North Carolina Spine Society
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Application

Residency Grant Project 2016-2017

Section I

Project Leader: Michael P. Catalino		Credentials: ☒ MD, ☐ DO, MS
☒ Male ☐ Female	Date of birth: 6/24/1987	NC medical license no.: RTL

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Current Residency program University of North Carolina	Est. completion date 2022

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Additional Project Team Members

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Section II

Personal Statement: Please indicate how this grant, if funded, will help toward your career goals and intended area of specialization. Outline your expected career path and how this aligns with the Residency Research Grant program objectives and criteria. (500 words max.)

This grant will enable the completion of a very important and timely study. I not only desire to be a great technical neurosurgeon but also a leader in what is becoming the discipline of population neurosurgery - that is, the impact of the practice of neurosurgery on the larger community and nation. As CMS enforces new regulations on reimbursements, bundled payments, and prioritizes diagnosis related groups (DRGs) for hospital illness severity and treatment reimbursement it will be critical to accurately define the severity of the illnesses that neurosurgeons treat and the usual outcomes based on standard of care in our country. My experience in public health (masters in science of global health) and interest in spine surgery has led me to develop this extensive protocol which will require not only this pilot grant but future NIH funds for research that will expand our understanding of the nationwide outcomes of patients with spine fractures and those who undergo surgical treatment of spine fractures. This grant will lead to research that can earn these future grants and help me gain national recognition as a leader in spine outcomes research and population neurosurgery. It will also provide critical experience working with our interdisciplinary group of epidemiologists and health service researchers. Furthermore, I plan on looking for jobs in spine surgery in North Carolina after fellowship, so having this experience will provide tremendous perspective on both local and national trends in spine outcomes for my own patients.

Section III – Details of the proposal

Abstract summary

Spine fracture is a common problem in the elderly with high mortality. Current guidelines are lacking large scale population based outcomes studies looking at current mortality rates for surgical fixation of spine fractures, especially axis fractures which are common and can be lethal. Preliminary analysis of pilot data from the Medicare 20% random sample database suggests the mortality rate in the US is close to 20% in the first 6 months after axis fractures. We will conduct a full analysis looking at ICD codes to identify incidence spine fractures and their outcomes, CPT codes for surgical treatments, and HCPC codes for conservative treatments. We will use propensity weighting and survival curves to compare surgical versus conservative management.

Outline of the problem

Spine fractures and surgical outcomes are of significant concern due to the morbidity and mortality associated with structural injuries to the spine and the resultant functional limitations. A Canadian population based study found an annual incidence of spinal fracture of 64/100,000.[1] The annual hospitalization rate was 29/100,000. Falls accounted for the majority of fractures and motor vehicle collision came in second overall. Anatomical distribution was as follows; 19.3% were cervical, 30% were thoracic, and 42.5% were lumbar fractures. Thirty-three percent of patients with cervical fractures had an accompanying neurological injury. Sixteen percent of patients with thoracic fractures had neurological injuries and 29% of patients with lumbosacral fractures had neurological deficits.[1] Average length of stay was 38.5 days for all patients. The mortality in the hospitalized population was 4.1%. If the fracture was associated with spinal cord injury, mortality increased to 10.7%. Surprisingly, the mortality rate in the neurologically intact population was 3.3%, which was significantly different but close to the average mortality rate for the population. Over 90% of deaths in neurologically intact patients were in those older than 60 years of age with 6.3% mortality in seventh decade, 3.4% in the eighth, and 10.5% in those older than 80 years of age. Fracture of the second cervical vertebrae (axis) may be the most deadly and costly. Using the National Inpatient Sample, Daniel and colleagues estimated the incidence of hospitalized axis fractures as 9.77 per 10,000 per year in 2010.[2] In that same sample, from 2000 to 2010, non-operative management decreased and operative management increased over that time frame. The estimated cost in 2010 of non-operative management ($63,222) was half that of surgery ($133,064) and the cost of surgery nearly doubled from 2000 to 2010. Finally, they projected the annual cost of axis fractures to be $1.5 billion in 2010.[2] Data on surgical outcomes in the elderly are sparse. One retrospective study of 56 patients found no difference in 30-day mortality in those managed surgically versus conservative management.[3] No nationwide study, of the magnitude we are proposing, has been done to date.

State of the art in this field

No US study of this magnitude has been published.

Past research of the applicant in this field

None specific to spine surgery outcomes. Prior work in epidemiology done during master's work in global health (see. Catalino et al 2015 http://www.ncbi.nlm.nih.gov/pubmed/26026142) and comparative effectiveness research (CER) methods. Study group consists of leaders in the field of CER from the North Carolina Translational and Clinical Sciences Institute at UNC (Sturmer and Haydon).

Open questions

None

Hypothesis

Null hypothesis: Axis fractures have a high mortality rate. Surgical outcomes after fixation of axis fractures in the elderly are no better than conservative management.

What are the aims you want to reach with this study?

Our primary objective is estimate the incidence and mortality of spine fractures in the United States. Our secondary objectives are to compare this to data on hip fracture incidence and mortality in order to understand the scale of this problem for the elderly in our country.[4] Lastly, by using CPT coding we will also be able to obtain data on the frequency of operative

management and estimate association between surgery and mortality. Our null hypothesis is that mortality is equal in patients who have surgery and in those that do not.

Anticipated results

We expect axis fractures to have a high mortality rate in the elderly, higher even than for hip fractures. We expect elderly patients to have similar outcomes with and without surgical fixation.

Study subjects, specimen or materials

We will analyze the Medicare database (20% random sample) from 2006 to 2014, using inclusion criteria of age 66 years and older, continuous enrollment of at least one year prior to the diagnosis of spine fracture(s), and at least one inpatient or outpatient claim for C2 spine fracture(s). The requirement to have a continuous enrollment of at least one year prior to diagnosis was included in order to identify individuals with a new diagnosis and to assess covariates. The denominators for incidence study calculations will be person years contributed to the database by all patients with at least one claim in the Medicare database. This will be calculated by subtracting the date of the last claim from the date of the first claim for each patient. No patient can be counted twice. The denominator for the mortality study will depend on the groups being compared (outlined in detail below under the comparison groups section). Note, all patients in the comparisons for the mortality study will come from the denominator of the incidence study.

Claims data on spine fractures often include prevalent rather than incident fractures.[5]We plan to focus on the incidence and mortality of cervical spine fractures while using all spine fracture data and hip fracture data for comparison. We chose to focus on cervical spine fractures because most are typically acute and clinically relevant. Incidentally found and chronic clinically insignificant compression fractures of the cervical spine are rare in comparison with the thoracolumbar spine, therefore, the incidence of cervical spine fractures will be easier to interpret. This limitation will also be less pronounced in the inpatient diagnosis group, which will be compared with outpatient incident diagnoses of fractures. Furthermore, we plan to reduce the proportion of clinically irrelevant prevalent fractures by restricting data to inpatient diagnosis of vertebral body fractures and selecting for trauma codes (fall or motor vehicle collision).

In order to capture new diagnoses of clinically significant fractures, claims with a previous diagnosis of fracture in the past year will be excluded and incident fractures must occur in conjunction with a treatment code such as a surgery or spine orthosis code.

Patients with metastatic cancer or osteomyelitis to the spine will be excluded from the cohort study but reported as a subgroup incidence. These patients will be excluded by using the ICD-9 code 733.13 (pathologic fracture of vertebra).

Effect and outcome variables

Our primary outcome is a) the incidence of C2 spine fractures and b) all-cause mortality at 30, 180, and 360 days after C2 spine fracture. Secondary outcomes include management type (surgical or nonsurgical), length of hospital stay, discharge disposition (home, skilled nursing facility, acute inpatient rehabilitation), and rates of medication use (proton pump inhibitors, bisphosphonates, calcitonin, etc.). Covariates to be used in the analysis are listed below.

Methods for taking measurements

Exposure groups

Primary exposure, or disease, is spine fracture. We will focus on C2 fractures but include all spine fractures in our analysis.

A. Patients with C2 fractures: ICD-9-CM categories 805.02 (closed C2 fracture) or 805.12 (open C2 fracture)

B. Patient with surgical fixation of C2 fractures: 22318, 22319, 22548, 22551, 22554, 22590, 22595, and 22600

Comparison groups

A. Patients without a spine fracture: those in denominator without a fracture code claim ICD-9-CM categories 800-829,

B. Patients with a non-spine traumatic fracture: those in denominator with ICD-9-CM categories 800 to 829, excluding vertebral fractures 805 and 806 above

C. Patients with a spine fracture other than a C2 fracture: those in denominator without 805.02 (closed C2 fracture) or 805.12 (open C2 fracture)

D. Patients with hip fracture: with ICD-9-CM categories 733.14 (non-traumatic hip fracture) OR 820 (fracture of the neck of femur). We are not including 808 (traumatic fracture of the pelvis) as this is associated with major trauma and not considered a true "hip" fracture.

In order to analyze the impact of surgery we will use surgery as the exposure and compare it to 1) no treatment and 2) conservative management with a collar/halo (codes in Table 1).

Table 1. Codes used to Identify Incident Fractures and Treatment

Surgical procedures that may be indicated for the treatment of an acute vertebral fracture.

A. ICD-9-CM diagnostic codes[*]:

1. 805 (fracture of the vertebral column without mention of spinal cord injury)
2. 806 (fracture of the vertebral column with spinal cord injury)

B. CPT codes for treatment of vertebral fractures[+]:

1. 22100 to 22318, Excision procedures and spinal instrumentation
2. 63001 to 63308, Laminectomy, decompression and excision of lesions of the spinal canal
3. 22840 to 22855, Spinal instrumentation
4. 22532 to 22634, Arthrodesis of the spine
5. 22318, 22319, 22548, 22551, 22554, 22590, 22595, and 22600 are all codes specific for surgical treatment of C2 fractures
6. The CPT code 20661 is used for Halo Placement

C. HCPC system for non-surgical treatment[$]

1. The Healthcare Common Procedure Coding (HCPC) system 'L codes', which denote orthotic or prosthetic procedures will be used for all other non-surgical treatments
    a. These codes include L0810 through L0861

D. Groups

1. Traumatic Spine fracture = A AND [B OR C]
2. Surgical group = A AND B
3. Conservative group = A AND C
4. No treatment = A only

*ICD-9-CM International classification of disease, Ninth Revision, Clinical Modification

+CPT Current Procedural Terminology

$HCPCS Healthcare Common Procedure Coding System

Methods for data management and analysis (including biostatistical check)

Fracture incidence trends will be standardized based on the age/sex distribution of the year 2010. We will use visual inspection to identify any specific trends. We will compare gender-specific incidence and mortality as well as mortality between patients treated surgically and non-surgically by spinal level. Propensity score methods will be used to control for confounding variables. We will use propensity-weighting methods due to unequal treatment grouping. We will also use Inverse Probability of Treatment Weighting and Standardized Morbidity Ration Weighting. Weighted Kaplan-Meyer survival functions will be compared between those with and without C2 fractures and those who undergo surgery versus conservative management. Mortality risk will be calculated at 30, 180 and 360 days. The main effect measure estimate will be mortality risk and mortality risk differences.

For our primary endpoint of C2 fractures we will conduct a sensitivity analysis. We have thus far generated a study of incidence and mortality that prioritizes specificity in diagnosis. Sometimes providers use non-specific ICD codes, such as 805 (vertebral fracture) without defining it as 805.02 (C2 vertebral fracture). This may also occur in CPT coding for the treatment of spine fractures. Table 1 incorporates the broadest ICD and CPT coding categories. Thus in order to conduct a sensitivity analysis we will begin with exposure groups A and B (C2 fracture and surgery for C2 fracture, respectively) and compare the primary outcomes with a less specific but more sensitive ICD and CPT code grouping according to the range of Table 1 coding categories. The most broad CPT inclusion procedures will be CPT 20005 to 29999 (Surgery on the musculoskeletal system) and 61000 to 64999 (Surgery on the nervous system). We will analyze the results for significant variation in our endpoints.

Estimation of sample size and power

Not applicable, we will use the entire Medicare 20% random sample database

Animal model

If an in vivo animal model is used in the planned research work, please describe the model in detail. The description should include: anesthesia protocols, treatment protocols, pain management, surgical techniques, post-operative care, criteria for removal from the study if necessary, and euthanasia protocols.

AAALAC accreditation (Association for assessment and accreditation of Laboratory Animal Care International) www.aaalac.org

Please indicate whether the institution (main applicant and co-applicants) is AAALAC accredited and specify in which institution the animal research will be carried out. If the institution is not AAALAC accredited, please detail what agency and standards are used to oversee animal use and care.

Not applicable

Relevance of the project

This will serve as a landmark study by characterizing the outcomes of spine fractures in the US and the effectiveness of surgical versus conservative management.

Time schedule

We will complete this study in 18 months. Data Use Agreement is being submitted. IRB approval is already granted. We will spend 9 months analyzing the data and 9 months submitting the manuscript.

Relevant literature by the investigators

None

Relevant literature by other authors

References

1. Hu R, Mustard C, Burns C. Epidemiology of incident spinal fracture in a complete population. *Spine (Phila Pa 1976)*. 1996;21(4):492-499.

2. Daniels AH. Incidence and cost of treating axis fractures in the united states from 2000 to 2010. *Spine (Philadelphia, Pa.1976)*. 08;39(18):1498; 1498-1505; 1505.

3. Chen YR, Boakye M, Arrigo RT, et al. Morbidity and mortality of C2 fractures in the elderly: Surgery and conservative treatment. *Neurosurgery*. 2012;70(5):1055-9; discussion 1059. doi: 10.1227/NEU.0b013e3182446742 [doi].

4. Brauer CA, Coca-Perraillon M, Cutler DM, Rosen AB. Incidence and mortality of hip fractures in the united states. *JAMA*. 2009;302(14):1573-1579. doi: 10.1001/jama.2009.1462 [doi].

5. Cadarette SM, Katz JN, Brookhart MA, Sturmer T, Stedman MR, Solomon DH. Relative effectiveness of osteoporosis drugs for preventing nonvertebral fracture. *Ann Intern Med*. 2008;148(9):637-646. doi: 148/9/637 [pii].

Section IV – Budget for proposed project period

Personnel			**Amount**
Surname / First name	Academic qualification	Effort in %	
Haydon/Abigail (Project Manager)		25%	$1,000
Lowman/Amy (Data Programming Assistant)		75%	$2,000
Total cost for personnel			**$3,000**

Material	**Amount**
Devices, equipment, extension to existing equipment, etc.	
Data Re-use Agreement	$2,000

Total cost for material	**$0**

Supplies	**Amount**
Itemize below	
Total cost for supplies	**$0**

Rental of equipment	**Amount**
Itemize below	
Total cost for rental equipment	**$0**

Section V

If selected for participation in the program, the grantee agrees to conduct herself/himself professionally according to the principles of medical ethics and to be governed by the Bylaws of the North Carolina Spine Society.

Applicant's signature: Michael P. Catalino Date: 6/4/16

Program Director's signature: [illegible] Date: 6/7/2016

To be considered for the 2016-2017 grant year,
this application and the applicant's CV are due by 5:00 pm on June 13, 2016.

Please sign your completed form and return it along with your CV by email, mail or fax to:
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