Emergency general surgery specific frailty index: A validation study

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INTRODUCTION: Assessment of operative risk in geriatric patients undergoing emergency general surgery (EGS) is challenging. Frailty is an established measure for risk assessment in surgical cases. The aim of our study was to validate a modified 15-variable EGS-specific frailty index (EGSFI).

METHODS: We prospectively collected geriatric (age older than 65 years) EGS patients for 2 years. Postoperative complications were collected. Frailty index was calculated for 200 patients based on their preadmission condition using 50-variable modified Rockwood frailty index. Emergency general surgery–specific frailty index was developed based on the regression model for complications and the most significant factors in the frailty index. Receiver operating characteristic curve analysis was performed to determine cutoff for frail status. We validated our results using 60 patients for predicting complications.

RESULTS: A total of 260 patients (developing, 200; validation, 60) were enrolled in this study. Mean age was 71 ± 11 years, and 33% developed complications. Most common complications were pneumonia (12%), urinary tract infection (9%), and wound infection (7%). Univariate analysis identified 15 variables significantly associated with complications that were used to develop the EGSFI. A cutoff frailty score of 0.325 was identified using receiver operating characteristic curve analysis for frail status. Sixty patients (frail, 18; nonfrail, 42) were enrolled in the validation cohort. Frail patients were more likely to have postoperative complications (47% vs. 20%; $p < 0.001$) compared to nonfrail patients. Frail status based on EGSFI was a significant predictor of postoperative complications (odds ratio, 7.3; 95% confidence interval, 1.7–19.8; $p = 0.006$). Age was not associated with postoperative complications (odds ratio, 0.99; 95% confidence interval, 0.92–1.06; $p = 0.86$).

CONCLUSION: The 15-variable validated EGSFI is a simple and reliable bedside tool to determine the frailty status of patients undergoing EGS. Frail status as determined by the EGSFI is an independent predictor of postoperative complications and mortality in geriatric EGS patients. (*J Trauma Acute Care Surg.* 2016;81: 254–260. Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.)

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The absolute number of the elderly population is rapidly growing in the United States.[1] In 2011, every day, 10,000 Americans crossed the age limit of 65 years. It is expected to double its present size by the year 2025, and one in three persons will be older than 65 years.[2] Number of emergency general surgeries (EGSs) performed annually in elderly population is increasing.[3] This growth presents a new challenge for surgeons who face an increasing number of elderly patients requiring emergency surgeries. Providing an optimal medical care for this already at risk population is a critical problem and is associated with the definition of pre-existing conditions, identification of the preoperative factors, definition of the criteria predicting the operative risks, and identification of the ways to improve patient care.[1]

Assessment of the operative risk in elderly patients undergoing EGS is challenging. Frailty syndrome measured by a variety of frailty scores is a well-established measure of physiological reserve of elderly population and is comprised of four domains: social, cognitive, psychological, and physical. Emerging surgical literature has reported the usefulness of frailty syndrome in identification of at risk elderly population who are more susceptible to develop adverse outcomes. The term *old* does not reflect an accurate image of a patient's status, as it only refers to the chronological age of the patient. Furthermore, commonly used tools for the prediction of complications and risk adjustment cannot measure the physiologic reserve of elderly patients, as they are mostly subjective and based on the medical diagnoses and comorbidities and often limited to a single organ system.[4]

Along with the emerging literature, we in our previous studies have demonstrated that frailty is an independent predictor of major morbidity, mortality, prolonged length of stay (LOS), and institutional discharge in elderly trauma patients who demonstrate different vulnerability to external factors. Despite the potential association between frailty and outcomes in elderly patients undergoing a surgical procedure, relatively few studies have examined the concept of frailty, and there is still a room for improvement in assessing the operative risk in elderly patients undergoing EGS.[5]

The aim of our study was to develop and validate a simplified 15-variable EGS-specific frailty index (EGSFI) in elderly EGS patients. We hypothesized that frailty measured by EGSFI can reliably predict postoperative outcomes in elderly patients undergoing EGS.

METHODS

Study Settings and Patients

After obtaining approval from the institutional review board at the University of Arizona College of Medicine, we performed a 2-year (2013–2014) prospective cohort analysis of consecutive EGS patients 65 years or older with a surgical procedure and at least one day of hospital admission at our acute care surgery–verified Level 1 trauma center. We excluded the patients who refused to consent or in whom FI cannot be calculated secondary to an altered mental status and unavailability of family historians. The prospective design and exclusion criteria eliminated the possibility of missing variables. Surgical procedures were defined as appendectomy, cholecystectomy, hernia repair, bowel resection, incision and drainage, and wound debridement.

Data Points and Definitions

After enrollment, data were collected prospectively by trained researchers for each subject including age, sex, vital parameters (Glasgow coma scale score, systolic blood pressure (SBP), heart rate, and body temperature), initial diagnosis, type of procedure (appendectomy, cholecystectomy, hernia repair, bowel resection, incision and drainage, and wound debridement), ASA score, comorbidities, insurance status, and hospital and intensive care unit (ICU) LOS, hospital and ICU free days, ventilator days, ventilator free days, discharge disposition (home, skilled nursing facility, rehabilitation center), postoperative

TABLE 1. Demographics of Development Phase Cohort

Variables	Frail n = 98	Nonfrail n = 102	*p*
Age, mean ± SD	74.6 ± 8.5	75 ± 7.1	0.77
Male, % (n)	53% (52)	51% (52)	0.77
White, % (n)	81% (80)	86% (87)	0.09
SBP, mean ± SD	138 ± 33	137 ± 25	0.85
HR, mean ± SD	87 ± 22	85 ± 19	0.76
RR, mean ± SD	19 ± 6	21 ± 9.1	0.47
FI, mean ± SD	0.38 ± 0.09	0.17 ± 0.05	**<0.001**

HR, heart rate; RR, respiratory rate.

complications, and in hospital mortality. Hospital free days were defined as the number of the days between hospital discharge and day 28 after hospital admission. Ventilator-free days were defined as the number of days between successful weaning from mechanical ventilation and day 28 after hospital admission. Intensive care unit–free days were defined as the number of days between ICU discharge and day 28 after hospital admission.

Development of EGSFI

Patients were approached by a single investigator within the first 24 hours of their hospital admission for enrollment in the study. We enrolled 200 consecutive elderly EGS patients as the development phase cohort. After obtaining informed consent, frailty data were gathered using modified Rockwood frailty questionnaire and FI was calculated for each patient by dividing the sum of all scores by 50.[6] The variables comprising the FI were explained to each patient, and it was clarified that the answers should state the patient's preadmission health condition. Univariate analysis was performed to identify associations among variables in the 50-variable FI for development of postoperative complications. Fifteen variables with the strongest association for development of postoperative complications were selected to develop the EGSFI. We then enrolled 60 more consecutive EGS patients older than 65 years to validate our EGSFI. We performed the same process for this cohort, and after providing a written consent form, we calculated both EGSFI and modified Rockwood FI for this validation phase cohort.

Study Protocol

We categorized the development phase cohort (n = 200) into two groups based on their FI: frail, and nonfrail. Frail was defined as an FI of 0.25 or greater, while nonfrail was defined as FI of less than 0.25. We chose established cutoff point of 0.25 for dichotomizing based on previously published studies.[7,8] Additionally, we dichotomized the validation phase cohort into two groups of frail and nonfrail based on their frailty status measured by the EGSFI. Frail status based on EGSFI was defined as FI of 0.325 or greater after performing receiver operating characteristic (ROC) analysis to identify the cutoff point of frailty. We also calculated the modified Rockwood FI for this validation cohort.

The EGSFI questionnaire covers the following domains: patient comorbidities, activities of daily living, nutritional status, and health attitude. The presence of a deficit was given a point. Most of the variables in the EGSFI were dichotomized, while others had multiple categories. The EGSFI was calculated as total score of deficits present in a patient divided by the total number of variables (n = 15) in the EGSFI questionnaire. The EGSFI ranged from 0 (representing nonfrail status) to 1 (representing severely frail status). Our primary outcome measure was postoperative complications. Our secondary outcome measures were hospital and ICU LOS, discharge disposition (home, skilled nursing facility [SNiF], rehabilitation center), and mortality.

Using American College of Surgeons National Surgical Quality Improvement Program definitions, we categorized overall in-hospital complications into minor and major complications. Major complications were defined as sepsis, intra-abdominal abscess, enterocutaneous fistula, delirium/confusion, pneumonia, deep venous thrombosis, cholangitis, pulmonary emboli, hemorrhage/ischemia, acute respiratory distress syndrome, acute kidney injury, deep surgical site infection, and take back to the operating room. Minor complications were defined as urinary tract infection (UTI), superficial surgical site infection, and gastroenteritis.[9]

Statistical Analysis

Data are presented as mean ± SD for continuous variables, as medians [range] for ordinal variables, and as proportions for categorical variables. We used the Student *t* test to assess the difference between parametric variables and the Mann-Whitney *U* test to assess the difference between nonparametric variables. The χ^2 test was used to assess the difference between proportions for categorical variables. Univariate analysis was performed to identify the predicting factors of postoperative complications in EGS elderly patients. Variables with a $p \leq 0.20$ were defined as significant variables for predicting postoperative complications. Additionally, we performed a multivariate binary logistic regression analysis for the predictors of postoperative complications in our validation phase cohort. Variables with $p \leq 0.05$ were considered significant.[10,11] Receiver operating characteristic (ROC) curve analysis was used to identify the optimal EGSFI cutoff point for development of complications. Area under the ROC (AUROC) curve was compared for EGSFI

TABLE 2. Univariate Analysis for Postoperative Complications

Variables	Odds Ratio	95% CI	*p*
Cancer history	0.50	(0.26–0.97)	0.04
Coronary heart disease	3.33	(1.39–7.99)	0.007
Dementia	2.80	(1.36–5.77)	0.005
Hypertension	0.45	(0.24–0.88)	0.01
Help with grooming	1.89	(1.04–3.43)	0.03
Help managing money	3.34	(1.43–7.80)	0.005
Help doing household work	2.75	(1.12–6.76)	0.02
Help toileting	1.78	(0.98–3.24)	0.05
Help walking	3.25	(1.43–7.36)	0.005
Feel less useful	2.94	(1.47–5.86)	0.002
Feel sad	3.93	(1.80–8.58)	0.001
Feel effort to do everything	2.75	(1.29–5.85)	0.008
Feel lonely	4.19	(1.75–7.6)	0.001
Sexual active	2.51	(1.22–5.12)	0.01
Albumin, g/dL	2.25	(1.18–4.27)	0.01

and the 50-variable FI for complications. All statistical analyses were performed using software for social sciences (SPSS, version 21; IBM, Inc, Armonk, New York).

RESULTS

A total of 280 eligible elderly patients were enrolled during the study period of which 260 patients met the inclusion criteria (development phase cohort, 200; validation phase cohort, 60). We excluded 20 patients secondary to denial of consent (seven patients) or unavailability of family historians in patients with altered mental status (13 patients). Following is the overall demographics of the development phase cohort: mean ± SD age was 74.8 ± 7.8 years; 52% (104) were male, and 88% (176) were white. Mean ± SD SBP was 138.5 ± 31.2 mm Hg, and mean ± SD modified Rockwood FI was 0.27 ± 0.12. Overall, 33% (66) of the population developed postoperative complications. Pneumonia (12%) followed by UTI (9%) were the most common complications in this cohort. In the development phase cohort, mean ± SD FI was significantly higher in frail patients compared to nonfrail patients (0.38 ± 0.09 vs. 0.17 ± 0.05; $p < 0.001$). There was no difference in age ($p = 0.77$), male sex ($p = 0.77$), white race ($p = 0.09$), SBP ($p = 0.85$), and HR ($p = 0.76$) between the two groups. Table 1 shows the comparison of demographics between frail and nonfrail patients in development phase cohort.

Table 2 shows the univariate analysis for the factors that significantly predict postoperative complications. Of all the variables that were included in FI, 15 variables with the highest odds of ratio and significant *p* values were used to define the EGSFI score (Fig. 1). Receiver operating characteristic curve analysis revealed a cutoff of 0.325 as the most appropriate cutoff for predicting complications.

We validated our results using 60 patients of which 30% (18) were frail based on the newly developed EGSFI. Mean ± SD age of this population was 75.4 ± 7.8 years and 55% were male. Mean SBP was 138.9 ± 36.7, and mean EGSFI was 0.28 ± 0.14. Overall, 37% (22) of the population developed postoperative complications. Wound infection (17%) followed by pneumonia (13%) were the most common complications in our validation

EMERGENCY GENERAL SURGERY SPECIFIC FRAILTY INDEX					
Co-Morbidities					
Cancer	Yes (1)		No (0)		
Hypertension	Yes (1)		No (0)		
Coronary heart disease	MI (1)	CABG (0.75)	PCI (0.5)	Medication (0.25)	No (0)
Dementia	Mild (0.25)	Moderate (0.5)	Severe (1)	No (0)	
Daily Activities					
Need help with grooming	Yes (1)		No (0)		
Help managing money	Yes (1)		No (0)		
Need help with housework	Yes (1)		No (0)		
Need help toileting	Yes (1)		No (0)		
Help walking	Wheel chair (1)	Walker (0.75)	Cane (0.25)	None (0)	
Health Attitude					
Feel less useful	Most of time (1)	Sometime (0.5)	Rarely (0)		
Feel sad	Most of time (1)	Sometime (0.5)	Rarely (0)		
Feel effort to do everything	Most of time (1)	Sometime (0.5)	Rarely (0)		
Feel lonely	Most of time (1)	Sometime (0.5)	Rarely (0)		
Feel sexually active	Yes (0)		No (1)		
Nutrition					
Albumin	<3 mg/dl (1)		>3mg/dl (0)		

Figure 1. Emergency general surgery frailty index (EGSFI).

TABLE 3. Demographics of Validation Phase Cohort

Variables	Frail n = 18	Nonfrail n = 42	p
Age, mean ± SD	73.5 ± 9.2	75.3 ± 6.4	0.42
Male, % (n)	56% (10)	55% (23)	0.97
White, % (n)	72% (13)	93% (39)	0.07
SBP, mean ± SD	141 ± 41	135 ± 33	0.76
HR, mean ± SD	88 ± 15	75 ± 11	0.09
RR, mean ± SD	18 ± 3	18 ± 2.5	0.69
EGSFI, mean ± SD	0.38 ± 0.10	0.17 ± 0.05	**<0.001**

Boldface indicates statistical significance.
HR, heart rate; RR, respiratory rate.

population. Mean EGSFI was significantly higher in frail patients compared to nonfrail (0.38 ± 0.10 vs. 0.17 ± 0.05; p < 0.001). There was no difference in age (p = 0.42), male sex (p = 0.97), white race (p = 0.07), SBP (p = 0.76), and HR (p = 0.09) between the two groups. Table 3 reflects the comparison between frail and nonfrail patients for demographics in validation phase cohort.

In the development phase cohort, frail patients were more likely to be discharged to a rehabilitation center (43% vs. 14%; p = 0.0001) and less likely to be discharged home (31% vs. 68%; p = 0.0001) compared to nonfrail patients. There was no significant difference in being discharged to a SNiF between the two groups (p = 0.85).Overall mortality rate was 4% (n = 8), and frail patients had a significantly higher rate of mortality compared to nonfrail patients (7% vs. 1%; p = 0.03).

In the validation phase cohort, frail patients were more likely to develop postoperative complications compared to nonfrail patients (67% vs. 24%; p = 0.003). On analysis of individual complications, pneumonia was significantly higher in frail patients compared to nonfrail patients (33% vs. 5%; p = 0.05). There was no difference in wound infection (p = 0.46), UTI (p = 0.57), and sepsis (p = 0.08) between the two groups. Overall mortality rate of the validation population was 7%.[4] Mean hospital LOS was 7.8 ± 6.2 days, and frail patients had significantly a longer hospital LOS compared to nonfrail patients (frail, 13.38 ± 8.5 vs. nonfrail, 5.7 ± 3.2; p < 0.001). Mean ICU LOS was 0.5 ± 0.57 days and was not different between the two groups (p = 0.21). In the validation phase cohort, we had similar results to development phase cohort regarding discharge disposition status as frail patients were more likely to be discharged to a rehabilitation center (44% vs. 13%; p = 0.01) and less likely to be discharged home (28% vs. 69%; p = 0.004) compared to nonfrail patients. There was no significant difference in being discharged to a SNiF between the two groups (p = 0.99). Moreover frail patients were more likely to have a higher rate of mortality compared to non-frail patients (frail: 22% vs. non-frail: 0%; p = 0.006). Table 4 demonstrates the outcomes of the validation phase cohort.

On multivariate regression analysis for the predictors of postoperative complications, frailty based on EGSFI was a significant predictor of postoperative complications (odds ratio, 7.3; 95% confidence interval [CI], 1.7–19.8; p = 0.006), and frail patients were 7.3 times more likely to develop postoperative complications compared to nonfrail. Age was not associated with postoperative complications (odds ratio, 0.99; 95% CI, 0.92–1.06; p = 0.86). The area under the ROC [95% CI] for EGSFI was 0.712 [0.638–0.787], which was similar to that of the 50-variable FI of 0.659 [0.581–0.738].

DISCUSSION

Risk assessment in elderly population with an emergency surgical procedure is an important component of health care.[1] High prevalence of frailty and divergent outcomes in elderly patients who present for a surgical procedure highlights the vulnerability of this patients group for dependency and adverse outcomes.[12] Our study is the first prospective study of its kind, which used a 50-variable modified Rockwood FI to develop a convenient and easy to use 15-variable frailty index specific for geriatric EGS population. We defined cutoffs for frail status in this model and then validated our model on further 60 elderly patients undergoing EGS. Results of our study demonstrated that frail patients had a higher rate of postoperative complications and mortality and longer hospital LOS compared to the nonfrail patients.

Comprehensive frailty models rely on 50 variables or even more to calculate the FI of patients. Although such comprehensive questionnaires are accurate in assessing the frailty status of these patients, their practical application is often difficult owing to the extensive time required to conduct these assessments. We narrowed down a 50-variable frailty questionnaire to 15 most valid questions with the highest predictability to create an EGS-specific FI. The area under the curve for EGSFI using a ROC curve analysis was 0.712. This was similar to the AUROC with a 50-variable model, demonstrating that our 15-variable EGSFI has equivalent ability to predict complications in geriatric patients undergoing EGS.

Emerging literature has demonstrated that patients with the same chronological age can have a variation in outcomes. A consistent explanation is that this variation results from the difference in the functional reserve of these patients. Frailty is a well-established concept that provides an objective measure of the functional reserve. It can provide an objective assessment of postsurgical outcomes in elderly population undergoing EGS. Several assessment tools such as the APACHE and

TABLE 4. Secondary Outcomes

Variables	Frail (n = 18)	Nonfrail (n = 42)	p
Complications, % (n)	67% (12)	24% (10)	**0.003**
Wound infection, % (n)	22% (4)	14% (6)	0.46
Pneumonia, % (n)	33% (6)	5% (2)	**0.05**
UTI, % (n)	11% (2)	5% (2)	0.57
Sepsis, % (n)	11% (2)	0	0.08
Hospital LOS, mean ± SD	13.38 ± 8.5	5.7 ± 3.2	**<0.001**
ICU LOS, mean ± SD	0.71 ± 3.9	0.11 ± 0.31	0.21
Discharge disposition			
Home	28% (4)	69% (30)	**0.004**
Rehab	44% (7)	13% (6)	**0.01**
SNiF	17% (3)	15% (6)	0.99
Mortality, % (n)	22% (4)	0	**0.006**

Boldface indicates statistical significance.
Rehab, rehabilitation center.

SOFA scores exist that reliably predict outcomes in critically ill patients. However, these scores estimate the disease severity and do not reflect the actual functional status and reserve of these patients. Therefore, literature is still lacking in tools to calculate FI in EGS patients.

The American College of Surgeons National Surgical Quality Improvement Program is the leading nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care in the private sector. The American College of Surgeons National Surgical Quality Improvement Program has shown excellent predictability of outcomes in patients. However, this tool was developed and validated for elective surgeries, and it does not cover the frailty components that reflect the true frailty status and the physiologic reserve of these patients.[13] Our EGSFI score was developed to bridge this gap in literature, and it includes the variables related to comorbidities, physical activities, health attitude, nutrition, and cognitive status of patients that can be used simply in the clinical assessment of patients. It provides a reliable estimate of the predisease physiologic status of the elderly individual. We previously used a similar approach in elderly trauma patients to develop and use a 15-variable trauma-specific FI.[14,15] We found this frailty score was efficient to use and at the same time reliable to predict outcomes of elderly trauma patients.[8] We felt the need for a similar frailty assessment tool existed for elderly patients undergoing EGS. Interestingly, the variables that most reliably predict the outcomes in EGS patients were very similar to the ones that predict outcomes in the geriatric trauma patients. The most plausible explanation for this may be that these variables are most reflective of the physiological status of the elderly.

Once developed, we validated our EGSFI score on 60 elderly patients and divided them into frail and nonfrail based on the cutoff values. We found that frail patients had a significantly higher rate of overall postoperative complications compared to the nonfrail group. Additionally, subanalysis of individual complications demonstrated that frail patients were more prone to develop pneumonia. This is in harmony with several other frailty studies. Courtney-Brooks et al.[16] in their study found that 30-day surgical complications increased with increasing of frailty score (frail, 67% vs. non-frail, 24%). Similarly, in another study by George et al.[5] frailty was associated with adverse outcomes in patients who underwent hysterectomy owing to a gynecological cancer.

Increasing the frequency of surgical procedures has been associated with an increase in the operative mortality rate. Between 1931 and 1959, 40% of surgical procedures were performed in elderly patients, but 76.5% of deaths occurred in this at risk population.[1] Rate of mortality in our study also increased in elderly frail patients who underwent surgical procedures and developed postoperative complications. Similarly, hospital LOS defined as one of the outcome measures of our study was significantly longer in frail patients. In a study on cancer patients older than 70 years, a comprehensive assessment of health and function was performed by using different risk instruments, and the results demonstrated that frailty was associated with 50% increase in postoperative complications and extended hospital stay.

One important aspect of frailty highlighted in our present study is its superiority over the age. Previous studies have mainly focused on age and comorbidities as the predictors of adverse postoperative outcomes in elderly EGS patients. In our study, we found that frailty calculated by EGSFI was a significant predictor of postoperative complications while age was not. Similar to our findings, Boyd et al.[1] reported that age as an isolated factor had no effect on the mortality rate of colon resections.

In our study, frailty had a significant impact on adverse discharge disposition. Frail patients were less likely to be discharged home and more likely to be discharged to a rehabilitation facility. Identification of patients who are more likely to require discharge to an institutional facility can expedite this tedious process and ultimately shorten prolonged hospital stays. Similarly, Robinson et al. found that patients with frailty were likely to require institutional care after a major surgical procedure. However, their study was retrospective, and there was a variability in their frailty scores. In our study, we demonstrated that the results of the implementation of EGSFI in EGS patients could give a reliable prediction of patients who require discharge to a rehabilitation facility.

Our study has several implications. We highlight that physiologic reserve of patients is a better predictor of postoperative outcomes compared to age. We present a simple 15-variable validated tool that can be easily applied at the bedside to stratify patients based on their postoperative risk for complications. In our experience, this questionnaire can easily be completed less than 5 minutes by asking patients or their nearest family members 15 simple questions, making it convenient for bedside use. When applied preoperatively, it can help inform patients and their families of their likely postoperative outcomes. Based on these predictions, it may aid physicians and their families in informed decision making. Since frail patients are more likely to develop complications and stay longer in the hospital, it may also help in allocating greater hospital resources to these patients.

Despite the prospective nature of our study, our findings should be interpreted in the context of the limitations. Our findings are representative of data from a single institution and may not be generalizable in entirety. We had a relatively small validation cohort. Additionally, we did not evaluate the impact of frailty on long-term functional outcomes and quality of life, which remains one of the most important end points of care in geriatric patients.

CONCLUSION

The 15-variable validated EGSFI is a simple and reliable bedside tool to determine the frailty status of patients undergoing EGS. Frail status as determined by the EGSFI is an independent predictor of postoperative complications and mortality in geriatric EGS patients. This may serve as a helpful tool for informed decision making, efficient allocation of hospital resources, and opportunities for early intervention in high-risk frail patients.

AUTHORSHIP

T.O.J., M.J.M., P.R., and B.J. conceptualized and designed the study. T.O.J., N.K., K.I., and B.J. acquired the data for this study. T.O.J., P.R., M.F., A.H., and H.A.P. analyzed and interpreted the data. T.O.J., H.A.P., N.K., J.M., and P.R. drafted the manuscript. T.O.J, N.K., K.I., and B.J. performed critical revision of the manuscript.

DISCLOSURE

No support was received for this study. The authors declare no conflicts of interest.

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