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## **Evaluation of quality of life after nonoperative or operative management of proximal femoral fractures in frail institutionalized patients: the FRAIL-HIP study**

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### **Citation**

Loggers, S. A. I., Willems, H. C., Balen, R. van, Gosens, T., Polinder, S., Ponsen, K. J., ... Joose, P. (2022). Evaluation of quality of life after nonoperative or operative management of proximal femoral fractures in frail institutionalized patients: the FRAIL-HIP study. *Jama Surgery*, 157(5), 424-434. doi:10.1001/jamasurg.2022.0089

Version: Publisher's Version  
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Downloaded from: <https://hdl.handle.net/1887/3514693>

**Note:** To cite this publication please use the final published version (if applicable).

# Evaluation of Quality of Life After Nonoperative or Operative Management of Proximal Femoral Fractures in Frail Institutionalized Patients

## The FRAIL-HIP Study

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**IMPORTANCE** Decision-making on management of proximal femoral fractures in frail patients with limited life expectancy is challenging, but surgical overtreatment needs to be prevented. Current literature provides limited insight into the true outcomes of nonoperative management and operative management in this patient population.

**OBJECTIVE** To investigate the outcomes of nonoperative management vs operative management of proximal femoral fractures in institutionalized frail older patients with limited life expectancy.

**DESIGN, SETTING, AND PARTICIPANTS** This multicenter cohort study was conducted between September 1, 2018, and April 25, 2020, with a 6-month follow-up period at 25 hospitals across the Netherlands. Eligible patients were aged 70 years or older, frail, and institutionalized and sustained a femoral neck or pertrochanteric fracture. The term *frail* implied at least 1 of the following characteristics was present: malnutrition (body mass index [calculated as weight in kilograms divided by height in meters squared] <18.5) or cachexia, severe comorbidities (American Society of Anesthesiologists physical status class of IV or V), or severe mobility issues (Functional Ambulation Category  $\leq 2$ ).

**EXPOSURES** Shared decision-making (SDM) followed by nonoperative or operative fracture management.

**MAIN OUTCOMES AND MEASURES** The primary outcome was the EuroQol 5 Dimension 5 Level (EQ-5D) utility score by proxies and caregivers. Secondary outcome measures were QUALIDEM (a dementia-specific quality-of-life instrument for persons with dementia in residential settings) scores, pain level (assessed by the Pain Assessment Checklist for Seniors With Limited Ability to Communicate), adverse events (Clavien-Dindo classification), mortality, treatment satisfaction (numeric rating scale), and quality of dying (Quality of Dying and Death Questionnaire).

**RESULTS** Of the 172 enrolled patients with proximal femoral fractures (median [25th and 75th percentile] age, 88 [85-92] years; 135 women [78%]), 88 opted for nonoperative management and 84 opted for operative management. The EQ-5D utility scores by proxies and caregivers in the nonoperative management group remained within the set 0.15 noninferiority limit of the operative management group (week 1: 0.17 [95% CI, 0.13-0.29] vs 0.26 [95% CI, 0.11-0.23]; week 2: 0.19 [95% CI, 0.10-0.27] vs 0.28 [95% CI, 0.22-0.35]; and week 4: 0.24 [95% CI, 0.15-0.33] vs 0.34 [95% CI, 0.28-0.41]). Adverse events were less frequent in the nonoperative management group vs the operative management group (67 vs 167). The 30-day mortality rate was 83% (n = 73) in the nonoperative management group and 25% (n = 21) in the operative management group, with 26 proxies and caregivers (51%) in the nonoperative management group rating the quality of dying as good-almost perfect. Treatment satisfaction was high in both groups, with a median numeric rating scale score of 8.

**CONCLUSIONS AND RELEVANCE** Results of this study indicated that nonoperative management of proximal femoral fractures (selected through an SDM process) was a viable option for frail institutionalized patients with limited life expectancy, suggesting that surgery should not be a foregone conclusion for this patient population.

JAMA Surg. 2022;157(5):424-434. doi:10.1001/jamasurg.2022.0089  
Published online March 2, 2022.

← Invited Commentary  
page 434

+ Supplemental content

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A proximal femoral fracture is a devastating injury for older individuals. The injury diminishes quality of life (QOL), including health-related quality of life (HRQoL), and is associated with morbidity and mortality.<sup>1-3</sup> Despite considerable efforts, the mortality rates, which are as high as 55% within 6 months of the injury for institutionalized patients with advanced dementia, have not improved in the past few decades. Proximal femoral fractures therefore are often a prelude to the end of life.<sup>4-7</sup>

For life-threatening illnesses, the World Health Organization supports a holistic approach to treating individuals with a limited life expectancy.<sup>8</sup> This approach means that, in the case of a proximal femoral fracture, both operative and nonoperative management should be considered. To ensure that the best management strategy is chosen for each individual, the goals of care must be established through a shared decision-making (SDM) process. Improving communication by presenting treatment options with realistic outcomes, eliciting patients' values, and incorporating these values into a collaborative deliberation may reduce unnecessary surgery with the risk of iatrogenic complications.<sup>9-11</sup>

Although surgery could be performed in the context of palliative care, the nonoperative management option for a subgroup of frail patients with limited life expectancy might also be satisfactory. However, there is limited insight into the true implications of nonoperative management for frail older adults with a proximal femoral fracture.<sup>12,13</sup> Consequently, treatment guidelines provide no clear advice on the nonoperative treatment of frail patients with limited life expectancy.<sup>14,15</sup> Instead, these guidelines focus mainly on regaining function, but other considerations may be more important to patients at the end of life. In current practice, more than 95% of all proximal femoral fractures are managed surgically.<sup>16</sup>

The central question remains: is nonoperative management of a proximal femoral fracture a satisfactory alternative for frail patients? In this cohort study, we aimed to investigate the outcomes of nonoperative management vs operative management of proximal femoral fractures in institutionalized frail older patients with limited life expectancy.

## Methods

This prospective, multicenter cohort study with a noninferiority hypothesis was conducted at 25 hospitals across the Netherlands. The Medical Research Ethics Committee of VU University Medical Center Amsterdam approved the study. Participants provided written informed consent. The study protocol has been published elsewhere.<sup>17</sup> All of the procedures performed were in accordance with the Declaration of Helsinki.<sup>18</sup> We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Between September 1, 2018, and April 25, 2020, we enrolled institutionalized frail patients aged 70 years or older with limited life expectancy who had sustained a proximal femoral fracture and were hospitalized in 1 of the 25 participating hospitals. These patients were followed up for 6 months, with planned outcome measurements at 1, 2, and 4 weeks and

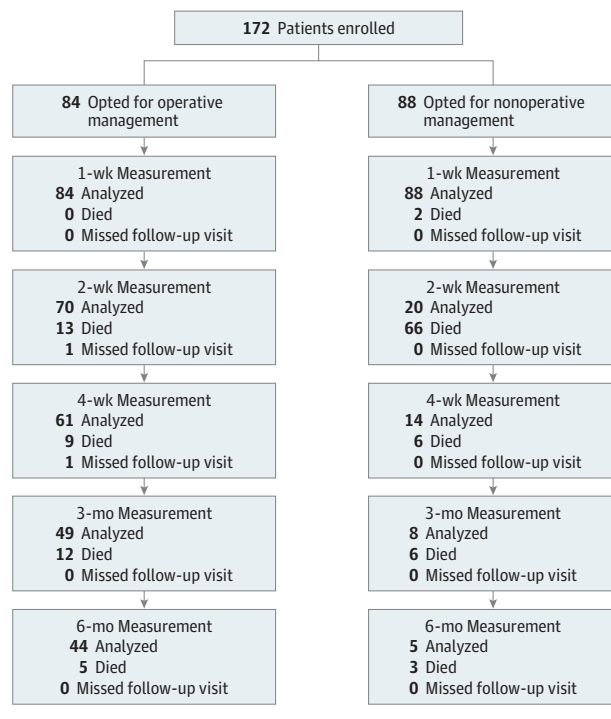
## Key Points

**Question** Is nonoperative management of proximal femoral fractures a viable treatment option for selected frail patients with limited life expectancy compared with operative management?

**Findings** In this cohort study of 172 frail patients with proximal femoral fractures, 88 opted for nonoperative management and 84 opted for operative management after a shared decision-making process. In patients who chose nonoperative management, the health-related quality of life was not inferior to that in patients who received surgical treatment and treatment was highly satisfactory.

**Meaning** Findings from this study suggest that, following shared decision-making, nonoperative management is a viable option for frail institutionalized patients with a proximal femoral fracture at the end of life and that surgery should not be a foregone conclusion for these patients.

Figure 1. Flowchart of Participants and Measurements During the Study Period



after 3 and 6 months (Figure 1). The term *frail* implied that at least 1 of the following characteristics was present: malnutrition, with a body mass index (calculated as weight in kilograms divided by height in meters squared) that was lower than 18.5 or cachexia; severe comorbidities, with an American Society of Anesthesiologists physical status class of IV or V; or severe mobility issues, with a Functional Ambulation Category (FAC) of 2 or lower (with FAC 2 indicating the need for at least [intermittent] manual assistance from 1 person during ambulation, and FAC 0 indicating no functional ambulation abilities).<sup>19</sup> The Box provides a complete overview of the inclusion and exclusion criteria.

**Box. Inclusion and Exclusion Criteria****Inclusion Criteria**

- Aged 70 y
- Femoral neck or pertrochanteric fracture
- Nursing home residency before injury
- Classification as frail with at least 1 of the following
  - Body mass index <18.5 (calculated as weight in kilograms divided by height in meters squared) or cachexia
  - Severe comorbidities, with American Society of Anesthesiologists physical status class IV or V
  - Mobility issues, with Functional Ambulation Category (FAC) 0-2<sup>a</sup>

**Exclusion Criteria**

- Subtrochanteric fractures
- Bilateral proximal femoral fractures
- Periprosthetic fractures
- Delayed diagnosis by >7 d
- Known metastatic disease
- Confirmed pathological fracture of proximal femur
- Insufficient comprehension of Dutch language by patients or proxies
- Participation in another surgical intervention or drug study

<sup>a</sup> Indicates a person who needs at least (intermittent) manual assistance from 1 person during ambulation (FAC 2) or who has no functional ambulation abilities (FAC 0).

A treatment decision was reached using a structured SDM process. With this process, the advantages and disadvantages of both nonoperative management and operative management are discussed by the patient, proxies or relatives, and all relevant health care practitioners. After this deliberation, a joint decision on the treatment is made. Although some form of SDM is used in current practice, it is not specifically mentioned in current guidelines, and no SDM tools are available. In this study, we implemented a more structured SDM approach by providing the health care practitioners in the study a full, unbiased forecast on both nonoperative management and operative management for use as a general guiding tool. Patients received usual care throughout the study period, and no specific recommendations were made by the study team.

The primary outcome was the HRQoL as reported by patient proxies and caregivers (nursing staff) and indicated by the utility scores on the EuroQol 5 Dimension 5 Level (EQ-5D) questionnaire.<sup>20-24</sup> The EQ-5D questionnaire was converted into utility scores using the Dutch tariff, and the scores ranged from -0.33 to 1, with lower scores indicating worse HRQoL. Views of proxies or caregivers regarding the patient's health were established using a vertical visual analog scale, with scores ranging from 0 to 100.

Secondary outcomes were QOL as measured by QUALIDEM (a dementia-specific QOL instrument for persons with dementia in residential settings), which includes 9 domains (care relationship [score range, 0-21], positive affect [score range, 0-18], negative affect [score range, 0-9], restless tense behavior [score range, 0-9], positive self-image [score range, 0-9],

social relations [score range, 0-18], social isolation [score range, 0-9], feeling at home [score range, 0-12], and having something to do [score range, 0-6])<sup>25</sup>; activities of daily living (ADL) dependency, as evaluated with the Katz ADL score (score range: 0-6, with 0 indicating independence and 6 indicating total dependency); level of pain, as assessed using the Pain Assessment Checklist for Seniors With Limited Ability to Communicate, which resulted in a dichotomous outcome of pain or no pain<sup>26</sup> and analgesic drug use (daily 1 mg oral equivalent); adverse events, with corresponding Clavien-Dindo classification<sup>27</sup>; mobility; and mortality. Furthermore, satisfaction of the proxies and caregivers with the chosen treatment was assessed with a numeric rating scale, where 0 was extremely dissatisfied and 10 was extremely satisfied. The quality of dying was assessed by proxies using the Quality of Dying and Death Questionnaire, and the quality may be classified under 3 categories: terrible-poor, intermediate, and good-almost perfect.<sup>28,29</sup> A detailed description of the instruments used is included in the study protocol.<sup>17</sup> One of us (S.A.I.L.) gathered all of the data. Race and ethnicity data were not collected because this variable is not a relevant factor in the Netherlands where all individuals are insured by law and nursing home stay is funded by the Long-term Care Act; therefore, the decision on operative or nonoperative management was not affected by race and ethnicity or income.

**Statistical Analysis**

Data were analyzed using SPSS Statistics, version 25.0 (IBM SPSS) on a per-protocol basis. Continuous data were reported as medians (25th and 75th percentile [P25-P75]) or means (95% CI), and categorical data were reported as numbers with percentages. Absolute differences with 95% CI were calculated using MedCalc Statistical Software, version 18.2.1 (MedCalc Software Ltd). For continuous variables, the Hodges-Lehmann risk differences with corresponding 95% CI were calculated. Univariate comparison between groups was performed using a Mann-Whitney test,  $\chi^2$  test, or Fisher exact test, where applicable. A 2-sided  $P < .05$  was the threshold of statistical significance.

Continuous subjective outcomes (EQ-5D and QUALIDEM scores) that were repeatedly measured over time were compared between treatment groups using linear mixed-effects regression models. These multilevel models included random effects for the intercepts of the model and time coefficient of individual patients. Because the outcome measures were not linearly related with time, the time points were entered as a factor. The models included fixed effects for treatment group, age, sex, and American Society of Anesthesiologists physical status classification. The interaction between treatment group and time was included in the model to test for differences between the groups over time. For each follow-up moment, the estimated marginal mean with 95% CI was computed per treatment group. Descriptive statistical tests were performed only if both groups contained 10 or more participants. Risk factors for mortality were identified using Cox proportional hazards regression analysis.

The sample size calculation indicated a need for 80 participants per treatment group and is detailed in the study

protocol.<sup>17</sup> For the primary outcome measure, a noninferiority margin of 0.15 points of the 95% CI of the EQ-5D utility score was used, with the null hypothesis that nonoperative management was inferior to operative management.<sup>30</sup> As was done in previous studies, the noninferiority limit was based on 50% of the SD of previous EQ-5D data on proximal femoral fractures.<sup>30</sup>

## Results

A total of 172 patients (median [P25-P75] age, 88 [85-92] years; 37 men [22%] and 135 women [78%]) were included in the study, of whom 88 opted for nonoperative management and 84 opted for operative management (Figure 1). No participants were lost to follow-up. Patient and fracture characteristics were statistically similar for both treatment groups (Table 1 and Table 2). A high number of comorbidities and high level of preinjury ADL dependency were found in both nonoperative and operative management groups. Elder care physicians were more often involved in the SDM process for patients in the nonoperative vs operative management group (46 [53%] vs 18 [23%];  $P < .001$ ). After choosing nonoperative management, 39 patients (44%) returned to their nursing home residency without hospital admission.

In the nonoperative management group, the EQ-5D utility score remained within the set 0.15 noninferiority limit of the 95% CI of the operative management group (week 1: 0.17 [95% CI, 0.13-0.29] vs 0.26 [95% CI, 0.11-0.23]; week 2: 0.19 [95% CI, 0.10-0.27] vs 0.28 [95% CI, 0.22-0.35]; and week 4: 0.24 [95% CI, 0.15-0.33] vs 0.34 [95% CI, 0.28-0.41]) (Figure 2A and B; eTable 1 in Supplement 1). The EQ-5D visual analog scale score for patient health status was significantly lower in the nonoperative management group than in the operative management group according to proxies and caregivers (Figure 2C and D; eTable 1 in Supplement 1). The levels of the problems experienced, according to proxies and caregivers, across the 5 domains of the EQ-5D are shown in eFigure 1 and eTables 2-6 in Supplement 1. In both treatment groups, the levels of problems with self-care (eTable 3 in Supplement 1) and ADL (eTable 4 in Supplement 1) were high. Among the surviving patients in the operative management group, total ADL dependency (Katz ADL score of 6) was found in 25 cases (50%) after 3 months and in 18 cases (41%) after 6 months.

The level of mobility significantly decreased from the preinjury level (eTables 2 and 7 in Supplement 1). In the operative management group, although 66 of 84 patients (79%) were mobile before the injury, only 19 of 66 (29%) regained mobility during the study period. In the nonoperative management group, 78 patients (89%) remained bedbound. The QUALIDEM scores in the 9 domains were similar between the treatment groups without clinically relevant differences (eFigure 2 and eTable 8 in Supplement 1).

The level of pain or discomfort gradually decreased over time, but pain was frequent in the first weeks after the injury in both treatment groups (eFigure 3A and eTables 5 and 9 in Supplement 1). After 1 week, more patients in the nonoperative management group experienced pain compared with

those in the operative management group (75 of 85 [88%] vs 56 of 84 [67%];  $P = .001$ ) (eFigure 3 in Supplement 1). However, this finding was not the same after 2 weeks (11 [55%] vs 37 [53%];  $P > .99$ ). Morphine was administered to almost every patient during the first week after the injury (eFigure 3 and eTable 10 in Supplement 1). The daily administration of morphine in the nonoperative management group was significantly higher than in the operative management group at all points of time (eTable 10 and eFigure 3 in Supplement 1).

In the first 2 weeks after the injury, we observed no statistically significant differences in the daily administered dose of morphine in the nonoperative management group between patients who did and patients who did not experience pain. In the first week, the median (P25-P75) daily morphine dose was 70 (49-95) mg in patients with pain ( $n = 75$ ) and was 43 (20-113) mg in those without pain ( $n = 10$ ) (median difference, 22 mg; 95% CI, -49 to 13 mg;  $P = .15$ ). In the second week, the median (P25-P75) dose was 33 (2-62) mg in patients with pain ( $n = 11$ ) and 29 (17-53) mg in patients without pain ( $n = 9$ ) (mean difference, 5 mg; 95% CI, -27 to 22 mg;  $P = .88$ ). In the operative management group, patients with pain received statistically higher median (P25-P75) doses of analgesia at all points of time compared with patients without pain (week 1: 19 [3-21] mg [ $n = 28$ ] vs 19 [13-26] mg [ $n = 56$ ],  $P = .02$ ; week 2: 4 [0-13] mg [ $n = 33$ ] vs 13 [3-25] mg [ $n = 37$ ],  $P = .03$ ; and week 4: 0 [0-9] mg [ $n = 44$ ] vs 14 [0-30] mg [ $n = 17$ ],  $P = .005$ ).

Adverse events (AEs) were frequent but more frequent in the operative than nonoperative management group (167 vs 67) (Table 3). Significantly more patients in the operative management group vs nonoperative management group experienced at least 1 AE (68 [81%] vs 46 [52%];  $P < .001$ ) or multiple AEs (47 [56%] vs 16 [18%];  $P < .001$ ). Pressure ulcers were the most common AE in both groups (operative group: 35 [42%]; nonoperative group: 31 [35%]). A third of all patients who opted for operative management developed delirium (27 of 84 [32%]). Most AEs were registered after patients returned to their nursing homes (82% in the nonoperative management group [ $n = 55$ ] and 62% in the operative management group [ $n = 103$ ]). Surgery- or fracture-related AEs occurred in 13 patients (15%) in the operative management group. After initially opting for nonoperative management, 2 patients were treated surgically within the index admission because of progressive pain.

In addition, antibiotic therapy (33 [39%] vs 7 [8%]) and blood transfusion (24 [29%] vs 2 [2%]) were frequently required in the operative management group but were less common in the nonoperative management group. All 12 readmissions (14%) in the operative management group were associated with surgery-related AEs or recurrent falls with new traumatic injuries.

The 30-day mortality rate was 83% ( $n = 73$ ) in the nonoperative management group and 25% ( $n = 21$ ) in the operative management group. Six months after the injury, 83 patients (94%) in the nonoperative management group and 40 patients (48%) in the operative management group had died (eTable 11 and eFigure 4 in Supplement 1). The median (P25-P75) time to death was 7 (5-12) days in the nonoperative management group and 29 (12-62) days in the operative management group

Table 1. Patient Characteristics

Characteristic	Nonoperative management group (n = 88)		Operative management group (n = 84)		Absolute or median difference (95% CI), % <sup>a</sup>	P value
	Total No. of patients with measurement	No. of patients with measurement (%)	Total No. of patients with measurement	No. of patients with measurement (%)		
Age, median (P25-P75), y	88	88 (84-93)	84	88 (85-91)	1.0 (-2.0 to 1.0)	.57
Female sex	88	67 (76)	84	68 (81)	1.0 (-10.8 to 12.9)	.28
Male sex	88	21 (24)	84	16 (19)		
BMI, median (P25-P75)	68	20.4 (18.0-25.2)	77	23.2 (18.4-26.3)	1.0 (-0.3 to 2.6)	.10
Nursing home resident	88	88 (100)	84	84 (100)	0 (-4.4 to 4.2)	>.99
CCI, median (P25-P75)	88	3 (2-5)	84	3 (2-5)	0 (0.0 to 1.0)	.44
≥4		35 (40)		41 (49)	9.0 (-5.7 to 23.2)	.28
Dementia diagnosis	88	83 (94)	84	75 (89)	5.0 (-3.7 to 14.1)	.23
Mobility FAC						
0		6 (7)		5 (6)	1.0 (-7.1 to 9.1)	
1		13 (15)		5 (6)	9.0 (-0.4 to 18.5)	
2	88	28 (32)	84	27 (32)	0 (-13.7 to 31.8)	.20
3		13 (15)		8 (10)	5.0 (-5.2 to 15.1)	
4		38 (45)		28 (32)	13.0 (-1.5 to 26.7)	
5		1 (1)		0	1.0 (-3.5 to 5.9)	
≤2 <sup>b</sup>	88	47 (53)	84	37 (44)	9.0 (-5.8 to 23.3)	.23
Mobility						
Bedbound		0		0	0 (-4.2 to 4.4)	
Bed-chair transfer	88	15 (17)	84	10 (12)	5.0 (-5.8 to 15.6)	.12
Few steps (AR, <10 m)		16 (18)		8 (10)	8.0 (-2.6 to 18.5)	
Mobile (AR, ≥10 m)		57 (65)		66 (78)	1.03 (-0.5 to 25.8)	
Katz ADL score <sup>c</sup>						
0		0		0		
1		0		2 (2)	2.0 (-2.6 to 7.8)	
2		4 (5)		4 (4)	1.0 (-6.3 to 8.4)	
3	84	13 (16)	82	17 (21)	5.0 (-6.9 to 16.8)	.40
4		12 (14)		17 (21)	7.0 (-4.7 to 18.6)	
5		23 (27)		18 (22)	5.0 (-8.1 to 17.8)	
6		32 (38)		24 (29)	9.0 (-5.3 to 22.8)	
ASA physical status class <sup>d</sup>						
II		4 (5)		1 (1)	4.0 (-1.9 to 10.8)	
III	88	53 (60)	84	54 (64)	4.0 (-10.4 to 18.1)	.41
IV		31 (35)		29 (35)	0 (-14.0 to 14.0)	
Prescription drugs, median (P25-P75)	88	6 (4-8)	84	7 (5-9)	1.0 (0.0 to 2.0)	.05
Hemoglobin level, median (P25-P75), mmol/L	74	7.0 (6.8-8.0)	84	7.6 (7.2-8.3)	0.4 (0.1 to 0.7)	.004
Creatinine level, median (P25-P75), μmol/L	73	86 (65-104)	84	86 (65-104)	5.0 (-4.0 to 14.0)	.27

Abbreviations: ADL, activities of daily living; AR, action radius; ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CCI, Charlson Comorbidity Index; FAC, Functional Ambulation Category; P25-P75, 25th and 27th percentile. SI conversion factor: To convert mmol/L to g/L, multiply by 10.0.

<sup>a</sup> Absolute difference applied to female sex, male sex, nursing home resident, CCI ≥4, dementia diagnosis, mobility FAC, mobility, Katz ADL score, and ASA status. Median difference was applied to age, BMI, prescription drugs, hemoglobin level, and creatinine level.

<sup>b</sup> Indicates a person who needs at least (intermittent) manual assistance from 1 person during ambulation (FAC 2) or who has no functional ambulation abilities (FAC 0).

<sup>c</sup> Score range: 0-6, with 0 indicating independence and 6 indicating total dependency.

<sup>d</sup> ASA status ranged from class I to V, with V indicating the highest perioperative risk of death.

( $P < .001$ ). Nonoperative management (odds ratio, 5.3; 95% CI, 3.6-7.8;  $P < .001$ ) and male sex (odds ratio, 1.53; 95% CI, 1.0-2.4;  $P = .05$ ) were independent factors in mortality 6 months after the injury (eTable 12 in Supplement 1).

At the end of the follow-up or after a patient's death, treatment satisfaction according to proxies and health care prac-

tioners was high in both groups, with a median numeric rating scale score of 8 (eTable 13 in Supplement 1). Both proxies and health care practitioners of the patients who died during the study were more satisfied with the choice of nonoperative management than operative management (median [P25-P75] satisfaction, proxies: 8 [8-9] vs 8 [7-8] [ $P = .001$ ]; health

Table 2. Fracture Characteristics and Management

Characteristic	Nonoperative management group (n = 88)		Operative management group (n = 84)		Absolute or median difference (95% CI), % <sup>a</sup>	P value
	Total No. of patients with measurement	No. of patients with measurement (%)	Total No. of patients with measurement	No. of patients with measurement (%)		
Fracture type						
Femoral neck	54	54 (61)	45	45 (54)	7.0 (-7.6 to 12.3)	.30
Garden 1-2	54	13 (24)	45	7 (16)	8.0 (-8.3 to 23.1)	.33
Garden 3-4	54	41 (76)	45	38 (84)	8.0 (-8.3 to 23.1)	NA
Pertrochanteric	34	34 (39)	39	39 (46)	7.0 (-7.6 to 21.3)	NA
AO 31-A1	34	11 (32)	39	14 (36)	4.0 (-17.3 to 24.5)	.94
AO 31-A2	34	19 (56)	39	21 (54)	2.0 (-20.0 to 23.6)	NA
AO 31-A3	34	4 (12)	39	4 (10)	2.0 (-13.1 to 18.1)	NA
Other injuries	88	9 (10)	84	9 (11)	1.0 (-8.5 to 10.7)	>.99
Attendance for SDM <sup>b</sup>						
Proxy	87	85 (98)	77	71 (92)	6.0 (-1.0 to 14.4)	.10
Geriatrics	86	57 (66)	77	42 (55)	11.0 (-3.9 to 25.4)	.13
Trauma surgery	88	56 (66)	84	45 (60)	6.0 (-8.3 to 20.0)	.44
Elderly care	87	46 (53)	77	18 (23)	30.0 (15.2 to 42.9)	<.001
Orthopedic surgery	83	20 (24)	74	23 (31)	7.0 (-6.9 to 20.8)	.33
Emergency medicine	87	3 (3)	78	4 (5)	2.0 (-4.8 to 9.6)	.71
Anesthesiology	87	1 (1)	78	3 (4)	3.0 (-2.6 to 10.0)	.35
Cardiology	87	1 (1)	78	1 (1)	0 (-5.1 to 5.5)	>.99
Palliative care	87	1 (1)	78	0	1.0 (-3.8 to 6.0)	>.99
Hospital admission	88	49 (56)	84	84 (100)	44.0 (33.2 to 54.4)	<.001
Time to surgery, h						
<24	NA	NA	84	43 (51)	NA	NA
24-48	NA	NA	84	32 (38)	NA	NA
>48	NA	NA	84	9 (11)	NA	NA
Anesthesia type						
General	NA	NA	84	55 (66)	NA	NA
Spinal	NA	NA	84	29 (35)	NA	NA
Lead surgeon						
Surgeon	NA	NA	84	64 (78)	NA	NA
Resident	NA	NA	84	18 (22)	NA	NA
Implant						
Osteosynthesis	NA	NA	84	7 (8)	NA	NA
Intramedullary	NA	NA	84	37 (44)	NA	NA
Hemiarthroplasty	NA	NA	84	40 (48)	NA	NA
Femoral nerve block	88	14 (16)	84	18 (21)	5.0 (-6.6 to 16.7)	.35
PENG block	88	1 (1)	84	0	1.0 (-3.5 to 5.9)	>.99
Hospital length of stay, median (P25-P75), d	49	2 (2-3)	84	6 (4-7)	3.0 (2.0 to 4.0)	<.001
Outpatient follow-up	88	2 (2)	84	13 (16)	15.0 (5.6 to 23.4)	<.001
Follow-up, median (P25-P75), d	88	8 (5-14)	84	176 (31-198)	131.0 (50 to 169)	<.001

Abbreviations: NA, not applicable; P25-P75, 25th and 75th percentile; PENG, pericapsular nerve group; SDM, shared decision-making.

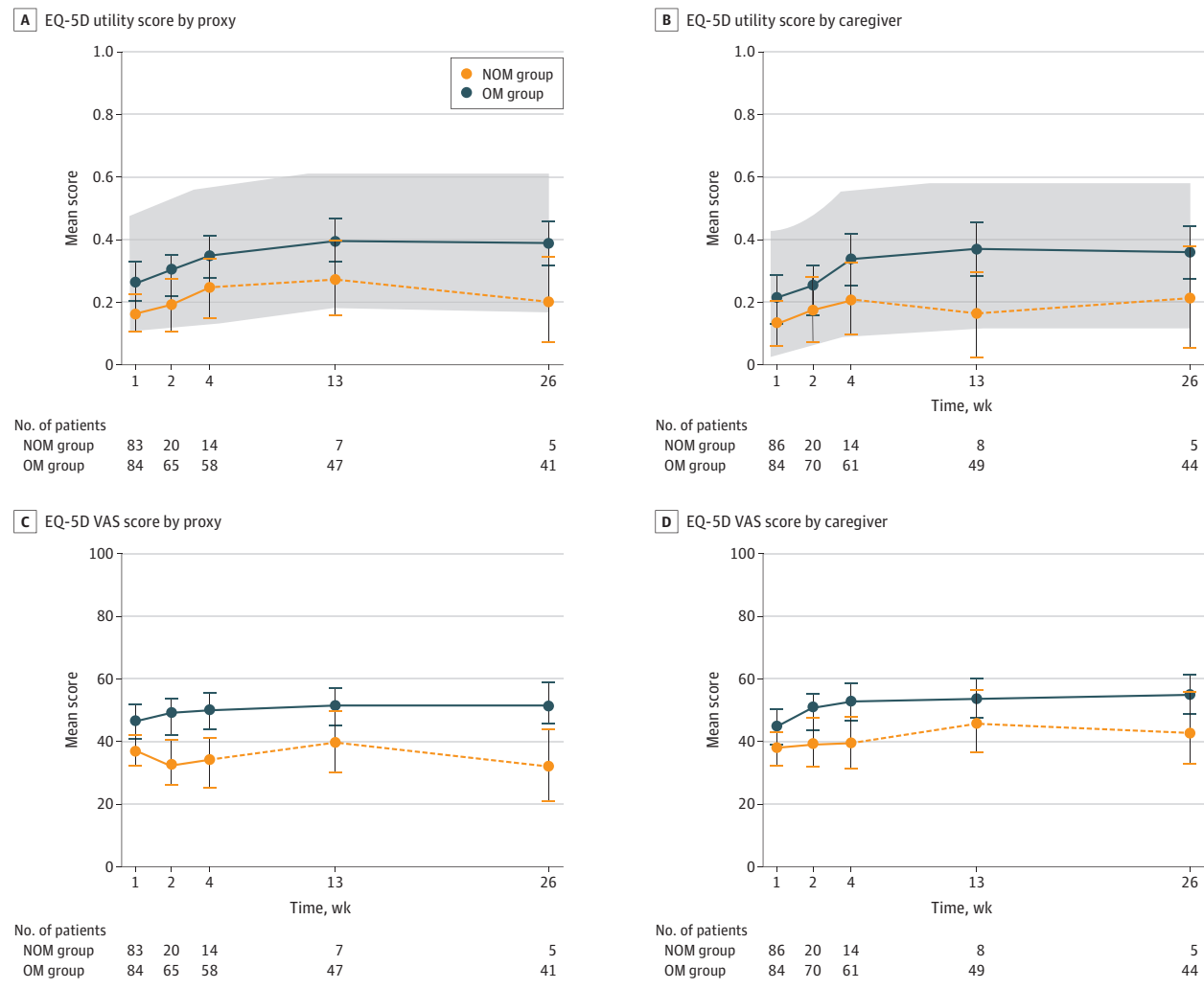
<sup>a</sup> Absolute difference applied to all variables except for hospital length of stay and follow-up (median difference).

<sup>b</sup> Attendance refers to a representative from a hospital department involved in SDM.

care practitioners: 8 [8-9] vs 7 [5-8] [ $P < .001$ ]). There was no statistically significant difference in treatment satisfaction between the treatment groups for patients who survived beyond 30 days after the injury. The dying process in both groups was judged as humane (eTable 13 in Supplement 1). The

quality of dying was rated as good-almost perfect by 26 proxies (51%) in the nonoperative management group, with only 2 proxies (4%) rating the process as terrible-poor. The quality of dying in the operative management group was scored as intermediate by most proxies (13 [62%]).

Figure 2. EuroQoL-5 Dimension 5 Level (EQ-5D) Utility Score and Visual Analog Scale (VAS) Score for Patients in the Nonoperative Management (NOM) and Operative Management (OM) Groups, According to Proxies and Caregivers



The gray area indicates the 0.15 noninferiority limit of the 95% CI of the utility score in the OM group (the reference group). The dotted line indicates the unadjusted measurements for fewer than 10 patients. Circles represent the

mean score and the error bars indicate the 95% CI. The numbers of patients indicate those for whom EQ-5D utility and VAS scores could be ascertained at different follow-up times.

## Discussion

This study showed that, following SDM in a group of institutionalized frail patients with limited life expectancy who were hospitalized with a proximal femoral fracture, nonoperative management of proximal femoral fractures was a viable treatment option in properly selected patients and not inferior to operative management in terms of HRQoL. Although the short-term mortality in the nonoperative management group was higher than in the operative management group, there was no loss of QoL and HRQoL, and there was high treatment satisfaction and humane quality of dying. The high mortality rate was as expected given that we hypothesized that the frailest patients would opt for nonoperative management and that the explicit choice for

nonoperative management would most likely result in an earlier palliative care approach compared with patients who opted for operative management.

When interpreting the results, one should consider that the HRQoL and life expectancy of nursing home residents are low, even without the additional event of a proximal femoral fracture. A previous study reported a mean (SD) EQ-5D utility score of 0.48 (0.09) for the general nursing home population in the Netherlands.<sup>31</sup> A proximal femoral fracture further diminishes HRQoL. Among nursing home residents who were surgically treated for their injury, the mean (SD) EQ-5D utility scores at 3 months after the injury decreased from 0.6 (0.2) to 0.35 (0.24) in a Canadian study and 0.43 (0.34) to 0.39 (0.35) in a German study.<sup>3,32</sup> The EQ-5D utility scores in the current study were even lower, most likely because of the added criteria of frailty. To our knowledge, no previous study has



Table 3. Adverse Events, Severity, and Consequent Interventions

Characteristic	No. (%)	
	Nonoperative management group	Operative management group
All patients	88 (100)	84 (100)
AEs		
Total No.	67 (100)	167 (100)
Patients with		
Any AE	46 (52)	68 (81)
Multiple ( $\geq 2$ ) AEs	16 (18)	47 (56)
Time to AE, d (P25-P75)	6 (3-16)	11 (5-32)
General AE		
Pressure ulcer	31 (35)	35 (42)
Multiple pressure ulcers	4 (5)	7 (8)
Delirium	10 (11)	27 (32)
Multiple deliria	0	4 (5)
Pneumonia	5 (6)	20 (24)
Multiple pneumonias	0	2 (2)
UTI	5 (6)	16 (19)
Multiple UTIs	0	4 (5)
Severe dehydration	1 (1)	8 (10)
Recurrent severe hydration	0	1 (1)
Retention bladder	0	8 (10)
Fracture after recurrent fall	2 (2)	6 (7)
Sepsis of unknown origin	0	2 (2)
CVA	1 (1)	1 (1)
COVID-19 pneumonia	1 (1)	1 (1)
COPD exacerbation	1 (1)	0
Depression	1 (1)	0
Phlebitis	0	1 (1)
Morphine intoxication	1 (1)	0
Oral fungal infection	0	1 (1)
Cardiovascular AE		
Heart failure	3 (3)	7 (8)
Arrhythmia	0	2 (2)
Myocardial infarction	0	1 (1)
Surgery/fracture-related AE		
Deep wound infection	NA	4 (5)
Hemiarthroplasty dislocation	NA	2 (2)
Superficial wound infection	NA	1 (1)
Progressive pain <sup>a</sup>	0	2 (2)
Rebleed	NA	1 (1)
Osteosynthesis malposition	NA	1 (1)
Peroperative respiratory failure	NA	1 (1)
Therapy refractive pain	0	1 (1)
Flexion contracture	1 (1)	0
Clavien-Dindo grade		
II	17 (25)	72 (43)
IIIa	1 (2)	3 (2)
IIIb	0	6 (4)
IV	0	1 (1)
V	13 (19)	27 (16)

(continued)

Table 3. Adverse Events, Severity, and Consequent Interventions (continued)

Characteristic	No. (%)	
	Nonoperative management group	Operative management group
Interventions AE		
Pharmacological	28 (42)	100 (60)
Nonpharmacological	9 (13)	13 (8)
Pharmacological and nonpharmacological	13 (19)	30 (18)
Invasive	1 (2)	10 (6)
Expectative, no intervention	16 (24)	14 (8)
Reoperation	NA	5 (6)
Residence when diagnosed		
Hospital	12 (18)	64 (38)
Nursing home	55 (82)	103 (62)
Other undesirable events		
Physical fixation	2 (2)	12 (14)
Antipsychotic drug use	29 (33)	48 (57)
Sedative drug use	65 (75)	38 (45)
Antidepressant drug use	1 (1)	1 (1)
Antibiotic drug use	7 (8)	33 (39)
Blood transfusion	2 (2)	24 (29)
Readmission ED	0	12 (14)
Reoperation	NA	5 (6)

Abbreviations: AE, adverse event; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; ED, emergency department; NA, not applicable; P25-P75, 25th and 75th percentile; UTI, urinary tract infection.

<sup>a</sup> Patients who initially opted for nonoperative management but eventually underwent surgery because of progressive pain but were grouped in the operative management group because of per-protocol analyses.

reported on the HRQoL in this specific group of patients who received nonoperative treatment.

In addition, the mean 1-year mortality after admission to a nursing home is approximately 30% for all age groups and 40% for those 90 years or older.<sup>33</sup> Mortality for patients with advanced dementia was even higher at 24% to 37% after 6 months of injury.<sup>33,34</sup> These findings further strengthen the assumption that a proximal femoral fracture in frail older patients is merely a symptom of the frail health status and thus often the start of an inevitable cascade breakdown at the end of life regardless of treatment used.

With regard to functional outcomes, the postinjury outcome in this study population was generally poor. Even in the operative management group, only some patients returned to their preinjury level of independence or mobility, and AEs or distressing symptoms were almost always observed. However, satisfactory outcomes after operative management can be achieved, and operative management remains a good treatment option for properly selected patients. Therefore, both operative and nonoperative management should be openly discussed. However, no selection criteria for operative management in this patient population could be identified.

The study results do suggest that pain in the nonoperative management group was undertreated and was a factor

in end-of-life care that should be improved. This finding is consistent with previous study results.<sup>35</sup>

Decision-making on the treatment of proximal femoral fracture in frail patients in the final phase of life not only poses challenges and ethical dilemmas but also requires the consideration of many factors. Surgery in these patients is a decisive fix for an isolated problem (the fracture itself), but it is not an intervention that resolves the complex, multifaceted implications of aging and frailty and is not always beneficial to the patient.<sup>11</sup> Therefore, the viability and consideration of a treatment option at the end of life require a multifaceted, comprehensive assessment of all aspects of care and not merely the stand-alone outcomes. To our knowledge, this study is the first to apply this multifaceted approach to both nonoperative and operative management of proximal femoral fractures.

Research suggests that approximately 60% of the proxies of nursing home residents feel that only treatments that promote comfort would best align with their goals of care, which has often meant foregoing life-sustaining treatments.<sup>36</sup> Nonoperative management can align with the goals of care in this study population, which was indirectly reflected in the high proportion of patients or proxies who opted for nonoperative management and the high satisfaction with the chosen treatment. Properly discussing treatment options with frail patients who sustain a proximal femoral fracture may presumably be associated with higher rates of nonoperative management. This idea was demonstrated in the study by van der Zwaard et al,<sup>37</sup> which found that, by using a comprehensive geriatric assessment followed by an SDM process, patients were 3.6 times more likely to opt for nonoperative management. Furthermore, this idea is reflected in the current study in which elder care physicians were found to be more often involved in the SDM process in patients who opted for nonoperative management. However, this involvement could have been owing to the frailer patients featuring in the nonoperative management group.

We believe this study presents a unique, evidence-based insight into the true outcomes of nonoperative and operative management in this specific frail patient population. Treatment decisions require careful consideration and should not be made hastily. Ultimately, an SDM process that is based on the expectations and goals of care of frail patients with a proximal femoral fracture and at the end of life may prevent surgical overtreatment, but careful patient selection remains pivotal. We believe the results of this study can be used to optimize SDM, to aid realistic expectation management, and to support advance care planning in long-term care facilities for this selected group of patients with proximal femoral fracture.

### Limitations

This study has some limitations. First, selection bias is an important factor to consider because patients who opt for

nonoperative management may be in worse preinjury condition that may not have been taken into account. The levels of cognitive function and preinjury HRQoL in this patient population were not explored and should be regarded as unmeasured bias because they could play a major role in the treatment decision. Furthermore, type 2 errors in preinjury characteristics could be present because of a relatively low sample size, as was reflected by the absolute differences between both groups. Only a randomized clinical trial would have avoided selection bias through the SDM process but was considered unfeasible and unethical. Second, no preoperative HRQoL questionnaires were administered because of the expected recall bias with the hypothesis that prefracture HRQoL would be overestimated, especially in the nonoperative management group.<sup>38</sup> Although this cohort was the largest to date given the number of patients decreasing over time because of mortality, the results of the linear mixed-effects regression model should be interpreted with caution.

Third, no studies have previously evaluated the proxy- and caregiver-reported outcome measures in this population with such a high short-term mortality. However, the results seem valid, not only because of the minimal differences in scores between the proxies and caregivers but also because of the consistency of the results across all instruments. Furthermore, because, to our knowledge, no previous studies have evaluated the EQ-5D utility scores in this population of patients who received nonoperative management, the minimal important change is unknown; therefore, the noninferiority limit was based on 0.5 SD.<sup>30</sup> Fourth, given the even-higher-than-expected mortality rate in the nonoperative management group, the validity of the results comparing nonoperative management with operative management was reduced 30 days after the injury. However, the high early mortality rate in the nonoperative management group suggests that, together, health care practitioners or caregivers and patients or proxies can adequately select patients via the SDM process who are good candidates for nonoperative management and for whom this treatment would achieve a high degree of satisfaction.

### Conclusions

This cohort study found that, following the SDM process, nonoperative management of proximal femoral fractures is a viable treatment option for institutionalized frail patients with limited life expectancy. A return to preinjury levels of independence or mobility was achieved in some patients who were surgically treated, and a postoperative period without AEs was rare. Surgery in this specific patient population should not be a foregone conclusion.

#### ARTICLE INFORMATION

**Accepted for Publication:** December 19, 2021.

**Published Online:** March 2, 2022.  
doi:10.1001/jamasurg.2022.0089

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**Conflict of Interest Disclosures:** Dr Van Lieshout reported being a scientific manager of the Osteosynthesis and Trauma Care Foundation research program during the conduct of the study. Dr Joosse reported receiving personal fees from Stryker outside the submitted work. No other disclosures were reported.

**Funding/Support:** This study was funded by grant 843004120 from the Netherlands Organization for Health Research and Development and grant 2019-PJKP from the Osteosynthesis and Trauma Care Foundation.

**Role of the Funder/Sponsor:** The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Group Information:** The FRAIL-HIP Study Group members are listed in [Supplement 2](#).

**Additional Contributions:** We acknowledge the support of the following societies: Dutch Surgical Society, Dutch Association for Trauma Surgery, Dutch Orthopaedic Association, Dutch Association for Orthopaedic Trauma Surgery, Dutch Association for Clinical Geriatrics, Association of Elderly Care Physicians, and Dutch Patient Federation. We also acknowledge the staff and physicians of the participating nursing homes for their collaboration and assistance with the data curation. We thank Peter van Gelder, MSc, Communication Matters, for proofreading the manuscript. These individuals

received no additional compensation, outside of their usual salary, for their contributions.

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### Invited Commentary

## A Holistic Approach for Treating Fragility Fractures in Older Adults

Kevin C. Chung, MD, MS

**Proximal femoral fractures** are common in older adults, particularly those who are frail and have osteoporosis. The multicenter cohort study by Loggers et al<sup>1</sup> compared operative and nonoperative treatments for proximal femoral fractures in frail older patients who were institutionalized in the Netherlands. The study found that, for those with limited life expectancy, nonoperative treatment was an ethical and compassionate option.

As often stated, “good surgeons know how to operate, better ones when to operate, and the best when not to operate.”<sup>2</sup> Just because a patient has a fracture does not mean that operative fixation of the fracture is necessary. It is of utmost importance to examine the patient, to consider that patient's functional status and wishes (as well as the family's wishes), and to inform the patient and family of the complications and outcomes associated with surgical and nonsurgical treatments.

The scenario of proximal femoral fracture is analogous to that of distal radius fracture from osteoporosis in older individuals. Previous studies involving 24 participating centers have shown that a personalized approach is needed, such as considering the patients' functional status and assessing their physiological status rather than judging treatment options on the basis of age and fracture patterns.<sup>3,4</sup> Those who are frail can be treated with nonoperative means. Although a sophisticated plating system is available that can restore the anatomic alignment of the fractured bone, nonoperative treatment is a suitable consideration, assuming that the patient understands the consequences and there is a predictable fracture displacement leading to malunion and wrist deformity. An informed patient who participates in the shared decision-making process, as advocated in this study by Loggers et al,<sup>1</sup> equates to a satisfied patient.

In the WRIST (Wrist and Radius Injury Surgical Trial) randomized clinical trial, the functional status of the patient, which was assessed using the Rapid Assessment of Physical Activity questionnaire, served as a proxy for the patient's physiological status.<sup>3,4</sup> Studies on older adults often apply chronological age in the regression analysis, which is imprecise because a 70-year-old person may have minimal comorbid conditions and functions more like a 50-year-old person. The opposite may be true when a 60-year-old person may have an infirmity that is associated with obesity, diabetes, and/or an assortment of other ailments. Therefore, there is a similarity between proximal femoral fracture and distal radius fracture. Both are related to osteoporotic fractures. Many of these fractures are associated with a fragile patient falling from a standing height. The physiological status of older adults who are institutionalized is even more dire than that of older adults who live independently and are ambulatory.

Because the prospective cohort study by Loggers et al<sup>1</sup> involved engaging caregivers and the patient and/or the family members in shared decision-making, selection bias was definitely in play because those who chose nonoperative treatments were at the end of their life span; the 30-day mortality was 83% in the nonoperative management group vs 25% in the operative management group.<sup>1</sup> The high mortality rate in the nonoperative management group revealed that the terminally ill patients opted not to undergo surgery. Even for those in the operative management group, only 29% of the previously mobile patients regained mobility.<sup>1</sup> Most important was that the pain from the fracture was well managed, particularly in patients in the nonoperative management group, who ought to require a fair amount of morphine to overcome the discomfort from fracture motion. Because of the shared decision-making process and clear informed consent by the



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