Disorder-related risk factors for revision total hip arthroplasty after hip hemiarthroplasty in displaced femoral neck fracture patients: a nationwide population-based cohort study

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Abstract

Background: The choice of primary hip hemiarthroplasty or total hip arthroplasty for displaced femoral neck fracture is still controversial. Revision hip arthroplasty not only increases risk and cost but also could result in worse outcome. Determining the risk factors for revision can help inform medical decision-making and aid in risk stratification of publicly reported outcomes. Therefore, we conducted a nationwide population-based study to identify the disease-related risk factors and construct a risk score nomogram to predict revision surgery.

Methods: Records of all 68,030 femoral neck fracture patients receiving partial hemiarthroplasty (HA) in 2000–2010, with no total hip arthroplasty (THA) or revision HA history, were collected from the National Health Insurance Research Database. Cox proportional hazard regression was used to estimate the risk of revision hip replacement (RHA). The score of each risk factor was the quotient of the regression coefficient of the variable by the regression coefficient for a 10-year increase in age. The predictive accuracy was tested using the area under the receiver operating characteristic curve (AUROC).

Results: The revision risk for hemiarthroplasty increased in male, those with schizophrenia and end-stage renal disease patients had 1.58-, 1.88-, and 1.74-fold revision HA risk (95% confidence interval (CI) = 1.40–1.78, 1.26–2.79, and 1.29–2.34, respectively). In a predictive model, the cumulative risk score ranged from 0 to 13 with a 5.08 to 91.82 % 10-year predicted RHA risk. The percentage of AUROC for 10-year RHA risk in nomogram was 61.9 (95% CI = 60.0–63.4).

Conclusions: Males, schizophrenia and end-stage renal disease patients have higher risk of revision surgery after hemiarthroplasty for femoral neck fracture.

Background

With the rapid development of the aging population, the total number of patients worldwide with hip fracture is predicted to rise to 6.26 million per year by 2050 [1]. Based on location, femoral neck fractures account for 45 to 53 % of hip fractures. The three major treatments for femoral neck fractures in clinical practice are internal fixation, hemiarthroplasty (HA), and total hip arthroplasty (THA) [2, 3]. While internal fixation applies to undisplaced intracapsular fractures [4], the other two operative methods are advisable for displaced fractures in the elderly [5]. Since HA is a standardized surgical method that allows early weight bearing and recovery, it has become an established procedure with low risk of postoperative complications. Nonetheless, higher physical demands, even in older adults, occasionally necessitate conversion surgery to THA; this processes likely to increase both the possible risks and the associated costs.
While debate continues on whether primary THA or HA is best for displaced femoral neck fracture [6, 8–10], the high complication rate of revision HA in comparison with THA is clearly known [11]. Therefore, it has become critical to determine the specific risk factors associated with the conversion of HA to revision hip replacement (RHA), to better assess the relative risks of each surgical procedure. The few studies of the risk factors associated with conversion to THA for hemiarthroplasty have identified several risk factors, such as younger age and male gender [12]. However, the weight of each risk factor has not yet been determined. Thus, we conducted a population-based, case-control study using the nationwide population-based database of a universal insurance program to evaluate the disease-related risk factors for conversion of HA to THA in femoral neck fracture in older adults.

Methods
Data source
The Taiwan Bureau of National Health Insurance (TBNHI) set up a single-payer National Health Insurance (NHI) Program on March 1, 1995. Almost all residents in Taiwan join this program. TBNHI commissioned the National Health Research Institutes to maintain the National Health Insurance Research Databases (NHIRDs) derived from the NHI program. We obtained from the NHIRDs data on all inpatient claims from 1996 to 2011. To be in compliance with the Personal Information Protection Act, the insurance information was de-identified and the scientists signed an agreement that they had no intention of obtaining personal information. This study was approved by the local institutional review board. The identification of disease was based on the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes in the NHIRDs.

Study subjects and end-points
We collected adult patients with a new diagnosis of femoral neck fracture (ICD-9-CM code 820) who received partial hip arthroplasty (HA, ICD-9-operation code 81.52) in 2000–2010 (N = 68,755). The date of HA treatment was defined as the index date. Patients who had received total hip replacement (ICD-9-operation code 81.51, n = 592) or RHA (ICD-9-operation code 81.53, n = 133) before the index date were excluded. All study subjects were followed from the index date to the date of RHA treatment. Those without RHA treatment were followed until the date of withdrawal from the program or the end of 2011.

For the prediction model, we randomly assigned HA patients to either a derivation group or a validation group in a 3:1 ratio.

Risk factors
The risk factors included age, gender, and comorbidity. Comorbidities assessed (using ICD-9-CM codes) included diabetes (250), osteoporosis (733.0, V17.81, V82.81), rheumatoid arthritis (RA; 714), cancer (140–208), chronic obstructive pulmonary disease (COPD; 491,492, 496), previous osteoarthritis hip (715.5), end-stage renal disease (ESRD; 585), systemic lupus erythematosus (SLE; 710.0), ankylosing spondylitis (720), obesity (278.0), extrinsic asthma (493.0), human immunodeficiency virus (HIV; 042, V08, 795.71), atherosclerosis (440), smoking (350.1 and 649.0), psoriasis (696), viral hepatitis (070), depression (296.2, 296.3, 296.82, 300.4, 311), schizophrenia (295), heart failure (428), urinary tract infection (UTI; 599.0), ischemic heart disease (410–414), dementia (290, 294.1, and 331.0–331.2), and alcoholism (291, 303, 305.00–305.03, 790.3, V11.3). All comorbidities were defined before the index date.

Statistical analysis
Incidence of RHA and RHA-associated risk factors
The incidence of RHA (per 1000 person-years) was determined in patients by age, gender, and comorbidity. Cox proportional hazard regression was used to estimate the hazard ratios (HRs) and 95% confidence interval (CI) of RHA and the RHA-associated risk factor. Multivariable modeling was used, controlling for significant factors using crude Cox proportional hazard regression.

Prediction model
In future analysis, the prediction model was developed according to those risk factors identified as significant in this study. The score of each risk factor was the quotient of the regression coefficient of the variable by the regression coefficient for a 10-year increase in age. The cumulative score was the sum of the score of each risk factor. The area under the receiver operating characteristic curve (AUROC) of the nomogram was used to test the association of factors with RHA treatment using logistic regression. In future analysis, the patients were grouped into three groups based on risk scores: low (risk score 0–2), median (risk score 3–4), and high (risk score 5+). We plotted the cumulative incidence among risk score groups by Kaplan-Meier analysis in derivation and validation cohort. All statistical analyses were performed using the SAS software package SAS (version 9.4 for windows; SAS Institute, Cary, NC).

Results
All 68,030 femoral neck fracture patients who received hip hemiarthroplasty (HA) were selected for this study. Most patients were older than 70 years (80.8%) and the mean age was 77.3 years (standard deviation = 9.26, Table 1). Most HA patients were female (65.0 vs. 35.0%).
| Table 1 | Incidence and hazard ratio for revision hip replacement and associated risk factor |
|---------|---------------------------------------------------------------------------------|
|         | \( n \) (\%) | Event no. | PY | Rate\(^a\) | Crude HR (95 % CI) | Adjusted HR (95 % CI) |
|         | Total | 68,030 | 1114 | 238,875 | 4.66 | 23.6 (10.2–54.7)**[^3] |
| Age, year |       |         |       |       |       |       |
| 20–29   | 53 (0.08) | 9 | 260 | 34.57 | 30.9 (13.4–71.5)**[^3] | 23.6 (10.2–54.7)**[^3] |
| 30–39   | 158 (0.23) | 11 | 832 | 13.23 | 12.0 (5.43–26.4)**[^3] | 8.52 (3.85–18.9)**[^3] |
| 40–49   | 499 (0.73) | 25 | 2302 | 10.86 | 9.49 (4.93–18.3)**[^3] | 6.90 (3.56–13.4)**[^3] |
| 50–59   | 1862 (2.74) | 63 | 7908 | 7.97 | 6.65–3.73 (11.9)**[^3] | 5.48 (3.06–9.82)**[^3] |
| 60–69   | 10,492 (15.4) | 257 | 45,526 | 5.65 | 4.77 (2.79–8.17)**[^3] | 4.35 (2.54–7.46)**[^3] |
| 70–79   | 26,868 (39.5) | 458 | 101,757 | 4.50 | 3.59 (2.11–6.12)**[^3] | 3.38 (1.99–5.76)**[^3] |
| 80–89   | 24,095 (35.4) | 277 | 71,159 | 3.89 | 2.80 (1.64–4.80)**[^3] | 2.73 (1.60–4.68)**[^3] |
| ≥90     | 4003 (5.88) | 14 | 9132 | 1.53 | 1.00 | 1.00 |
| Mean (SD) | 77.3 (9.26) |       |       |       |       |       |
| Gender |       |         |       |       |       |       |
| Women | 44,241 (65.0) | 614 | 163,685 | 3.75 | 1.00 | 1.00 |
| Men | 23,789 (35.0) | 500 | 75,190 | 6.65 | 1.69 (1.50–1.90)**[^3] | 1.58 (1.40–1.78)**[^3] |
| Comorbidity |       |         |       |       |       |       |
| Diabetes |       |         |       |       |       |       |
| No | 51,877 (76.3) | 861 | 191,518 | 4.50 | 1.00 | 1.00 |
| Yes | 16,153 (23.7) | 253 | 47,357 | 5.34 | 1.09 (0.95–1.26) |       |
| Osteoporosis |       |         |       |       |       |       |
| No | 64,702 (95.1) | 1057 | 228,211 | 4.63 | 1.00 | 1.00 |
| Yes | 3328 (4.89) | 57 | 10,664 | 5.35 | 1.11 (0.85–1.45) |       |
| RA |       |         |       |       |       |       |
| No | 67,472 (99.2) | 1099 | 236,796 | 4.64 | 1.00 | 1.00 |
| Yes | 558 (0.82) | 15 | 2079 | 7.21 | 1.57 (0.94–2.61) |       |
| Cancer |       |         |       |       |       |       |
| No | 62,848 (92.4) | 1038 | 226,145 | 4.59 | 1.00 | 1.00 |
| Yes | 5182 (7.62) | 76 | 12,730 | 5.97 | 1.14 (0.90–1.44) |       |
| COPD |       |         |       |       |       |       |
| No | 60,835 (89.4) | 1008 | 219,410 | 4.59 | 1.00 | 1.00 |
| Yes | 7177 (10.6) | 106 | 19,465 | 5.45 | 1.07 (0.88–1.31) |       |
| ESRD |       |         |       |       |       |       |
| No | 66,073 (97.1) | 1068 | 234,698 | 4.55 | 1.00 | 1.00 |
| Yes | 1957 (2.88) | 46 | 4177 | 11.01 | 1.99 (1.48–2.68)**[^3] | 1.74 (1.29–2.34)**[^3] |
| SLE |       |         |       |       |       |       |
| No | 67,963 (99.9) | 1112 | 238,679 | 4.66 | 1.00 | 1.00 |
| Yes | 67 (0.10) | 2 | 196 | 10.19 | 2.03 (0.51–8.14) |       |
| Ankylosing spondylitis |       |         |       |       |       |       |
| No | 64,346 (94.6) | 1059 | 228,091 | 4.64 | 1.00 | 1.00 |
| Yes | 3684 (5.42) | 55 | 10,785 | 5.10 | 1.02 (0.78–1.34) |       |
| Extrinsic asthma |       |         |       |       |       |       |
| No | 67,850 (99.7) | 1112 | 238,299 | 4.67 | 1.00 | 1.00 |
| Yes | 180 (0.26) | 2 | 576 | 3.47 | 0.72 (0.18–2.89) |       |
The 10 most prevalent comorbidities in HA patients were diabetes (23.7 %), ischemic heart disease (18.2 %), UTI (17.9 %), COPD (10.6 %), heart failure (8.13 %), cancer (7.62 %), ankylosing spondylitis (5.42 %), osteoporosis (4.89 %), dementia (3.52 %), and ESRD (2.88 %).

After a cumulative 12-years follow-up, 1114 patients received RHA treatment, with an incidence of 4.66 per 1000 person-years (Table 1). In multivariable Cox proportional hazard regression, the RHA risk decreased with aging from 23.6 to 2.73 in those aged 20–29 to 80–89 years, respectively, compared with those aged ≥90 years (95 % CI = 10.2–54.7 and 1.60–4.68, respectively). Compared with women, men had a significantly higher RHA risk (HR = 1.58, 95 % CI = 1.40–1.78). RHA-associated risk factors for the total cohort were schizophrenia (HR = 1.88, 95 % CI = 1.26–2.79) and ESRD (HR = 1.74, 95 % CI = 1.29–2.34).

Table 2 presents the distribution between derivation (75.0 %) and validation (25.0 %) cohort. There was no significant difference of age, gender, ESRD and schizophrenia between two groups. In derivation cohort, the risk score decreased one point with every 10 years of age increasing; for example, the risk score was 7 for patients aged 20–29 years, 6 for those 30–39 years, 5 for those 40–49 years, and so on (Table 3). The risk score was 2 for men, those with ESRD and schizophrenia patients. The percentage of AUROC for 10-year RHA risk in nomogram was 61.9 (95 % CI = 60.0–63.4). In the prediction model, the cumulative risk score ranged from

### Table 1 Incidence and hazard ratio for revision hip replacement and associated risk factor (Continued)

| HIV | No | (99.9) | 1114 | 238,853 | 4.66 | 1.00 |
|-----|----|--------|------|---------|------|------|
| Yes | 8  | (0.01) | 0    | 22      | 0.00 | —    |
| Atherosclerosis | No | 67,550 | (99.3) | 1106 | 237,521 | 4.66 | 1.00 |
|    | Yes | 480   | (0.71) | 8    | 1355 | 5.91 | 1.17 (0.58–2.35) |
| Psoriasis | No | 67,898 | (99.8) | 1112 | 238,505 | 4.66 | 1.00 |
|    | Yes | 132   | (0.19) | 2    | 370  | 5.40 | 1.09 (0.27–4.36) |
| Heart failure | No | 66,212 | (97.3) | 1080 | 234,523 | 4.61 | 1.00 |
|    | Yes | 1818  | (2.67) | 34   | 4353 | 7.81 | 1.46 (1.04–2.06)* |
| Schizophrenia | No | 67,399 | (99.1) | 1088 | 236,468 | 4.60 | 1.00 |
|    | Yes | 631   | (0.93) | 26   | 2408 | 10.80 | 2.43 (1.65–3.58)** |
| Depression | No | 66,091 | (97.2) | 1081 | 232,874 | 4.64 | 1.00 |
|    | Yes | 1939  | (2.85) | 33   | 6002 | 5.50 | 1.12 (0.79–1.59) |
| UTI | No  | 55,877 | (82.1) | 936  | 204,007 | 4.59 | 1.00 |
|    | Yes | 12,153 | (17.9) | 178  | 34,869 | 5.10 | 1.2 (0.87–1.19) |
| Ischemic heart disease | No | 55,681 | (81.9) | 915  | 203,038 | 4.51 | 1.00 |
|    | Yes | 12,349 | (18.1) | 199  | 35,837 | 5.55 | 1.13 (0.97–1.32) |
| Dementia | No | 65,633 | (96.5) | 1091 | 231,966 | 4.70 | 1.00 |
|    | Yes | 2397  | (3.52) | 23   | 6969 | 3.30 | 0.65 (0.43–0.98)* |

**PY** person-years, **HR** hazard ratio, **CI** confidence interval, **SD** standard deviation, **RA** rheumatoid arthritis, **COPD** chronic obstructive pulmonary disease, **ESRD** end-stage renal disease, **SLE** systemic lupus erythematosus, **HIV** human immunodeficiency virus, **UTI** urinary tract infection

*p < 0.05; **p < 0.01; ***p < 0.001

*a* Per 1000 person-years
Figure 2 presents cumulative incidence of RHA in different risk score groups. In derivation cohort, the cumulative incidences of RHA were 2.03, 3.85, and 6.06 % in low, median, and high after 10 years follow-up, respectively. In validation cohort, patients with higher risk score had highest cumulative incidence of RHA (6.24 %) and followed by median and low group (3.86 and 1.85 %).

Discussion

The current study revealed that the rate of RHA for primary HA for femoral neck fracture is 4.67 per 1000 person-years. Several risk factors, such as age, gender, ESRD, and schizophrenia, were identified. We also assessed the contribution of each factor to help clinicians predict future revision rate.

Traditionally, surgeons have preferred HA over THA because of concerns about the increased risk of complications of the more complex THA. However, more current data has showed no significant differences in the complication rates of patients undergoing HA versus THA [2, 9, 13, 14]. Moreover, the literature shows a lower risk of reoperation after THA compared with HA [6, 12, 14–16] and better functional outcomes for patients after THA versus HA [6, 8–10, 13, 14, 16, 17].

0 to 13 with a 5.08 to 91.82 %10-year predicted RHA risk (Fig. 1).

Table 2

|            | Derivation cohort | Validation cohort |
|------------|-------------------|------------------|
| N          | 51021 (75.0 %)    | 17009 (25.0 %)   |
| Age, year  | n   | %     | n   | %     | Chi-square p value |
| 20–29      | 40  | 0.08  | 13  | 0.08  | 0.98               |
| 30–39      | 113 | 0.22  | 45  | 0.26  |                   |
| 40–49      | 371 | 0.73  | 128 | 0.75  |                   |
| 50–59      | 1388 | 2.72 | 474 | 2.79  |                   |
| 60–69      | 7878 | 15.4 | 2614 | 15.4 |                   |
| 70–79      | 20,177 | 39.6 | 6691 | 39.3 |                   |
| 80–89      | 18,047 | 35.4 | 6048 | 35.6 |                   |
| ≥ 90       | 3007 | 5.89  | 996 | 5.86  |                   |
| Gender     | n   | %     | n   | %     |                   |
| Women      | 33,182 | 65.0 | 11,059 | 65.0 |                   |
| Men        | 17,839 | 35.0 | 5959  | 35.0 |                   |
| Comorbidity|      |       |      |       |                   |
| ESRD       | 1493 | 2.93  | 464 | 2.73  | 0.18               |
| Schizophrenia | 455 | 0.89  | 176 | 1.03  | 0.09               |

ESRD end-stage renal disease

Table 3

| Risk score | HR (95 % CI) | Regression coefficient | p       | Risk score |
|------------|--------------|------------------------|---------|------------|
| Age, year  |              |                        |         |            |
| 20–29      | 40.4 (16.0–10.2) | 3.700 < 0.0001 | 7       |
| 30–39      | 12.3 (4.85–31.0) | 2.506 < 0.0001 | 6       |
| 40–49      | 8.40 (3.76–18.8) | 2.128 < 0.0001 | 5       |
| 50–59      | 6.44 (3.14–12.2) | 1.862 < 0.0001 | 4       |
| 60–69      | 4.92 (2.52–9.62) | 1.593 < 0.0001 | 3       |
| 70–79      | 3.97 (2.05–7.71) | 1.380 < 0.0001 | 2       |
| 80–89      | 3.38 (1.74–6.59) | 1.218 < 0.0001 | 1       |
| ≥ 90       | Ref. | 0       |         | 0         |
| Gender     |              |                        |         |            |
| Women      | Ref. | 0       |         | 0         |
| Men        | 1.57 (1.36–1.80) | 0.449 < 0.0001 | 2       |
| ESRD       | No | Ref. | 0       | 0         |
| Yes        | 1.72 (1.22–2.43) | 0.542 0.002 | 2       |
| Schizophrenia | No | Ref. | 0       | 0         |
| Yes        | 1.84 (1.15–2.96) | 0.611 0.01 | 2       |

Baseline disease–free probability

At 96.89
10 years
AUROC % (95 % CI) 61.9 (60.0–63.4)

HR hazard ratio, CI confidence interval, AUROC the area under the receiver operating characteristic curve

Fig. 1 Nomograms for the prediction of the RHA risk
HA comes with considerable risk of reoperation with conversion to THA [18, 19]. Finite element mode study has proven that HA increases the biomechanical stresses on the acetabular bone that would result in migration of the head and destruction of the acetabulum [20]. Several studies found significant acetabular wear in up to 67% of cases [21, 22], quantified at an average rate of 0.7 mm per year [22]. The inability to restore the femoral offset is also a factor [23], impairing the ability to balance tissue tension. However, THA is not suitable for every patient, including those with multiple morbidities or those with limited life expectancy [24]. The disadvantages of THA include greater blood loss and higher costs compared with HA [13]. Despite higher initial costs, the overall costs of THA are lower.

Young age and male gender are well-identified risk factors for revision HA surgery [12], but no literature has described schizophrenia or ESRD as risk factors for revision HA surgery. Schizophrenia has been associated with higher odds of perioperative blood transfusion, adverse events, and non-routine discharge following total joint arthroplasty (TJA) [25, 26] or spine surgery [27]. ESRD is also a risk factor for perioperative allogeneic blood transfusions [28], as it increased both mortality and the complication rate in TJR [29, 30].

Risk equations and risk functions have been widely applied for patient counseling, clinical diagnosis, risk stratification, treatment selection, and prognosis prediction; these have especially been useful in medical fields such as cardiovascular disease [31], hepatic disease [32, 33], and cancer [34, 35]. Most risk score systems used in orthopedic surgery are constructed according to the preoperative damage condition [36, 37], bony destruction [38], or postoperative fixation status [39]. In preoperative assessment of displaced femoral neck fracture without complicated bony destruction, using demographic data and underlying comorbidity is an easy way to predict risk of revision. The nomogram of this study does not require complex calculations but allows surgeons to estimate the impact of demographic risk factors by easily adding the risk score. It helps facilitate clinician communication with patients about risk prediction and decision-making.

Our study has several limitations. First, we relied on NHIRDs to identify revisions and risk factors for revision HA surgery. Because the ICD-9 coding is representative of diseases, but not of the lifestyle neither the physical finding. We are not able to analyze the population of smoker, alcohol use, and obesity because the insurance system only could code when the patients ask for medical treatment, which means the life style has threaten the health. Therefore, our data cannot show the risk of RHA in smoker, alcohol use, either BMI for obesity. However, smoke is a risk factor to infection [40], early failure, and revision surgery in total hip arthroplasty. Dislocation risk will be increased in alcoholism after total hip arthroplasty [41].

Second, the most common cause of revision hip replacement is loosening of the prosthesis (Table 4); however, there is no coding about primary surgery method or revision method. Therefore, we were not able to assess the surgical approach and type of prosthesis used (including retained stem, cemented, or noncemented prosthesis). Surgical approach would play a role in dislocation rate after hemiarthroplasty. Direct anterior [42, 43] or anterolateral approach has less dislocation rate that posterior approach [44, 45]. Both cemented and uncemented stem have good functional results in hip hemiarthroplasty for displaced femoral neck fractures [46]. But the uncemented hemiarthroplasty has high risk of postoperative
Top ten reasons due to revision hip replacement (N = 1114)

| Disease (ICD-9-CM) | Percentage |
|---------------------|------------|
| Mechanical complication of internal orthopedic device, implant, and graft (996.4) | 62.6 |
| Infection and inflammatory reaction due to internal prosthetic device, implant, and graft (996.6) | 8.71 |
| Other complications of internal (biological) (synthetic) prosthetic device, implant, and graft (996.7) | 3.50 |
| Shaft or unspecified part, closed (821.0) | 2.69 |
| Acquired deformities of hip (736.3) | 2.60 |
| Peritrochanteric fracture, closed (820.2) | 2.60 |
| Unspecified part of neck of femur, closed (820.8) | 2.42 |
| Osteoarthrosis, localized, not specified whether primary or secondary (715.3) | 1.97 |
| Pyogenic arthritis (711.0) | 1.53 |
| Mechanical complication of other specified prosthetic device, implant, and graft (996.5) | 1.44 |

In conclusion, to assess the future risk of revision, a risk score system was developed, based on patient demographics and comorbidities. Although the permissible degree of postoperative activity depends entirely on the general health status of each patient, the current result scan help with arranging earlier rehabilitation and developing an appropriate follow-up program to prevent early complications.

Abbreviations
AUROC, area under the receiver operating characteristic curve; CI, confidence interval; HA, hemiarthroplasty; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; NHI, National Health Insurance; RHA, revision hip arthroplasty; THA, total hip arthroplasty

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Authors’ contributions
All authors made substantive intellectual contributions to this study to qualify as authors. CHT and CHH designed the study. TLL and TIW collected the subjects’ data. CHM performed the statistical analysis. An initial draft of the manuscript was written by CHT. CHH and YCF re-drafted parts of the manuscript and provided helpful advice on the final revision. All authors were involved in writing the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

Ethics approval and consent to participate
This study was approved by the Ethics Review Board of China Medical University (CMUH104-REC2-115).

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