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ORIGINAL ARTICLE

A combined fracture and mortality risk index useful for treatment stratification in hip fragility fractures

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ABSTRACT

Objectives: In this study, we aimed to assess the stratification ability of the Fracture and Mortality Risk Evaluation (FAME) index for reoperation, new fragility fracture, and mortality during one-year follow-up.

Patients and methods: Between November 2018 and July 2019, a total of 94 consecutive hip fragility fracture patients from two centers (20 males, 74 females; mean age: 79.3±8.9 years; range, 57 to 100 years) were retrospectively analyzed. The patients were classified into high, intermediate, and low fracture and mortality risk groups according to the Fracture Risk Assessment Tool (FRAX) score and Sernbo score, respectively, as well as nine combined categories according to the FAME index. Hospital records were reviewed to identify re-fractures (reoperations, implant failure, new fragility fractures on any site) and mortality at one year following the FAME index classification.

Results: Overall re-fracture and mortality rates were 20.2% and 33%, respectively. High fracture risk category (FRAX-H) was significantly associated with higher re-fracture (odds ratio [OR]: 2.9, 95% confidence interval [CI]: 1-8.2, p=0.037) and mortality rates compared to others (OR: 3.7, 95% CI: 1.5-9.3, p=0.003). The patients classified within the FRAX-H category (n=35) had different mortality rates according to their Sernbo classification; i.e., patients classified as low mortality risk (Sernbo-L) (n=17) had lower mortality rates compared to others in this group (n=18) (35.3% and 66.7%, respectively), indicating a low statistical significance (OR: 0.3, 95% CI: 0.1-1.1, p=0.063). Similarly, within patients classified in Sernbo-L category (n=64), those classified as high fracture risk (FRAX-H) (n=17) had significantly higher re-fracture rates compared to others in this group (n=47) (35.3% and 8.5%, respectively), (OR: 5.9; 95% CI: 1.4-24.5), (p=0.017). Multivariate logistic regression analyses adjusting for covariates (age, sex, length of hospital stay and BMI) yielded similar results.

Conclusion: The FAME index appears to be a useful stratification tool for allocating patients in a randomized-controlled trial for augmentation of hip fragility fractures.

Keywords: Augmentation, hip fracture, osteoporosis, risk factors, stratification.

Fragility fractures of the hip in the elderly are associated with high mortality within in the first postoperative year and high failure rates. Implant-related complication and revision rates in hip fractures have been reported to range from 4.9 to 18.3%, depending on the fracture type.[1-6] Considering the current age-quake,[7] reoperation would contribute substantially to the societal financial burden.[8,9] Strategies for improving the surgical technique in these frail patients with multiple comorbidities are being developed worldwide, mainly focusing on improving the fixation devices, and augmenting the osteoporotic bone around the implant.[10,11] Injection

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of polymethyl methacrylate (PMMA) into the femoral neck or trochanter, around a dynamic hip screw or proximal femoral nail has been shown to be effective in previous studies.[12] However, PMMA injection have important drawbacks, due to its non-resorbable nature and not being replaced by native bone which complicates potential revision surgeries.[13] Therefore, finding alternatives to improve immediate fracture fixation and enhance fracture repair is an ongoing area of research.[14-19] Despite promising results in laboratory studies, clinical efficiency of these methods is limited. Moreover, although high-quality randomized-controlled trials (RCTs) are a must for translation of new techniques into practice, they should also be feasible.[19] This poses difficulties, as patients with fragility fractures are known to have scattered bone quality and survival rates.[20,21] Stratification of patients may significantly decrease the size and cost of a RCT producing reliable results and shorten the time for clinical translation.

We earlier developed the Fracture And Mortality Risk Evaluation (FAME) index to stratify patients who would benefit most from improved fixation procedures, namely patients with high risk of mechanical failure and low early postoperative risk of mortality.[20] The FAME index combines three categories of high, intermediate, and low risk for *(i)* fracture risk, classified by the Fracture Risk Assessment Tool (FRAX) and *(ii)* mortality risk classified by the Sernbo score, adding up to a total of nine subcategories.[21,22] The FRAX uses basic clinical factors to provide a 10-year probability of a fragility fracture with or without the use of bone mineral density (BMD) measurement.[22] The categorization relies on a 2017 study which introduced age-dependent intervention thresholds based on FRAX scores.[22] The Sernbo score, on the other hand, is a four-element scoring system which was developed to guide the decision between total hip arthroplasty and hemiarthroplasty in hip fracture patients.[21] In 2017, Mellner et al.[21] showed that it could successfully estimate the one-year mortality after surgically treated femoral neck fractures in the elderly. Their follow-up registry based study on over 55,000 hip fracture patients further supported the initial findings.[23] They defined three mortality risk groups using the Sernbo score, which we adopted to develop the FAME index.

In the preliminary study that presented the index, we showed without follow-up that the FAME index applied before surgery in the clinical emergency setting was feasible.[20] In the present study, we aimed to assess the stratification ability of the FAME index for reoperation, new fragility fracture, and mortality during one-year follow-up.

PATIENTS AND METHODS

This two-center, retrospective study was conducted at Department of Orthopedics and Traumatology, Gazi University Faculty of Medicine and Department of Orthopedics and Traumatology, Lithuanian University of Health Sciences between November 2018 and July 2019. A total of 50 consecutive patients with low-energy fragility fractures of the cervical or intertrochanteric region of the femur admitted for surgery were included in the study. The study centers were from Turkey and from Lithuania, adding up to a total of 100 patients. The patients were operated with osteosynthesis (intramedullary nail, dynamic hip screw, cannulated screws) or arthroplasty, based on the surgeon preference. A total of 17 surgeons performed the procedures. All data to calculate FRAX without BMD and Sernbo scores were recorded on a form created for FAME index as described previously.[20] The patients were classified into high, intermediate, and low fracture risk groups according to FRAX score; high, intermediate, and low mortality risk groups according to Sernbo score, and nine combined categories according to the FAME index (Table I).

TABLE I

Classification of patients according to the FAME Index in each center

	Sernbo Low		Sernbo Int.		Sernbo High		Total	
	TUR	LIT	TUR	LIT	TUR	LIT	TUR	LIT
Frax low	13	11	3	2	1	1	17	14
Frax int.	7	17	1	1	2	3	10	21
Frax high	9	9	9	1	5	5	23	15
Total	29	37	13	4	8	9	50	50

Int.: Intermediate; TUR: Turkey; LIT: Lithuania; Each color represents one of the 9 subgroups in the FAME index. Yellow filled cells represent the subgroup with high risk of fracture while having a low risk of mortality

At the end of 12 months based on FAME index classification, hospital records were reviewed to identify fractures on any site sustained during the follow-up period, reoperations, and mortality. Those having incomplete follow-up data (n=6) were excluded from the study. Finally, 94 patients (20 males, 74 females; mean age: 79.3±8.9 years; range, 57 to 100 years) were included in the study. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were presented in mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. Normality for continuous data were assessed using the Shapiro-Wilk normality test. Descriptive data were analyzed using the chi-square for categorical variables, while the Student t-test or Mann-Whitney U test was used for continuous variables. The chi-square test was used to identify associations and calculate odds ratios (ORs) between categorical variables and both re-fracture and mortality as the endpoints. The Fisher's exact test was used for categorical data with a small expected count (<5). To increase the expected count or to be able use Fisher's exact test, fracture risk, mortality risk and FAME index categories were split into dichotomous variables formed as: high fracture risk (FRAX-H), low mortality risk (Sernbo-L), and high fracture-low mortality risk groups (FAME-HL), respectively versus the rest of the categories. For continuous univariate data, ORs were calculated using univariate binary logistic regression considering re-fracture and mortality at one year as the endpoint. Multivariate binary logistic regressions were used after initial analyses, to adjust for covariates. A p value of <0.05 was considered statistically significant with 95% confidence interval (CI).

RESULTS

Of a total of 94 patients, 57 were operated with hemiarthroplasty, while the remaining underwent osteosynthesis (intramedullary nailing, n=29; dynamic hip screw, n=4; cancellous screw, n=4). Overall re-fracture rate and mortality rate at one year was 20.2% (n=19) and 33% (n=31), respectively. Of the 19 events recorded as re-fractures, nine

TABLE II

Univariate statistics for re-fracture at one year

	No re-fracture			Re-fracture			All					
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	OR	95% CI	p
Mean age (year)			78.8±9.3			81.3±6.6			79.3±8.9	1.04	1-1.1	0.3
Sex										1	0.3-3.5	0.9
Male	16	80		4	20		20	21.3				
Female	59	79.7		15	20.3		74	78.7				
Hospital of follow-up										0.8	0.3-2	0.6
Turkey	34	77.3		10	22.7		44	46.8				
Lithuania	41	82		9	18		50	53.2				
Mean BMI (kg/m^2)			24.8±5.1			26.1±5.5			25±5.2	1.05	1-1.2	0.3
Fracture risk										2.9	1-8.2	0.037*
Rest of the categories	51	86.4		8	13.6		59	62.8				
FRAX-H	24	68.6		11	31.4		35	37.2				
Mortality risk										0.4	0.2-1.2	0.1
Sernbo-L	54	84.4		10	15.6		64	68.1				
Rest of the categories	21	70		9	30		30	31.9				
FAME category										2.7	0.8-8.6	0.1
FAME-HL	11	64.7		6	35.3		17	18.1				
Rest of the categories	64	83.1		13	16.9		77	81.9				

OR: Odds ratio; CI: Confidence interval; SD: Standard deviation; BMI: Body mass index; FRAX-H: High fracture risk category; Sernbo-L: Low mortality risk category; FAME-HL: High fracture-low mortality risk category; FRAX: Fracture risk assessment tool; FAME: Fracture and mortality risk evaluation index; * Statistical significance at p<0.05.

TABLE III
Univariate statistics for mortality at one year

	Alive			Dead			All					
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	OR	95% CI	p
Mean age (year)			78.3±9.4			81.1±7.4			79.3±8.9	1.04	1-1.1	0.2
Sex										3.5	1-12.8	0.054
Male	17	85		3	15		20	21.3				
Female	46	62.2		28	37.8		74	78.7				
Hospital of follow-up										0.9	0.4-2.2	0.8
Turkey	29	65.9		15	34.1		44	46.8				
Lithuania	34	68		16	32		50	53.2				
Mean BMI (kg/m^2)			24.8±5			25.5±5.8			25±5.2	1.03	1-1.1	0.6
Fracture risk										3.7	1.5-9.3	0.003*
Rest of the categories	46	78		13	22		59	62.8				
FRAX-H	17	48.6		18	51.4		35	37.2				
Mortality risk										0.4	0.2-1.02	0.053
Sernbo-L	47	73.4		17	26.6		64	68.1				
Rest of the categories	16	53.3		14	46.7		30	31.9				
FAME category										1.1	0.4-3.4	0.8
FAME-HL	11	64.7		6	35.3		17	18.1				
Rest of the categories	52	67.5		25	32.5		77	81.9				

OR: Odds ratio; CI: Confidence interval; SD: Standard deviation; BMI: Body mass index; FRAX-H: High fracture risk category; Sernbo-L: Low mortality risk category; FAME-HL: High fracture-low mortality risk category; FRAX: Fracture risk assessment tool; FAME: Fracture and mortality risk evaluation index; * Statistical significance at p<0.05.

were reoperations (cut-out, n=5; infection, n=2; periprosthetic fracture, n=1; pseudoarthrosis, n=1) and 10 were fractures located in other sites.

Age, sex, length of hospital stay, Sernbo score, and FAME index were not statistically significant predictors of any endpoint. However, high-fracture risk category (FRAX-H) was significantly associated with higher re-fracture and mortality rates compared to others (Tables II and III).

Although overall mortality was significantly higher in the FRAX-H category (Table 3), for patients in this category (n=35), who were also classified as Sernbo-L (FAME-HL category, n=17) had lower mortality rates than the others in FRAX-H category (n=18) (35.3% and 66.7%, respectively); however, it reached a low statistical significance (OR 0.3 [95% CI: 0.1-1.1], p=0.063). Similarly, for patients in the Sernbo-L category (n=64), the patients who were also classified as FRAX-H (FAME-HL

TABLE IV
Multivariate logistic regression analyses for re-fracture at one year, adjusting for age, sex, length of hospital stay, and BMI

	Model 1		Model 2		Model 3	
	OR	95% CI	OR	95% CI	OR	95% CI
Age	1	1-1.1	1	0.9-1.1	1.1	1-1.1
Sex	0.3	0.1-1.6	0.7	0.2-2.8	0.5	0.1-2
Hospital of follow-up	0.9	0.3-2.6	0.8	0.3-2.3	0.7	0.2-2
Body mass index	1.1	1-1.2	1.1	1-1.2	1.1	1-1.2
FRAX (dichotomous)	4.1*	1.1-15.9				
Sernbo (dichotomous)			0.5	0.1-1.8		
FAME (dichotomous)					3	0.8-10.4

CI: Confidence interval; BMI: Body mass index; FRAX: Fracture risk assessment tool; FAME: Fracture and mortality risk evaluation index; * Statistical significance at p<0.05.

TABLE V
Multivariate logistic regression analysis for mortality at one year, adjusting for age, sex, length of hospital stay, and BMI

	Model 1		Model 2		Model 3	
	OR	95% CI	OR	95% CI	OR	95% CI
Age	1	1-1.1	1	0.9-1.1	1	1-1.1
Sex	1.7	0.4-7.4	3.1	0.8-12.6	2.9	0.7-11.6
Hospital of follow-up	1.2	0.5-3	1.1	0.4-2.8	1	0.4-2.4
Body mass index	1	1-1.1	1	0.9-1.2	1	0.9-1.1
FRAX (dichotomous)	3.2*	1.1-9.1				
Sernbo (dichotomous)			0.4	0.1-1.3		
FAME (dichotomous)					0.9	0.3-2.7

CI: Confidence interval; BMI: Body mass index; FRAX: Fracture risk assessment tool; FAME: Fracture and mortality risk evaluation index; * Statistical significance at p<0.05.

category, n=17) had a significantly higher risk of re-fracture than the others in the Sernbo-L category (n=47) (35.3% and 8.5%, respectively) (OR: 5.9; 95% CI: 1.4-24.5), (p=0.017).

When the FRAX-H, Sernbo-L, and FAME-HL categories were analyzed in the multivariate binary logistic regression analysis adjusting for covariates (i.e., age, sex, length of hospital stay, body mass index), the results remained unchanged (Tables IV and V).

DISCUSSION

The present study results showed that combining FRAX and Sernbo scores could produce a plausible stratification tool for patients with fragility fractures in the hip. Risk stratification with FRAX alone could identify the patients with high risk of re-fracture. However, the parameters used to calculate the FRAX score are also commonly considered as surrogate markers of frailty, which possibly is the reason for FRAX-H category also having a significantly higher mortality. Therefore, we believe that using FRAX alone would not be feasible for stratifying hip fracture patients to be assigned in a RCT on augmentation. When the mortality risk classification according to the Sernbo score was utilized in this group, the patients with about half the mortality could be identified, although with a low statistical significance. Similarly, Sernbo-L category was hypothesized to have lower mortality than the other categories, and it had also low significance. Highlighting the relevance of our proposed combined approach in this category, the patients categorized as FRAX-H had a significantly higher risk of re-fracture. Thus, patients classified as high fracture-low mortality risk in the FAME index could have a higher risk of mechanical failure.

Identifying patients with a higher risk of mortality following a hip fracture and addressing their needs appropriately is undeniably important to improve general care and survival rates.[21] In a very recent study on 215,672 hip fragility fractures from the French National Health database, Roux et al.[24] reported that, in patients hospitalized for a hip fracture, the 12-month mortality rate was 16.6% and the rate of re-fracture at any site was 6.6%, indicating the burden of mortality. However, it should also be noted that occurrence of re-fracture substantially contributes to the mortality risk.[25] Therefore, by identifying the patients who have a lower bone quality while having a relatively lower risk of death, researchers can focus efforts and resources on developing strategies against mechanical failure and subsequent excess mortality more efficiently.

Recent research has focused on improving implant fixation, implant design and type of biomaterials, in combination with bone active molecules.[26,27] Recently, Kok et al.[15] reported that fixation could be improved with utilization of calcium sulfate/hydroxyapatite (CaS/HA) biomaterial injected through cannulated hip screws, increasing the pullout strength on synthetic bone models. Another recent *in vivo* study by Raina et al.[28] found that the tissue engineering strategy of using CaS/HA ceramic biomaterial to locally deliver zoledronic acid (ZA) with or without recombinant human bone morphogenic protein-2 in femoral necks of osteoporotic rats had potential to regenerate cancellous bone in the femoral neck canal and, therefore, enhance fixation and implant anchorage in osteoporotic bone. As ceramic biomaterial alone may have a limited effect on bone formation, its utilization as a carrier for local delivery of ZA emerges as a promising strategy against mechanical failure of hip fractures. These new augmentation strategies based on tissue engineering with their ability to initiate peri-implant cancellous bone formation could mitigate fixation failures and has potential to replace conventional PMMA-based, augmentation methods in the current clinical practice. The use of FAME index to stratify patients for inclusion in a RCT with ceramic materials can accelerate the clinical translation.

Nonetheless, there are several limitations to our study. Despite enrolling the same number of consecutive patients in each center and demographics, fracture and mortality rates being similar, as well as distribution of patients in different FAME categories, we consider selection bias and heterogeneity of patients as limitations related to the retrospective design. Moreover, six patients from the Turkish cohort were excluded from the analysis due to loss of follow-up, which further limited the sample size and potentially further increased heterogeneity. Another limitation is that FRAX has not previously been studied as a predictor for mechanical failure following fragility fractures of the hip. Nevertheless, our aim was to assess its effectiveness in stratifying patients according to bone quality which was portrayed by the re-fracture outcomes. This study is limited in size which potentially can lead to excluding patients that could potentially benefit from augmentation. Yet, augmentation is on its early stage in translation into clinical practice and, therefore, the initial objective would be to test whether it prevents fixation failure and revisions at a reasonable cost and with a low risk of adverse events. With further developments in this field, modifications to the FAME index can be done to increase its ability to identify suitable patients for inclusion in registry-nested RCT trials.[27,28]

In conclusion, the FAME index appears to be a useful stratification tool for allocating patients in a RCT studying augmentation of hip fragility fractures. Further well-designed, large-scale, prospective RCTs are warranted to draw more reliable conclusions on this subject.

Declaration of conflicting interests

LL is a board member of Bone Support AB, Lund, Sweden and Ortho Cell, Australia. The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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