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Prospective study of femoral neck system fixation combined with enhanced recovery after surgery for the treatment of unstable intracapsular femoral neck fracture

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Prospective study of femoral neck system (FNS) vs. cannulated compression screw (CCS) fixation has not been appropriately reported. We prospectively investigate the efficacy of FNS vs. CCS fixation combined with ERAS in the treatment of unstable intracapsular FNF. 70 consecutive patients with unstable intracapsular femoral neck fracture met the inclusion criteria were randomly divided into FNS group and CCS group (each 35 cases). ERAS was applied in both groups. The perioperative period and follow-up results were compared. The operation time, fluoroscopy time, fracture reduction quality and follow-up time were not significantly different between the two groups ($P > 0.05$). The blood loss in the FNS group was significantly more than that in CCS group whereas the time to start weight-bearing, fracture healing time, internal fixation failure in the FNS group were significantly less than those in the CCS group ($P < 0.05$). The neck shortening and revision surgery of the FNS group showed a trend of superiority to CCS group but the difference was not significantly different ($P > 0.05$). The AVN in the two groups was similar. At the last follow-up, the Harris hip score in the FNS group was higher than that in the CCS group ($P < 0.05$). Hence, FNS fixation with ERAS for FNF can provide earlier weight-bearing, fewer complications related to the implant, faster healing and better functional recovery than CCS fixation with ERAS, which is consistent with the better biomechanical properties of FNS.

Keywords: Femoral neck fracture, internal fixation, femoral neck system, cannulated compression screw, ERAS, prospective.

INTRODUCTION

Femoral neck fracture (FNF) is a common fracture in orthopedic practice and result in significant morbidity and mortality. For patients of FNF with physiological age < 70 years, CRIF or ORIF is still the first choice[1,2]. Anatomical reduction and effective fixation are essential for obtaining good prognosis and function. However, there is no consensus on the best internal fixation device. Cannulated compression screw (CCS) and dynamic hip screw (DHS) are the most widely used methods in clinical practice. However, the incidence of fixation failure after CCS fixation for unstable FNF was 15% - 28%, followed by 12% - 15% of nonunion, and there was defect of inability to weight-bear in the early postoperative period; DHS cannot be minimally invasive implanted and has poor anti- rotation stability[3-8].

Recently, the lower limb expert group of AO Technical Advisory Committee of International Association tion of Internal Fixation developed a new minimally invasive implant for dynamic fixation of FNF, called the femoral neck system (FNS)[9,10]. Biomechanical experiment and preliminary results showed that the stability of FNS was better than that of CCS[9-12]. However, nearly all clinical studies were retrospectively ones, i.e., prospective study of FNS vs. CCS fixation has not been appropriately reported. Enhanced recovery after surgery (ERAS) pathways are now implemented worldwide with strong evidence that that adhering to this protocol can reduce postoperative complications, costs, and hospital stay, as well as promote recovery[13,14]. Accordingly, the objective of this study was to prospectively investigate the efficacy of FNS vs. CCS fixation combined with ERAS in the treatment of unstable intracapsular FNF.

MATERIALS AND METHODS

This single-centre, prospective cohort study conducted between April 2019 to December 2021 at the

Orthopaedic Department in Wuxi Ninth People's Hospital, China, was approved by the ethics committee of our hospital (WXSJY-LY-2019–0047) and performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

Inclusion criteria: (1) 17 < age < 70 years old; (2) fresh FNF; (3) subcapital and transcervical types of FNF; and (4) Pauwells type III. Exclusion criteria included: (1) incomplete fractures, (2) via open reduction and internal fixation, (3) history of hip disease, (4) old fractures or pathologic fractures, (5) bilateral fractures, (6) hormone use, (7) severe osteoporosis (≤ Singh index level III); and (8) follow-up time ≤ 12 months. The protocol was approved by the Medical Ethics Committee of our hospital.

The main complications including nonunion, nonunion and avascularnecrosis (AVN) of the femoral head, internal fixation failure and severe neck shortening were taken as the main observation index. According to the literature reports, the incidence of main complications of CCS fixation was about 35%. Assuming that the complication rate of FNS fixation fractures is about 15%. Setting α= 0.05% and power = 80%, the ratio of cases in the two groups is 1:1. According to the formula for the number of samples in the randomized controlled study, 70 patients are required for the study, i.e., 35 each group.

Among the initially enrolled consecutive 74 patients, we excluded 4 patients from the study. Finally, 70 patients were enrolled in this study and were randomly divided into 2 groups (35 each): FNS fixation (FNS group) and CCS fixation (CCS group). Randomization was performed with a random table of numbers (odd: FNS, even: CCS). ERAS was applied in both groups. Both patients and researchers, evaluating clinical outcome, were blinded to the allocated treatment. The demographic characteristics and clinical profiles including age, sex, fracture type and location, course (time from injury to surgery), Singh index, fracture side and co-existing diseases were recorded. There was no significant difference in preoperative general information between the two groups ($P > 0.05$) as shown in Table 1.

Spinal epidural anaesthesia or general anaesthesia was administered to the patient. All surgeries were performed by an associate chief physician and an assistant. The patient was placed in the supine position on an orthopedic traction table. For displaced fractures, satisfactory reduction can usually be achieved via longitudinal traction and internal rotation. After the C-arm X-ray machine confirmed that the fracture was in an adequate reduction position, conventional sterilization was performed.

CCS group Three Kirschner wires forming an inverted triangle configuration, which were positioned approximately 5 mm beneath the surface of the femoral head cartilage, were inserted into the femoral head. After ensuring the proper location, 7.3-mm cannulated cancellous screws were inserted along the guide wires.

Table I. — Comparison of patients' preoperative data between the two groups

Variables	FNS (n=35)	CCS(n=35)	Statistics (t/c^2)	*P*
Age (yrs)	47.6±13.9	50.6±11.7	0.985	0.328
Gender	16	18	0.229	0.632
Male	19	17		
Female	4.5 ± 1.5	4.7± 1.4		
Course(d)			0.408	0.685
Fracture type(Pauwels)	2	3	0.229	0.892
I	18	17		
II	15	15		
III				
Fracture location	9	11	0.295	0863
Infracephalic	22	20		
Cervical	4	4		
Basal				
Singh index	6	5	0.245	0.885
IV	9	8		
V	20	22		
VI				
Fracture side	16	17	0.057	0.811
Left	19	18		
Right	10	8		
Coexisting disease			0.299	0.584

Abbreviations: FNS, femoral neck system. CSS, cannulated compression screw.

FNS group A 2.5-mm guide pin was placed in the anterior superior part of the femoral neck to maintain fracture reduction. A 130° guide was inserted along the femoral neck. Under C-arm fluoroscopy, the needle insertion point and angle were adjusted by adjusting the guide so that the central guide was in the centre of the femoral neck in the anteroposterior and lateral positions, 5 mm from the subchondral bone. After reaming along the central guide, the bolt-and-plate assembly was inserted into the femoral head. Subsequently, the anti-rotation screw and locking screw were positioned in the proper location. Finally, the guide- wire and anti rotation Kirschner wire were taken out after the internal fixation position was confirmed by anteroposterior and lateral fluoroscopy.

The team composed of surgeons, anesthesiologists, nurses and rehabilitation therapists implements ERAS pathways, including perioperative psychological nursing, diet management and nutritional support, spinal anesthesia, intraoperative temperature maintenance, postoperative pain management and complication prevention nursing, early postoperative rehabilitation and discharge guidance. Diet management and nutritional support include preoperative 6 h fasting, water or carbohydrates were given 2 hours before operation, and enteral nutritional support was given gradually 6-12 hours after operation.

In the CCS group, patients were encouraged to perform all rehabilitation activities in bed except sitting. The intensity and scope of rehabilitation activities gradually increased over time. Depending the severity of fracture and quality of bone condition, patient began to get out off bed with crutches at the postoperative 1 - 6th week after operation. Full weight-bearing taken when fracture is clinically healed[15].

In the FNS group, patients were encouraged to perform all rehabilitation activities in bed except sitting on the postoperative 3th day. Depending the severity of fracture and quality of bone condition, patient began to get out off bed with crutches at the postoperative 1 - 2th week after operation. Full weight-bearing taken when fracture is clinically healed.

After ruling out blood disorders and or bleeding tendency preoperatively, low molecular weight heparin sodium (1 mg/kg body weight, once a day) was routinely used for anticoagulation. Antibiotics were administered 0.5 h before the operation, intraoperative and postoperative 2 days. After anesthesia and awakening, the patient was be instructed to actively exercise isometric contraction of the lower extremity muscles, active ankle pump exercises, and active/ assisted active hip and knee flexion exercises. Patients with osteoporosis were treated with calcium tablets and diphosphate. Partial weight-bearing training was performed according to the recovery of the affected limb. Approximately 3 months after the operation, walking with a load was permitted according to bone healing. X-ray examination was performed within 3 days after the operation.

All patients were followed-up monthly to assess fracture healing and then every 3 months after fracture healing. Patients were followed-up every 6 months after 1 year of fracture healing, the maximum follow-up time is 36 months. Each patient was evaluated clinically and radiologically. If the patient had hip pain on the surgical side during follow-up, computed tomography (CT) or magnetic resonance imaging (MRI) of the hip joint was performed to confirm the presence of fracture nonunion or femoral head necrosis.

The following data were collected: operation time, blood loss, fluoroscopy time, frature reduction quality, time to start with weight bearing, neck shortening, internal fixation failure, difficult healing, AVN, function and revision surgery. We used the Mercuriali et al.[16] method to calculate the volume of blood loss. The postoperative fracture reduction quality was evaluated based on standard AP and lateral radiographs of the femoral neck of the affected side using the Garden alignment index described by Haidukewych et al.[17]. According to Zlowodzki's method, the neck shortening was diagnosed and divided into mild (5-10 mm), moderate (10-20 mm) and severe (> 20 mm)[18]. Internal fixation failure was defined as obvious displacement or hip varus at the fracture site (displacement parallel to the fracture line more than 2 mm, or angle more than 10°)[15]. Difficult healing includes delayed healing and nonunion; Nonunion was defined as persistence of a fracture line in more than 8 months after surgery. Assessment for AVN of the femoral head mainly refers to the standard of Slobogean et al.[19]. We used the Harris hip score (HHS) to evaluate hip joint function at the last follow-up: a full score of 100 points, ≥90 points as excellent, 80-89 points as good, 70-79 points as medium, and <70 points as poor[20]. Patient satisfaction: 0 indicates dissatisfaction, 1 indicates satisfaction, 2 indicates relatively satisfied, and 3 indicates very satisfied. Revision surgery includes bone grafting and arthroplasty.

SPSS version 19.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. For comparison between two groups, Student's t-test for continuous variables with normal distribution and Mann - Whitney U test was used for continuous variables with non normal distribution. For categorical variables, the chi-

Table II. — Comparison of perioperative period results between the two groups

Variables	FNS(n=35)	CCS(n=35)	Statistics (t/c²)	*P*
Quality of reduction			0.094	0.759
excellent	28	29		
accepted	7	6		
Operation time(Min)	67.33±8.91	63.76±8.83	0.245	0.301
Blood loss(ml)	72.51±9.29	31.36±3.29	12.641	<0.01
Fluoroscopy time (Sec)	89.12±7.11	92.24±8.02	0.147	0.562

Abbreviations: FNS, femoral neck system. CSS, cannulated compression screw.

Table III. — Comparison of follow-up results between the two groups

Variables	FNS(n=35)	CCS(n=35)	Statistics (t/c²)	*P*
Follow-up period(Mon)	18.2±3.1	19.9±3.2	1.460	0.149
Time to weight bearing(d)	10.3±0.5	31.7±10.3	11.590	<0.001
Healing time(Mon)	5.1 ± 1.0	5.9±1.4	2.233	0.029
Neck shortening	12	16	0.952	0.329
Degree of neck shortening			3.681	0.159
5-10mm	8	7		
10-20mm	4	5		
>20mm	0	4		
Fixation failure	1	6	3.968	0.046
Difficult healing	2	8	4.200	0.040
AVN	4	4	0	1.000
Revision surgery	5	10	2.121	0.145
HHS	89.20±4.39	86.30±6.21	4.574	0.032

Abbreviations: FNS, femoral neck system. CSS, cannulated compression screw. HHS, Harris hip score. AVN, avascular necrosis.

Figure 1.—A 55-year-old female patient with left FNF fixed with FNS. A. Preoperative CT showing left FNF, Pauwels III. B,C. X-ray showing excellent reduction quality and fracture healed at postoperative 5 months.

square test or Fisher's exact test was used. Statistical significance was defined by a p value of less than 0.05.

RESULTS

All the operations were smooth without incision infection. The operation time, fluoroscopy time and fracture reduction quality were not significantly different between the two groups (*P* > 0.05). However, the blood loss in the FNS group was more than that in CCS group (*P* < 0.05). The perioperative period results are showed in Table II. All patients were followed up for 13-36 months with an average of 19.0 months, the follow-up time was not significant between the two groups (*P* > 0.05). The time to start with weight bearing, healing time, difficult healing, internal fixation failure in the FNS group were significantly less than those in the CCS group (*P* < 0.05), while the neck shortening and revision surgery in the FNS group showed a trend of superiority to those in the CCS group but the difference was not significant (*P* > 0.05). The AVN in the two groups was similar (*P* > 0.05). At the last follow-up, the HHS in the FNS group was significantly higher than that in the CCS group (*P* < 0.05). The follow-up results are shown in Table III. Typical cases are showed in Figs. 1-2.

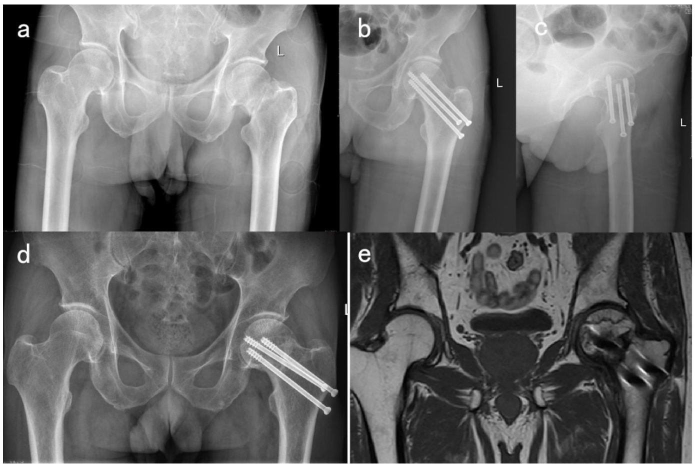

Figure 2.—A 65-year-old male left FNF fixed with CCS. A. Preoperative X-ray showing left FNF, Pauwels III. B,C. X-ray showing excellent reduction quality at postoperative 1 week. D. X-ray showing shorting healing of the fracture and screw-out at postoperative 5 months. E. MRI showing AVN at postoperative 1.5 years.

DISCUSSION

The ideal internal fixator for FNF should have reliable stability of anti-compression, anti-shear and anti-rotation, as well as sliding compression ability. Reliable stability is conducive to early postoperative rehabilitation and weight-bearing, while sliding compression is conducive to fracture healing[12,20-22]. Due to the lack of reliable connection between screw and the lateral femoral cortex, CCS has weak anti-pull-out force and anti-compressive or anti-bending force, especially in patients with unstable type of fracture and osteoporosis, the incidence of internal fixation failure including screw-out, screw loosening and coxa vara is high[2,3,20], which affects fracture healing and functional recovery of patients. Therefore, some scholars suggest CCS fixation enhanced with reconstruction plate for unstable FNF. However, implantation of reconstruction plate has great surgical damage[23]. Through the collection between the lateral plate and the proximal femur, the force of the screw rod and anti rotation nail suffered is transferred to the subtrochanteric cortical bone for fixation, FNS has strong anti-compression and anti-bending force; the screw rod and anti -rotation nail cross fixed in the femoral neck form a whole, FNS has good anti - rotation stability[9,11]; furthermore, the connection between screw rod and plate has a sliding compression distance of 2 cm. Therefore, FNS has better mechanical properties[9,10]. Stoffel et al.[9] made Pauwells type III femoral neck fracture model for mechanical experimental study, and compared the mechanical characteristics of FNS, DHS, hip dynamic blade screw and CCS. The end point of the experiment was the shortening of the femoral head to 5 mm under cyclic load of the femoral head. The results showed that FNS has similar anti-compression and anti-bending stability with DHS and hip dynamic blade screw ($P > 0.05$), all of which were stronger than that of CCS ($P < 0.05$). In addition, the bolt and anti-rotation screw of FNS are distributed in a fan-shaped pattern, which helps to prevent excessive shortening of the neck in theory.

Due to its better biomechanical properties, FNS has the following advantages in terms of clinical efficacy: (1) shorter time to start with weight-bearing; (2) faster healing time; (3) fewer complications related to the implant (screw-out, internal fixation failure). In the FNS group, only one case of internal fixation failure (hip varus) occurred, which was in a patient with osteoporosis and was due to excessive movement leading to screw-out. Therefore, in patients with osteoporosis, the time to start weight-bearing should be postponed and the weight-bearing timing should be limited according to the degree of osteoporosis; (4) better functionary recovery due to earlier rehabilitation and less overall complications of FNS; (5) less neck shortening and revision surgery. Tang Y et al.[12] reported that the femoral neck shortening was significantly less in the FNS group than that in the CCS group ($P < 0.05$). In the study, the neck shortening and revision surgery in the FNS were better than those in the CCS group, but the difference was not significant, which may be related to smaller sample size and bias.

Our study results were similar to the retrospective studies[12,26]. Tang Y et al.[12] reported 47 patients of FNF treated with FNS and 45 patients of FNF treated with

CCS, follow-up ranged from 14 to 24 months, in the FNS group, the fracture healing time was significantly shorter, the femoral neck shortening and HHS at the last follow-up were significantly better than those in the ICCS group ($P < 0.05$).

In this study, the AVN of FNS and CSS accounted for 11.4% each, which is similar to most studies[10-12,22-25]. According to existing research, AVN is a special complication caused by head blood supply disorder and mainly related to the degree of fracture injury, type of fracture, reduction timing, but not to the method of internal fixation, so there was no difference in AVN between the two groups[22,23,26,27].

Limitations of this study

This is a single center study. The number of cases is relatively small and the follow-up time is not long. Therefore, the results of this study require further validation from multiple centers and more cases.

CONCLUSION

FNS fixation with ERAS for FNF can provide earlier weight-bearing, fewer complications related to the implant, faster healing and better functional recovery than CCS fixation with ERAS, which is consistent with the better biomechanical properties of FNS.

Abbreviations: **FNF**: Femoral neck fracture; **FNS**: Femoral neck system; **CCS**: Cannulated ompression screw; **DHS**: Dynamic hip screw; **HHS**: Harris hip score; **AVN**: Avascular necrosis; **ERAS:** Enhanced recovery after surgery.

Conflict of interest: The authors have no conflicts of interest relevant to this article.

Consent to participate. Written consent was obtained from individual patients.

Consent for publication. Consent for the publication of images obtained from the patients.

Availability of data and materials. The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Ethical Approval. The study was approved by the Ethical Committee of Wuxi Ninth People's Hospital (WXSJY-LY-2019–0047, date of registration: April 20, 2019. Prospectively registered).

Consent for Publication. Written informed consent was obtained from all participants.

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