of archived VFSS recorded over the past decade revealed differences in protocols, framing, and temporal resolution that affected study interpretability. This observation led the Speech Pathology and Radiology services to collaborate and recommend procedures and equipment settings that balance the needs of information gathering and radiation exposure for all clinical VFSS procedures.[6,17,18] The comprehensive nature of a large database such as the WRNMMC Dysphagia Database is likely to identify many other trends and opportunities for improvement and investigation across the continuum of multidisciplinary health care.

The next iteration of the BBN analysis will be initiated after we complete entries for 200 patients into the WRNMMC Dysphagia Database. In addition, the completed database will include medications and results from VFSS analyses. The inclusion of standardized dysphagia rating scales (PAS, MBSImP) and quantitative measures of swallowing biomechanics will enrich the database with information that is meaningful across settings. Secondary analyses using multivariate regression and hypothesis testing are planned to further characterize the study sample and to explore relationships between specific variables of interest. The volume and scope of data available supports a wide range of inquiries. BBN analysis will identify superfluous variables that increase bias and overfitting, thereby facilitating selection of key variables to include in regression models. Ultimately, the goal is to

make a simplified, user-friendly database available to other Department of Defense and civilian clinics so that individual patient data can be entered, and a BBN model can be used to predict clinical outcomes based on each patient's specific injury and dysphagia characteristics.

SUMMARY

This article utilizes a multiyear Department of Defense funded project on dysphagia in TI-ADSMs to illustrate how existing medical records can be harnessed to reveal associations between various aspects of clinical care. These relationships could help clinicians predict the effects of care decisions, and guide the exploration of clinically relevant research questions. BBN modeling was the primary analysis tool, and clinically fluent investigators plus a highly accessible relational database structure formed the basis for project development. Early iterations of the BBN model on 48 cases, followed by 96 cases, and at the time of this report 161 cases, were useful for flattening data and elucidating predictive relationships that warrant further statistical analysis. The validity of the BBN model is already high (0.86) and is expected to improve further as more cases are added to the database. BBN methodology has clinical relevance, as it can guide treatment decisions for dysphagia and other complex medical issues. The richness of the Dysphagia Database invites queries about many aspects of wounded warrior injuries and care including hospitalization, medications, comorbid impairments, and treatment outcomes. Results from these analyses have the potential to enhance dysphagia care and maximize functional outcomes for patients with polytraumatic injuries.

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