Comparison of Cannulated Screw Combined with Medial Femoral Plate and Simple Cannulated Screw in the Treatment of Pauwels Type III Femoral Neck Fracture: A Meta-analysis with Trial Sequential Analysis

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ABSTRACT

This study aimed to compare the efficacy of cannulated screw combined with medial femoral plate and simple cannulated screw for Pauwels type III femoral neck fracture. In May 2022, relavent clinical trial articles were searched in seven online databases. After literature screening, quality evaluation, and data extraction according to the specific inclusion and exclusion criteria, the differences in therapeutic efficacy, complications, and intraoperative outcomes were compared between the two groups. A total of nine articles were finally included in the meta-analysis. The qualities of the nine articles were medium. Although the results showed that cannulated screw combined with medial femoral plate prolonged the operation time and increased blood loss ($p < 0.05$), it demonstrated better fracture reduction and Harris score, shorter healing time and less internal fixation failure than in the simple cannulated screw in the treatment of Pauwels type III fracture ($p < 0.05$). The sensitivity analysis, Egger's test, and trial sequential analysis (TSA) showed that the combination results were stable and reliable. This demonstrated that compared to that with the simple cannulated screw, the cannulated screw combined with medial femoral plate had better efficacy and less complication.

Key Words: *Femoral neck fracture, Therapy effect, Cannulated screw, Medial femoral plate, Trial sequential analysis.*

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INTRODUCTION

Femoral neck fracture (FNF) often occurs in elderly patients with osteoporosis and is the most common type of hip fracture.[1,2] The incidence of FNFs in young people is relatively low and is mainly caused by high-energy injuries, such as traffic accidents and high fall injuries.[1,3] Reduction and fixation is the basic principle of the therapy for such fractures, and the most common treatment is an internal fixation with closed reduction cannulated screws.[4,5] Numerous studies have demonstrated that equilateral triangular structures formed between screws effectively provide better biomechanical stability.[6,7]

Pauwels classification, introduced in 1935, evaluates the angle between the horizontal line and fracture line to assess the shearing stress and compressive force.[8] The more general the angle is, the greater the shear force at the fracture end, which is extremely unstable. Pauwels angle of more than 50° is classified into the Pauwels type III FNF. At present, one of the most common treatments for Pauwels III FNF is three cannulated compression screws for internal fixation.[9] However, postoperative complications following this treatment can easily occur, such as bone non-union and head necrosis.[10]

Recently, the treatment of Pauwels III FNF using cannulated screw combined with medial femoral plate (CSCMFP) is developing as a new surgical method.[11] Several studies have compared the efficacy of CSCMFP and simple cannulated screw (SCS) for the treatment of Pauwels III FNF.[9,12,13] Shen *et al*. demonstrated that the CSCMFP was more effective than SCS in the treatment of Pauwels III FNF.[14] The authors also emphasised that the incidence of postoperative complications like screw loss, head necrosis, hip varus, and femoral neck shortening in CSCMFP was significantly lower. These results are consistent with the findings in most randomised controlled trial (RCT) studies.[12,15] In contrast, Qin *et al*. reported that the incidence of bone non-union and head necrosis in the two groups was not significantly different.[16] These findings necessitate the urgent need to explore whether CSCMFP treatment has an advantage over SCS fixation.

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Meta-analyses provide a general, effective understanding of many inconsistent studies.[17] A meta-analysis conducted by Su *et al*. also demonstrated a more effective outcome for CSCMFP in the treatment of Pauwels III FNF compared to SCS,[18] providing a general understanding and selective tendency for clinical therapy of Pauwels III FNF. However, the meta-analysis was performed in January 2020 and only contained literature published up to December 2019. Additionally, although retrospective cohort studies and RCTs were included in this meta-analysis, the number of studies included in the meta-analysis was still small, resulting in poor reliability and stability of the conclusion. Thus, to better understand the differential efficacy of CSCMFP and SCS, this meta-analysis of nine publications (572 cases) was conducted that compared the efficacy of the two treatments for patients with Pauwels III FNF.

METHODOLOGY

All procedures were performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[19]

A protocol-driven systematic search for publications was performed in the PubMed, Embase, Cochrane Library, Web of Science, Wanfang data, China National Knowledge Infrastructure (CNKI), China Science and Technology Journal database (CQVIP). The search terms included femoral fracture, plate, screw, and randomised controlled trial. Database-specific controlled vocabulary terms and free-text terms were combined for the search, and keywords of the same and different categories were combined with “OR” and “AND” respectively. In addition, the retrieval formula was adjusted according to the characteristics of the database.

Each database was searched from inception to 22 May, 2022. To obtain more references for the meta-analysis, manual retrieval of the paper version of the literature was conducted for screening the relevant reviews and included references.

The inclusion criteria for the studies were: Adults patients with Pauwels III FNF; the experimental group was treated with CSCMFP, while the control group was only treated with SCS; study design being an RCT; one or more of the following outcomes were reported: efficacy (excellent rate of fracture reduction, fracture healing time, and postoperative Harris score), complications (femoral head necrosis, non-union, internal fixation failure, and wound Infection), and intraoperative ending (operation time and blood loss). The exclusion criteria for the studies were: Non-original articles like reviews, conference abstracts, and comments; non-RCT studies; and for repeated publication or the same data used in multiple articles, the one with the most complete research information was chosen.

To ensure the scientific integrity and rigor of the research, two investigators independently screened the references following the above protocol. Data extraction was accomplished independently according to the pre-designed table for the included references. Detailed information on the included references was obtained, including the name of the first author, publication year, the country in which the study was conducted, basic characteristics of the candidates (diagnostic criteria, sample size, gender, and age), intervention program, follow-up time, and outcomes. The Cochrane Collaboration's tool for assessing risk was utilised to estimate the methodological quality of all chosen studies.[20] In the case of disagreement in the process of literature data extraction and quality evaluation, a consensus was reached after a group discussion with a third author.

Assessment of the differences in continuous variables was performed using weighted mean difference (WMD) 95% confidence interval (CI). Evaluation of the differences in categorisation variables was performed using the Risk Ratio (RR) and 95% CI. Heterogeneity among the studies was determined using Cochran’s Q test and I^2 statistics.[21] Values of $p <0.05$ or $I^2 >50\%$ was determined as significant heterogeneity and the random effects model was constructed for meta-analysis; $p \geq 0.05$ and $I^2 \leq 50\%$ was determined as non-significant heterogeneity and fixed effect model was adopted for meta-analysis; $p <0.05$ indicated significant differences in therapy efficacy, complications, and intraoperative outcomes between CSCMFP and SCS.

In addition, sensitivity analyses removing one research at a time were performed to explore the effects of each single study on the combined results. Egger’s test was used to understand whether there was significant publication bias among the studies.[22] When a significant publication bias was found, the stability of the meta-analysis results was evaluated using the trim and fill method.[23] Statistical analyses were performed using the RevMan 5.3 and Stata 12.0 software.

Trial sequential analysis (TSA) was finished through TSA software version 0.9 Beta (Copenhagen Trial Unit, Copenhagen, Denmark),[24] evaluating whether there were sufficient sample sizes to confirm differences in outcomes, complications, etc. between the two groups.

RESULTS

A total of 1096 articles were screened through systematic searches (Figure 1). After the removal of duplicates, 784 remaining articles were further screened to yield 15 articles by reading the title and abstract. Five non-RTC studies and one review article were further excluded. In addition, the manual search failed to find studies that could be included in the analysis. Finally, nine articles were chosen and included in the meta-analysis.[9,12-16,25-27]

The basic information of the nine publications is listed in Table I. All the nine studies were conducted in China, and the publication years were from 2018 to 2021. The sample sizes ranged from 26 to 96, with a total of 572 cases (286 experimental samples and 286 control samples). Qin *et al*. reported the number of males and females in terms of all the participants,[16] while the other eight studies reported the number of males and females in the intervention and control groups, respectively. Of the total patients in the included studies, 380 were males and 192 were females.

Table I: Characteristics of the nine included studies.

Study	Definition of Pauwels III	Time from fracture to surgery, hours	Groups	Age, years	n, M/F	Site, L/R	Cause, TA/HFI/TI	Follow-up, months
Ding, WX 2018	Pauwels angle ≥70°	NR	Intervention Control	63 (37–69) 63 (37–69)	12, 8/4 14, 8/6	NR NR	NR NR	12
Gao, CJ 2020	Pauwels angle >50°	NR	Intervention Control	41.32 ± 12.28 43.03 ± 12.10	25, 20/5 30, 22/8	10/15 17/13	16/6/3 15/10/5	12
Li, P 2018	NR	NR	Intervention Control	45.56 ± 8.24 43.32 ± 8.87	31, 16/15 31, 19/12	NR NR	NR NR	3
Liu, HW 2020	Pauwels angle >50°	NR	Intervention Control	47.26 ± 8.54 47.90 ± 7.84	40, 23/17 40, 21/19	15/25 17/23	14/26 12/28	NR
Qin, YP 2018	Pauwels angle >50°	46.87 ± 17.33	Intervention Control	35.50 ± 8.68 35.50 ± 8.68	30, 41/19# 30	27/33	23/19/18	15 (12–18)
Shen, ZQ 2021	Pauwels angle >50°	74.4 ± 19.2 69.6 ± 24.0	Intervention Control	44.9 ± 7.8 44.8 ± 8.8	29, 19/10 29, 20/9	11/18 10/19	NR NR	30.6 (24–56)
Xu, YK 2018	Pauwels angle >50°	37.73 ± 8.27	Intervention Control	50.4 ± 10.6 49.9 ± 18.7	25, 19/6 20, 15/5	NR NR	21/11/13	12
Yang, B 2019	Pauwels angle >50°	40.53 ± 8.95 39.12 ± 9.30	Intervention Control	37.86 ± 9.12 38.05 ± 8.47	49, 35/14 47, 32/15	21/28 22/25	23/9/17 22/10/15	12
Zhou, YF 2021	Pauwels angle >50°	39.21 ± 6.15 39.05 ± 5.98	Intervention Control	38.12 ± 8.46 38.05 ± 8.35	45, 32/13 45, 30/15	NR NR	21/10/14 23/7/15	6

Treatment referred to cannulated screws combined with medial femoral plate and control referred to simple cannulated screws. *F, female; M, male; L, left; R, right; TA, traffic accident; HFI, high falling injury; TI, tumbling injury; NR, not reported. #, number of male/female of all participants.*

Table II: Outcomes of the sensitivity analysis and test of publication bias.

Outcomes	No. of studies	Sensitivity analysis	Egger's test
		RRs/WMDs (95% CI)	p-value
Excellent rate	6	1.22 (1.12, 1.32) to 1.24 (1.13, 1.36) #	0.096
Healing time	6	−1.30 (−1.83, −0.76) to −1.02 (−1.38, −0.67)	0.077
Harris score, 1 month	2	0.93 (−0.04, 1.90) to 5.17 (3.52, 8.82)	NA
Harris score, 3 months	3	1.55 (−0.02, 3.11) to 8.66 (−5.06, 22.39)	0.520
Harris score, 6 months	6	4.13 (1.46, 6.79) to 6.77 (2.25, 11.30)	0.386
Harris score, 12 months	5	6.18 (3.80, 8.57) to 9.21 (5.51, 12.90)	0.281
Femoral head necrosis	6	0.46 (0.19, 1.10) to 0.65 (0.26, 1.65) #	0.141
Non-union	7	0.48 (0.20, 1.15) to 0.57 (0.26, 1.27) #	0.004
Internal fixation failure	6	0.10 (0.03, 0.36) to 0.15 (0.05, 0.41) #	0.006
Operation time	8	26.06 (15.28, 36.84) to 31.78 (21.09, 42.48)	0.510
Blood loss	8	50.19 (28.65, 71.73) to 77.45 (54.48, 100.42)	0.072

NA, not available; #, effect size was RRs.

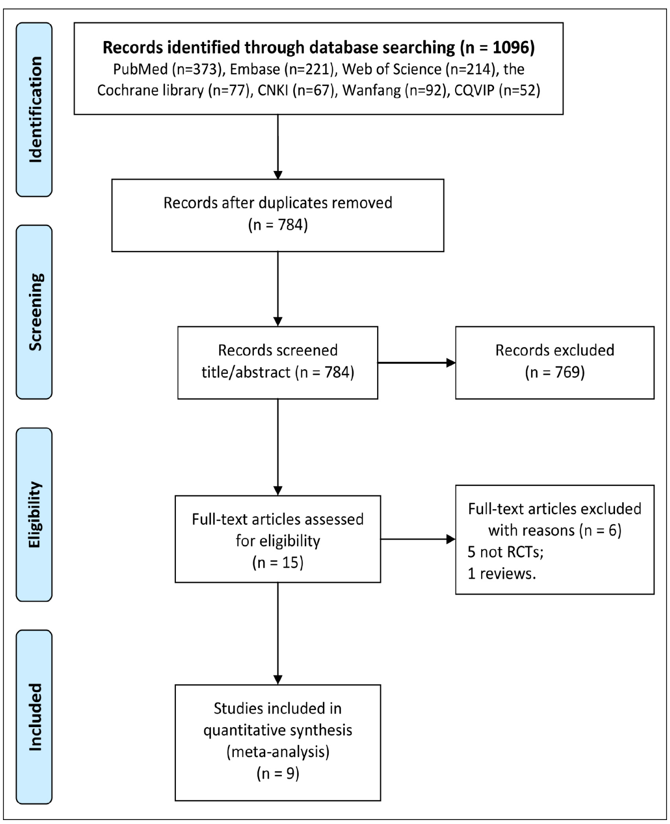

Figure 1: The process and results of literature screening. CNKI, China National Knowledge Infrastructure.

One article did not report the diagnostic criteria for Pauwels III FNF, one reported the diagnostic criteria as Pauwels angle ≥70°, and the other seven reported the criteria as all Pauwels angle >50°.[26,27] Among the nine articles, five reported the time from fracture to surgery,[9,13,14,16,25] five reported the site of the fracture,[12-16] and six reported the cause of fracture;[9,12,13,15,16,25] the differences between the two groups (CSCMFP and SCS) in terms of these features were not statistically significant. The average follow-up time of each included study was from 3 to 30.6 months.

The results of the methodological quality evaluation of the -nine studies are chosen. As the allocation concealment, outcome measurement information were absent in the included studies. The researchers and subjects were blinded, and the bias focused mainly on allocation concealment, performance bias, and detection bias. In addition, five RCTs did not report the specific random grouping methods;[9,12,14,15,26] therefore, the evaluation of random sequence generation was termed unclear risk. In general, the bias grade of the included studies was uncertain, and the methodological quality was medium.

The comparison outcomes of CSCMFP and SCS treatments in terms of excellent rate of reduction, healing time, and postoperative Harris scores are shown in Figure 2A–C. Six literature studies reported the differences in excellent rate of fracture reduction in CSCMFP and SCS.

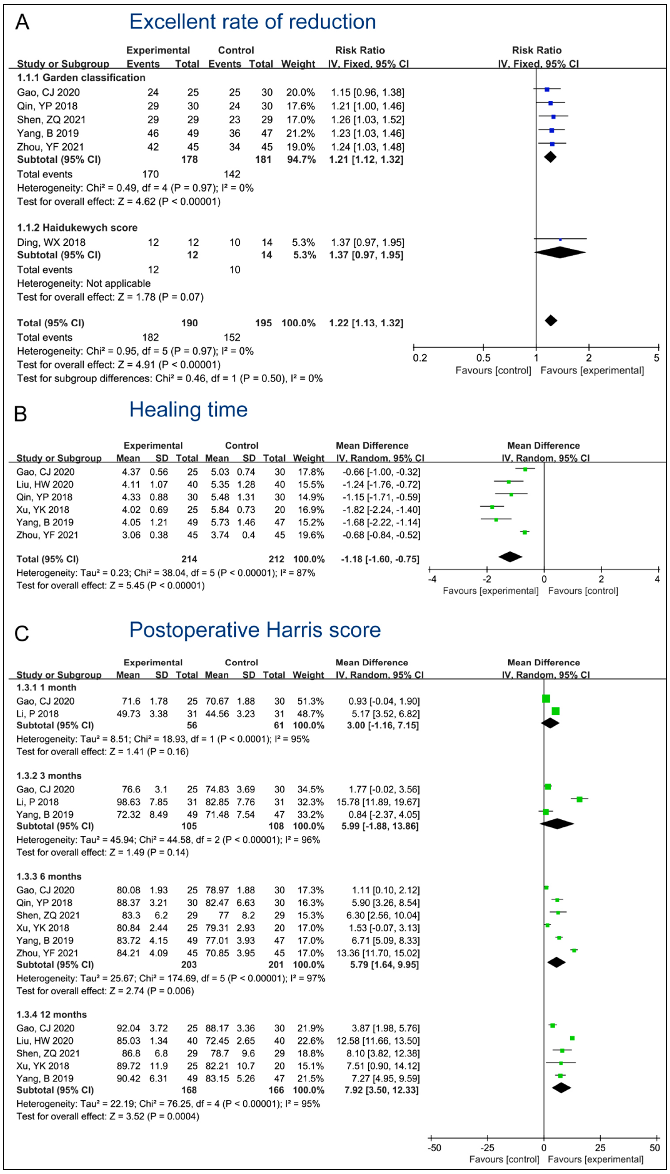

Figure 2: Forest plots comparing the therapy efficacy between cannulated screw combined with medial femoral plate and simple cannulated screw treatment. (A) The results of excellent rate of reduction; (B) The results of healing time; (C) The results of postoperative Harris score. Experimental group represent the cannulated screw combined with medial femoral plate treatment, and the control group represent the simple cannulated screw (the same as below).

The evaluation criteria for five studies were the Garden classification ≤2,[12-14,16,25] and one was Haidukewych scores ≤2.[26] The generated results indicated that there was no significant heterogeneity among the six studies (Figure 2A, I^2 = 0%, p = 0.97). Fixed effects model showed that CSCMFP had a better excellent rate than SCS (Figure 2A, RR = 1.22; 95% CI: 1.13, 1.32; p <0.001).

Six literature studies reported the difference in healing time between the two treatments.[9,12,13,15,16,25] The results of heterogeneity test were I^2 = 87% and p <0.001. The random effects model suggested that CSCMFP required a lower healing time than with SCS (Figure 2B; WMD = −1.18; 95% CI: −1.60, −0.75; p <0.001).

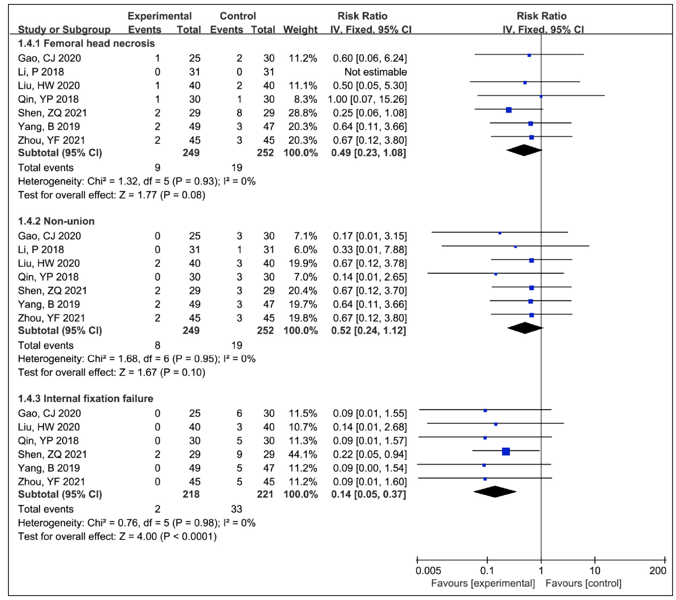

Figure 3: Forest plots comparing the complications between cannulated screw combined with medial femoral plate and simple cannulated screw treatments.

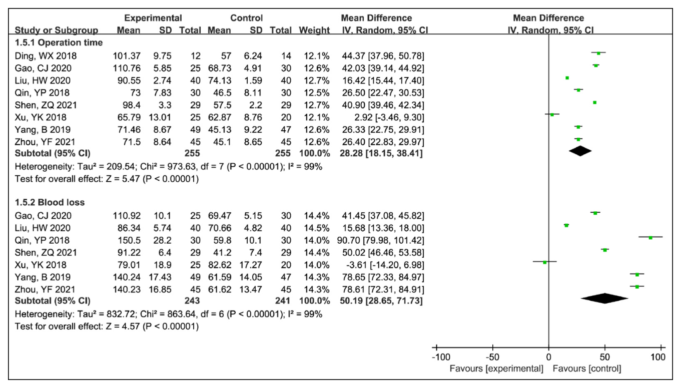

Figure 4. Forest plots comparing the intraoperative ending between cannulated screw combined with medial femoral plate and simple cannulated screw treatments.

The results of the analysis of differential postoperative Harris score were divided into Harris score in 1, 3, 6, and 12 months (Figure 2C). Significant heterogeneity existed in the four postoperative evaluation time (I^2 >50%, p <0.05). The random effects model showed that no significant differences existed in the Harris score between the two treatments in postoperative 1 month (WMD = 3.00; 95% CI: −1.16, 7.15; p = 0.16) and post 3 months (WMD = 5.99; 95% CI: −1.88, 13.86; p = 0.14). However, CSCMFP showed a higher Harris score in the postoperative 6 months (WMD = 5.79; 95% CI: 1.64, 9.95; p = 0.006) and 12 months (WMD = 7.92; 95% CI: 3.50, 12.33; p <0.001).

The comparison of three types of complications, including head necrosis, non-union, and internal fixation failure, between CSCMFP and SCS treatment are shown in Figure 3. The three complications exhibited non-significant heterogeneity (I^2 <50%, p >0.05). Fixed effects model showed no significant differences between the two groups in femoral head necrosis (RR = 0.49; 95% CI: 0.23, 1.08; p = 0.08) and non-union (RR = 0.52; 95% CI: 0.24, 1.12; $p = 0.10$). Regarding internal fixation failure, fixation failure occurred more easily with CSCMFP (RR = 0.14; 95% CI: 0.05, 0.37; $p < 0.001$).

The comparison of operation time and blood loss between CSCMFP and SCS treatment are shown in Figure 4. The two symptoms showed significant heterogeneity ($I^2 > 50\%$, $p < 0.05$). Random effects model implied that CSCMFP required more operation time (WMD = 28.28; 95% CI: 18.15, 38.41; $p < 0.001$) and caused more blood loss (WMD = 50.19; 95% CI: 28.65, 71.73; $p < 0.001$) in the operative process than in SCS.

Sensitivity analyses showed that all indices included in the study were stable, except the Harris score in postoperative 1 month (Table II). Omitting any one study, the results (except Harris score in postoperative 1 month) were still accurate. However, only two studies were included in Harris score at postoperative 1 month, and the instability of the results may be due to the differences between the two included studies. Moreover, Egger's test could not be carried out in the two studies. In addition, Egger's test showed that non-union ($p = 0.004$) and internal fixation failure ($p = 0.006$) exhibited significant publication bias. Analyses for other indices indicated no significant publication bias. Trim and fill method was used for non-union internal fixation failure; however, the program did not fill in the fictitious negative results to enhance the symmetry of the funnel plot, and the meta-analysis results did not change, indicating that the publication bias of these two indices may have been caused by small sample bias.

The results of TSA of the therapeutic efficacy, complications, and intraoperative outcomes are shown in figures. The sample size for excellent rate exceeded the expected sample size (n = 158), and Z was >1.96, indicating that the combined results were significant, and there was sufficient evidence to demonstrate the high reliability of the combined results. In addition, healing time, internal fixation failure (Figure S3C), and operation time had similar results.

The sample sizes of Harris score after 1/3/6 months, femoral head necrosis (Figure S3A), and non-union did not meet the expectations. This indicates that more studies are needed to verify the possibility of significant differences in these indices between the two treatments. The sample size of Harris score and blood loss at 12 months after surgery did not meet the expectations, while the Z-curve crossed the trial sequential monitoring boundary, indicating that there was sufficient evidence that the combined results are highly reliable.

DISCUSSION

Paulwels classifies FNF into three types based on the direction of the femoral neck fracture line. Among the three types, the angle between fracture line and horizontal line is maximum in the Pauwels III FNF and is extremely unstable. The most common treatment is internal fixation with three cannulated compression screws.[9] However, postoperative complications following this treatment can easily occur.[10] Recently, CSCMFP was developed as a new surgical method for the treatment of Pauwels III FNF.[11] The CSCMFP is fixed based on the traditional SCS and the medial femoral plate is placed on the inner part of the femoral neck. This surgical method maintains the anti-rotation ability of the internal fixated screw, and further prevents the shear force caused by the fracture end.[18] CSCMFP has been demonstrated to have increased efficacy and decreased postoperative complications.[9,12-14] To compare the efficacy of CSCMFP and SCS for the treatment of patients with Pauwels III FNF, we performed a meta-analysis by searching previous publications and explored the general results of all included studies. A total of nine literature studies were included in the combination analysis. The results demonstrated that CSCMFP effectively increased the excellent rate, Harries score (6/12 month), operation time, and blood loss, as well as decreased the healing time and internal fixation failure. These results were consistent with the most of previous single RCT studies.[12-14,16,25]

Regarding the main outcome index, compared to the SCS internal fixation, the CSCMFP treatment required more operation time and increased blood loss. These results may be attributed to the relative complexity of internal fixation of the medial plate;[25] thus, the prolonged operation time and increased blood loss.[28] Moreover, CSCMFP effectively increased the excellent rate and Harris score (6/12 months) and decreased the healing time and internal fixation failure. Supporting cannulated screw with a steel plate in the femoral medial, increases the contact area, strengthens biomechanical stability, prevents internal fixation loosening, reduces the stress at the fracture end,[29] protects blood flow around the femoral head, and promotes the healing of fracture; thus, promotes the fracture excellent rate of reduction, improves the function of the hip joint, and shortens patient recovery time.[14]

In this study, the advantages of the CSCMFP over SCS were demonstrated in treating Pauwels III FNF, such as increasing the excellent rate and postoperative Harris score and decreasing the healing time and internal fixation failure. All the included studies were RCTs and possessed a small methodological heterogeneity. The sensitivity analyses suggested that the combined results of most outcome indices were adequately stable, and there was no significant publication bias. Although there was a small sample bias in non-union and internal fixation failure, sensitivity analysis suggested that the meta-analysis results were still stable. Moreover, TSA further showed that significant differences occurred in outcome indices between the two treatments, except the postoperative 6-month Harris score. TSA analysis also suggested that there was sufficient evidence for the high reliability of the combined results.

Nevertheless, the study has several limitations. First, for continuous variables, the heterogeneity of the outcomes (such as operative time, blood loss, and Harris score) may be attributed to the experience of surgeons, patients' self-evaluation of postoperative pain and gait, etc. Second, the quality of methods used in the chosen studies was poor, and the control of selection, performance, and detection biases was not strictly carried out according to RCT standards. Third, all the nine included studies were conducted in China, and the extrapolation of the meta-analysis results was poor. High-quality RCT should be performed in other regions to evaluate the advantages and disadvantages of CSCMFP in the treatment of patients with Pauwels III FNF and whether it has the same effect in other ethnic groups. Finally, the Pauwels classification varied among the different literature included in the meta-analysis (Pauwels angle ≥70° or >50°). Nevertheless, this study demonstrated significant advantages of CSCMFP in the treatment of Pauwels III FNF and equally provided a general knowledge of the priority of CSCMFP because the criteria of angle >70° was included in the angle >50°.

CONCLUSION

Cannulated screws combined with medial femoral plates have a better prognosis and fewer adverse reactions than with cannulated screws alone for treating patients with Pauwels III femoral neck fracture. Therefore, it is suggested that cannulated screws combined with medial femoral plates may be a better choice for patients with Pauwels III femoral neck fracture.

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AVAILABILITY OF DATA AND MATERIALS

The data used to support the findings of this study are available from the corresponding author upon request.

COMPETING INTEREST:

The authors declare that they have no competing interest.

AUTHORS' CONTRIBUTION:

ZL, KZ: Designed the research.
ML, CR: Drafted the manuscript.
YL, QW, CR: Acquired the data.
TM, YX, CR: Analysed the data.
ML, CR, LS: Performed statistical analysis.
ZL, HX: Obtained the funding.
CR, TM, QH, HX: Revised the manuscript for important intellectual.
All authors have read and approved the final version of the manuscript to be published.

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