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ORIGINAL ARTICLE

Evaluations of Femoral Diaphyseal Fracture Treated by Flexible Nail versus Plate Fixation in Children: Meta-analysis study

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ABSTRACT

Background: The purpose of this Meta analysis study is to provide a good idea and characteristics about the optimal fixation methods for fracture shaft femur in children 5-14y of age based on the current evidence.

Methods: An electronic research was performed in PubMed, Medline, Elsevier, Google scholar and Cochrane Library database to identify the relevant literatures that published until 20 May 2020. By using RevMAN5.4 software the data of operative, postoperative, follow up and the reported complicationswas analyzed for the meta-analysis.

Results: The pooled data showed a statistically significant difference in Operative Time, Estimated Blood Loss, Union Time and Fracture Angulation.

Conclusion: According to the pooled data results we suggest the use of flexible nails with stable femoral shaft fractures in school age children, due to the minimally invasive technique, early union and weight bearing. In other hand using plate fixation is more stable and has lower rate of fracture mal alignment more than retrograde flexible nail and can be use with the unstable fractures due to the rigid fixation.

Keywords: Femur Fractures; Intramedullary Nail; Plate Fixation; Children; Meta-Analysis

INTRODUCTION

Fracture shaft of femur in children and adolescent has an incidence of 20 per 100.000 children in USA which is<2 % of all fractures in pediatrics. Actually about 76% of femoral fractures were at the shaft, which is the most common fractures type needing hospitals admission in young age [1]–[3]. The most common causes of femur fractures in children include falling from height, high velocity road traffic accidents, bicycle falls and abuse in younger age children[4].

Multiple fixation methods are available to the surgeons but the optimal approach is a point of debate in school age group for the fracture shaft femur[5]. Among the recent years a variable methods was used and described by different studies and authors for the management of femoral shaft fractures in children between the ages of 5 to 14 years, Some of techniques involving closed reduction and internal fixation (CRIF) with flexible nails, open reduction and internal fixation (ORIF) with plate, external fixators and traction with Spica casting[6]–[8]. Usually the preferred treatment of isolated femoral shaft fracture in pre-school age is closed reduction with conservative Spica casting, flexible intramedullary nailing in children weight <50kg has satisfactory outcomes, in adolescents and children weight >49kg the rigid intramedullary nailing and sub muscular plating was widely used [9]–[11]. The most important factors causing controversy in school age group are the evolving methods of treatment being available and lack of a high level evidence studies proving one treatment modality to be better than another, While flexible nails were the best regarded treatment since 1990 with features likeit'sshortening operation time, minimally invasive, and also due to early mobilization, less cost with shortening hospital stay, but the recent reports complications as shortening, malunion, nonunion and suggested technical difficulties in the procedure and also regarding compression plating to be appropriate alternative to elastic nails in comminuted or length unstable femoral fractures[12]–[15]. We could not find any relevant meta-analysis or systematic review in the recent years. A few comparative prospective and retrospective studies have been published to discuss this controversial that allows us conducting this meta-analysis. This study aims to provide a good idea and characteristics about the optimal fixation methods for fracture shaft femur in

children by reviewing the relevant literature studies.

METHODS

Our study protocol was registered to institutional review board (IRB) in Zagazig University at December 2019. Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Eligibility Criteria: We searched for the clinical studies that comparing the retrograde flexible nail versus plate fixation for treatment of femoral shaft fracture in children.

Search Strategy: Electronic research was performed in PubMed, Medline, Elsevier, Google scholar and Cochrane Library database to identify the studies comparing elastic stable intramedullary nail (ESIN) versus plate fixation that published until 20 May 2020.

A search including the single keyword or in combination: a "fracture shaft/diaphyseal of femur" "children/pediatric" "plate/plating" "intramedullary" "flexible nail/nailing".

Study Selection: In this meta-analysis we included studies which fulfill the following criteria:

1. Studies comparing flexible nails versus plate fixation.
2. Studies in English language.
3. Studies including children age between 4-15 years.
4. Studies including closed and Gustilo type (1) diaphyseal femoral fracture.

While we excluded studies containing pathological fracture, open fracture with Gustilo grade 2 and 3, studies investigating only plate fixation or only nail fixation, case report, review literature.

Data Collection Process: After duplicates removed, the two researchers (T.E) and (A.G) independently screened the titles and abstracts, any conflicts were discussed with the third researcher (A.S). Then the full text investigated based on inclusion and exclusion criteria for this study.

Data Items: Clinical outcomes data was operative and post-operative data like operative time (OT), estimated blood loss (EBL), and lengthening of hospital stay (LOS). Then the follow up data like union time (UT), angulation, leg length discrepancy (LLD), Knee joint ROM, implant failure, infection and other surgical wound complications.

Literature Search: The search strategy yielded 156 relevant articles, 139 articles were excluded based on their title and abstract. Seventeen articles were retrieved. Nine of these articles also excluded after full text review based on inclusion, exclusion criteria and eligibility. The process is shown in detail (fig – 1). At the end, a total of 8 studies (431 participants) ultimately met the inclusion criteria. All the included studies were comparing fracture shaft of femur in children treated with elastic stable intramedullary nail (ESIN) versus plate fixation. Also **Jolly et al.**[8] and **Arora et al.**[18] has been excluded, because they do not report the mean and SD for both groups and not published a statistical data to calculate them.

Synthesis of results : According to heterogeneity standard measures, if there is insignificant heterogeneity between the studies ($P>0.1$ and $I^2<50\%$) we choose the fixed effects model for meta-analysis. And vice versa, if the analysis cannot modify the significant heterogeneity between the studies ($P\leq0.1$ and $I^2\geq50\%$) we used a random effects model which is more moderate for high heterogeneity.[19]

Risk of Bias : We have not used the funnel plot because of the limited number of the included studies<10 studies. The risk of bias for the 6 prospective studies has evaluated and showed in table (1). The researchers were in charge of methodological quality assessment for each included study with the bias risk assessment tool of Cochrane handbook5.1.0, in which all the seven bias elements were assessed. Also the characteristics of all 8 included studies are demonstrated in table (2).

Quality Assessment of the Studies: All the included studies were clinical trial studies, which compare flexible nails to plate fixation for fracture shaft of femur in pediatric. They were 2 retrospective studies [20], [21], 6 prospective studies[22]–[27] and only three of them were randomized clinical trials RCTs **(22, 24, and 27)**. (Table–1) Also allocation concealment reported only in one study **[24]**, because other authors not reported enough information regarding randomization, allocation concealment and other elements of quality assessment.

STATISTICAL ANALYSIS

Review Manager(RevMan5.4) [16] software provided by Cochrane collaboration was used in our statistical analysis. Mean difference (MD) was used in continuous data, while odds ratio (OR) in dichotomous data. And P-value of 0.05 or less was considered statistically significant. Also Confidence interval (CI) 95% was used[17]**.** Also, we used the raw data of the studied groups in the studies, which do not reported the mean and standard deviation (SD) of the continuous data. the P-value and the mean was used to calculate the SD according to the Cochrane Handbook [16].

RESULTS

A. Operative and Postoperative Data:

1. Operative Time:

We included six studies [20], [22], [23], [25]–[27] that comparing operative time between ESIN and plate fixation. Based on the high heterogeneity (Chi^2 = 529.02, df = 5 (P < 0.00001); I^2 = 99%), Our analysis of random effects model demonstrated a high significant difference in operative time (mean difference MD = -27.32, confidence interval CI = -47.20 to -7.43, P value = 0.007) that indicating ESIN fixation had less operative time than plating for fracture shaft femur in children.

1. **Estimated Blood Loss (EBL):**
Three included studies [20], [25], [27] compared EBL between ESIN and plate fixation. Base on the high heterogeneity (Chi^2 = 529.02, df = 5 (P < 0.00001); I^2 = 99%). A random effects model was used and showed a highly significant difference in EBL (MD = -66.25, CI = -84.42, -48.07, P value = 0.00001) that favors ESIN over plate fixation.
2. **Lengthening of Hospital Stay (LOS):**
Searching for LOS in the available studies showed that only four studies [20], [21], [25], [27] compared LOS between ESIN and plate group. Again, a random effects model was used due to high heterogeneity of sampling (Chi^2 = 520.95, df = 3 (P < 0.00001); I^2 = 99%). The pooled data of hospital stay showed no statistical difference between the two groups (MD = -2.18 CI = -7.09 to 2.74, P value = 0.39).

B. Follow Up Data:

1. **Union Time:**
Four studies only [23], [25]–[27] reported the union time and were enrolled for this subgroup analysis. The pooled data showed rapid union time in ESIN group more than plate group (MD= -2.96, CI = -4.49 to -1.44, P value= 0.00001) for fracture shaft of femur in children. This was estimated by random effects model due to a high heterogeneity of the data (Chi^2 = 41.74, df = 3 (P < 0.00001); I^2 = 93%).
2. **Reported Outcomes:**
Flynn scoring system was introduced in (2001) by Flynn et al. it is formed by 4 parameters which end by a score of satisfaction of the patient from the management of femoral shaft fracture. (Table 4)
There was four studies reported their outcomes using Flynn Scoring system.[28]
Pooling of the data showed a significant homogeneity of the sample (Chi^2 = 0.99, df = 3 (P = 0.80); I^2 = 0%) in these four studies [50], [21], [25], [26]. Although the forest plot of the Flynn score of these four studies showed a shift of data in favor to the ESIN fixation, but comparing the poor outcomes for both groups showed insignificant difference (OR = 0.30, CI = 0.08 to 1.10, P value = 0.07).

C. Reported Complications:

1. **Angulation:**
All the included studies [20]–[27] provided data about fracture angulation. The heterogeneity test indicated an insignificant difference of heterogeneity so data pooled by fixed effects model (Chi^2 = 8.67, df = 7 (P = 0.28); I^2 = 19%). The analysis suggests a significant lower rate of angulations when using plate fixation in the management of femoral shaft fractures in children (OR = 2.81 CI = 1.34 to 5.87, P value = 0.006).
2. **Leg Length Discrepancy (LLD):**
Five studies [20], [21], [24]–[26] provided data about LLD, The fixed effects model was used for statistical analysis of LLD, (Chi^2 = 2.77, df = 4 (P = 0.60); I^2 = 0%) the analysis was statistically insignificant (OR = 1.10, CI = 0.53 to 4.56, P value = 0.82). Therefore, it suggests that selection of fixation method (ESIN or Plate) may not affect LLD.
3. **Knee Joint ROM:**
Knee ROM was recorded in five studies[20], [21], [24]–[26]. Due to the insignificant heterogeneity of the data in these studies, the fixed effects model was used (Chi^2 = 2.54, df = 4 (P = 0.64); I^2 = 0%). Analysis of pooled data showed insignificant difference between the two groups (OR = 1.24, CI = 0.46 to 3.34, P value = 0.67).
4. **Infection Rate:**
Only three studies [25]–[27] reported data of postoperative infection (superficial and deep infections). As there was no evidence of heterogeneity between data, the fixed effects model was used (Chi^2 = 3.48, df = 2 (P = 0.18); I^2 = 42%). The pooled data demonstrated insignificantly lower rate of infections in ESIN compared to plate fixation for fracture shaft femur in children (OR = 0.53, CI = 0.14 to 1.96, P value =0.34).
5. **Implant Failure:**
Implant failure after operation was the last reported complication in four studies [23]–[26]. The heterogeneity test indicated an insignificant difference, so fixed random effects was used (Chi^2 = 0.10, df = 3 (P = 0.99); I^2 = 0%). The pooled data analysis failed to reach statistically significant results (OR = 0.27 CI = 0.06 to 1.12, P value = 0.07).

Table (1): risk of bias in included studies

	Ahmed E et al. 2016	Caglar O et al. 2006	Olivo C et al. 2017	Reddy R et al. 2015	Said E et al. 2018	Wang W et al. 2019
Random sequence generation "Selection bias"	L	U	L	U	H	L
Allocation concealment "Selection bias"	U	H	L	H	H	U
Blinding of participants and personnel "Performance bias"	H	H	H	H	H	H
Blinding of outcome assessment "detection bias"	H	H	H	H	H	H
Incomplete outcome data "Attrition bias"	L	L	H	U	L	U
Selective reporting "Reporting bias"	H	H	H	L	L	H
Other bias	U	U	U	U	U	U

Annotations: (U = Unclear risk, H = High risk, L = Low risk)

Table (2): Characteristics of the included studies

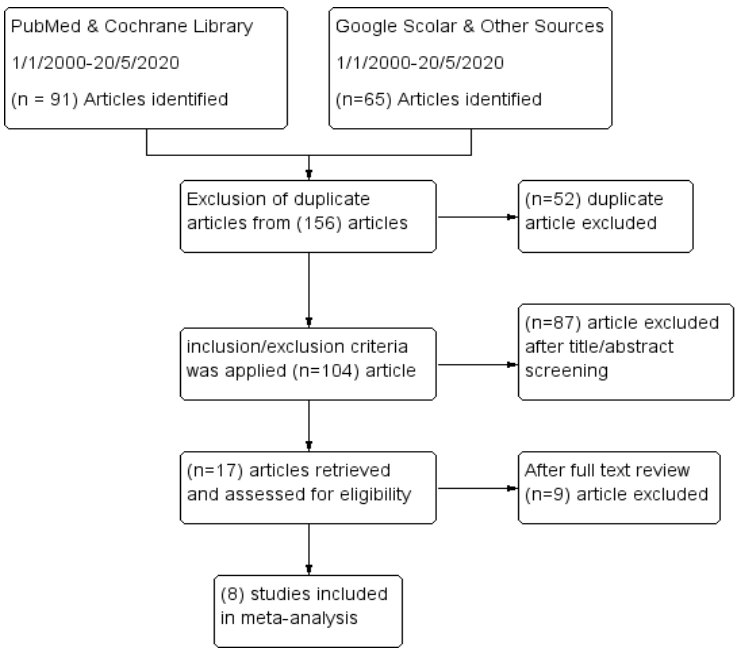
Author (year):	Study Design	Operative Treatment	Patient Characteristics	Fracture Classification	Union Time (mean/ weeks)	Follow Up, %followed
Ahmed, et al. (2016)	Randomized Prospective clinical trial	TENs (n=32) vs AO_ DCP (n=32)	N=64 Mean age: (8.75y for TENs) & (8.87y for plate). Male: 79.6%	Closed fracture &Gustilo type (1) Classification: NR	(6) for TENs (11) for plate	(6) months (2,4,6,8,12, 16,20, 24 weeks).
Allen , et al. (2018)	Retrospective study	TENs (n=50) vs compression plate (n=15)	N= 63 Mean age: (9y for TENs) & (8y for plate) Male: 68%	Closed fracture Classification: NR	NR	NR
Caglar, et al. (2006)	Prospective clinical trial	TENs (n=17) vs Compression plate (n=21)	N=38 Mean age: (8.1y for TENs) & (8y for plate). Male: 65%	Closed fracture, (20) transverse, (14) oblique, (6) comminuted	15.64 for TENs (19) for plate	Until complete union, at least (1year) follow up.
Milligan, et al. (2020)	Retrospective study	ESIN (n=14) vs plate (n=14)	N=28 Mean age(9.7y for ESIN)& (7.7y for plate) Male: 75%	Closed fracture Classification: NR	NR	Minimum follow up 2 years
Olivo, et al. (2017)	Randomized Prospective clinical trial	TENs (n=9) vs LCP n=١1)	N=20 Mean age: (8.4y for TENs) & (8.6y for LCP). Male:65%	Closed fracture AO classification: A1 (10), B3 (2), C1 (3), C3 (5).	NR	(10) Days, 3 & 6 weeks, 3 & 6months.
Reddy, et al. (2015)	Prospective clinical trial	TENS (n=20) vs	N=40 Age: 6-14y	Closed fracture	11.3 for TENs	At least (1) year.

Author (year):	Study Design	Operative Treatment	Patient Characteristics	Fracture Classification	Union Time (mean/ weeks)	Follow Up, %followed
		DCP (n=20)	Male & female included.	Classification: NR	16.1 for plate	
Said, et al. (2018)	Randomized Prospective clinical trial	TENs (n=28) vs AO plate (n=28)	N=56 Mean age: (6.75y for TENs) & (8.42y for plate) Male: 66%	Closed fracture Classification: NR	8.57 for TENs 9.28 for plate	2 & 6weeks, 3 & 6 Months, 1year. Mean: (10.51) Months
Wang, et al. (2019)	Randomized Prospective clinical trial	ESIN n=60) vs plate fixation (n=60)	N=120. Mean age: (10.36y for ESIN) and (6.55 for plates). Male:61%	Closed fracture Classification: NR	8.96 for ESIN 11.5 for plate	>6 months.

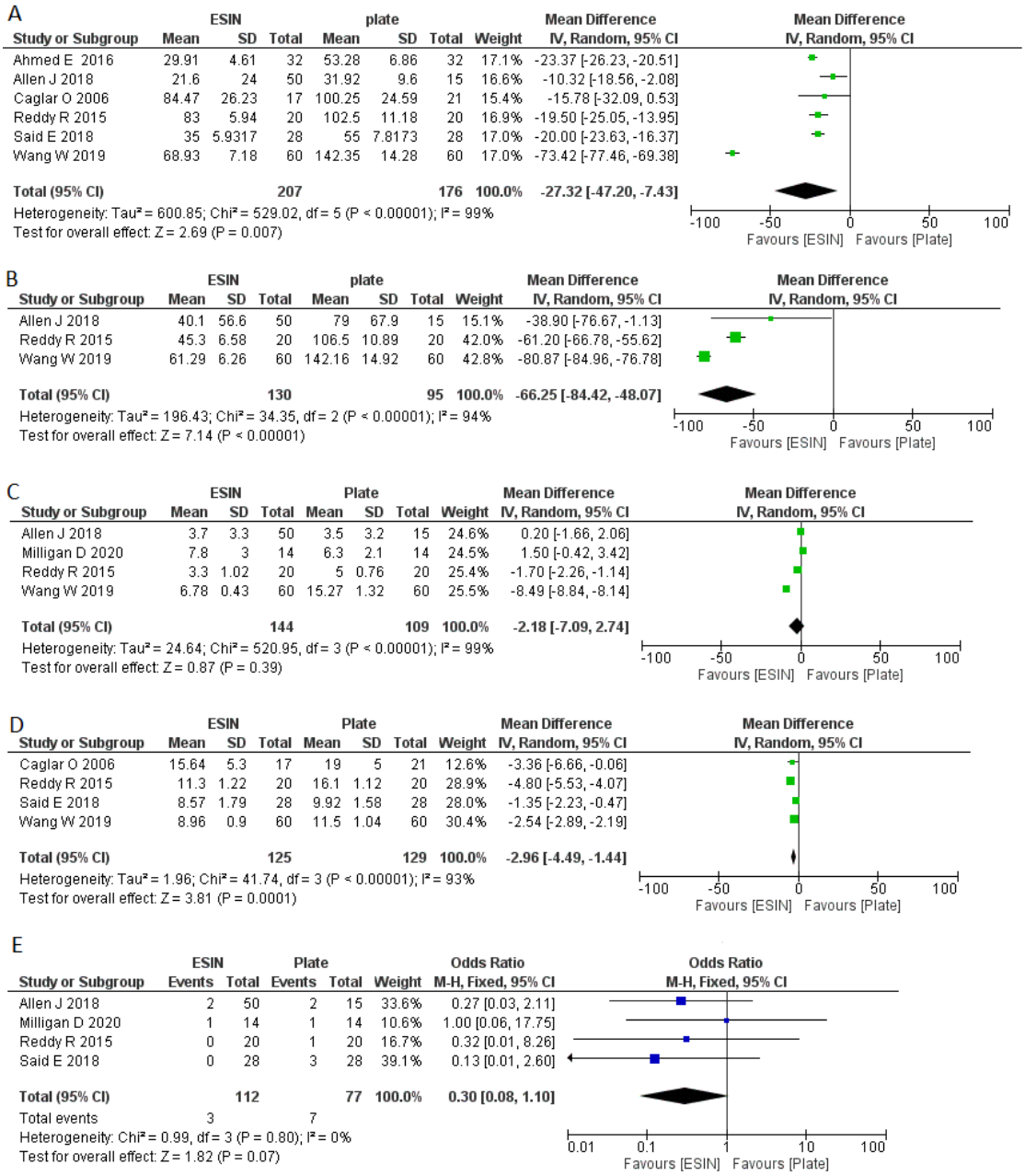
Annotations: The Papers are alphabetically organized. NR=Not Reported, LCP=Locking compression plate,DCP=Dynamic Compression Plate, TENs= Titanium Elastic Nails, ESIN=Elastic Stable intramedullary nail

Table (3): Flynn scoring system

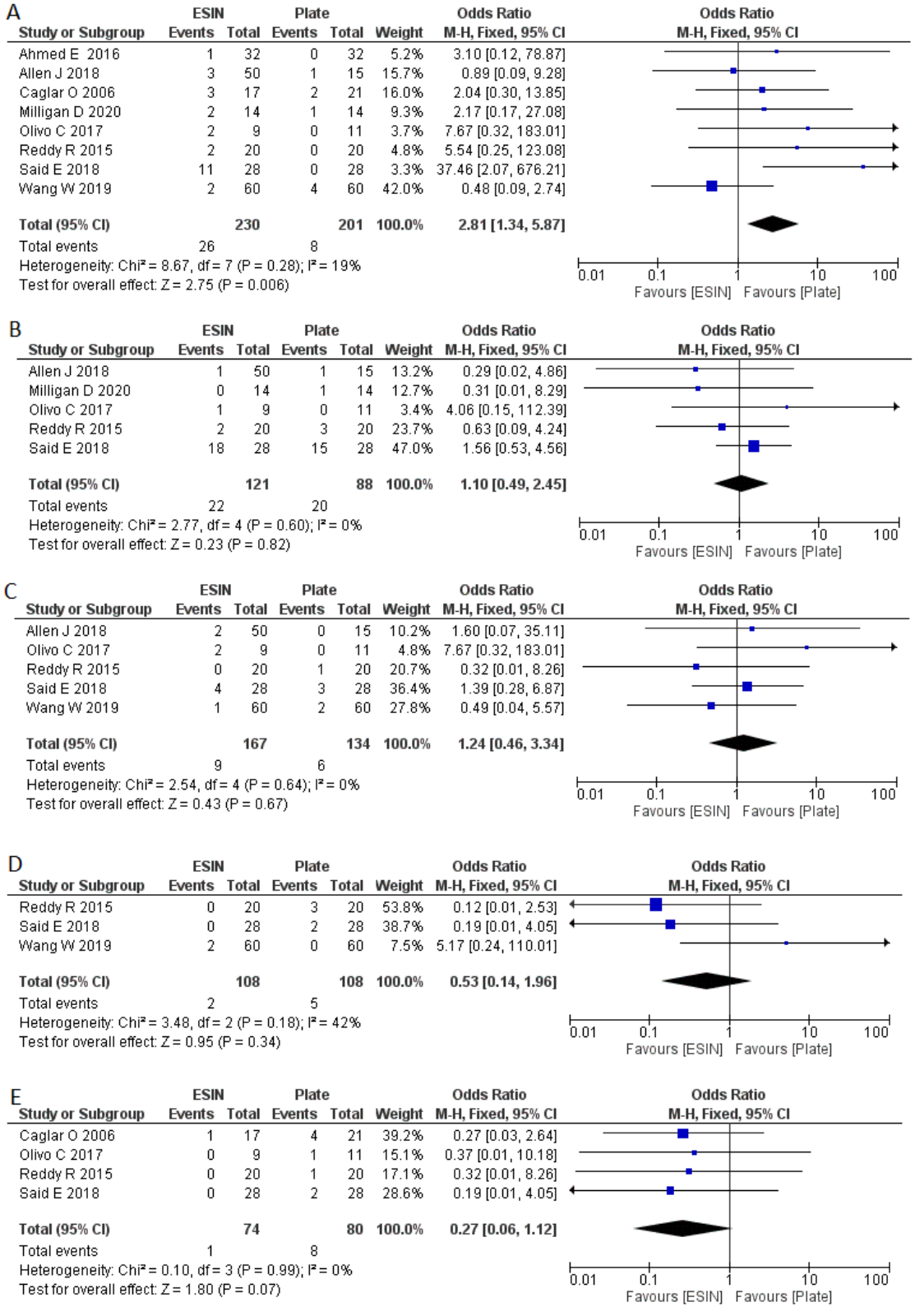
Parameter	Excellent	Good (satisfactory)	Poor
Limb Length discrepancy	<1cm	<2cm	>2cm
Angulation	<5 Degrees	<10 Degrees	>10 Degrees
Pain	None	None	Present
Complications	None	Minor and resolved	Major with long lasting morbidity



***(*Fig – 1):** Flow diagram for study selection



(Fig – 2): Forest plot shows A. Operative Time B. EBL C. LOS D. Union Time E. Flynn scoring system



(Fig – 3): Forest plot shows A. Angulation B. LLD C. Knee ROM D. Infection Rate E. Implant failure

DISCUSSION

The appropriate fixation method in pediatric femoral fractures especially in school age group (5-14y) should be a simple, load sharing, internal splint allow early weight bearing and maintaining the fracture reduction, length and alignment for several weeks until bridging callus formation, with keeping epiphyseal blood supply intact.[26]

Over the past few decades, pediatric orthopedic surgeons have been recognized the advantages of operative management for diaphyseal femoral fracture in children age 5y and above. The operative management has been proving its efficacy, by relatively rapid union, early mobilization and shortening hospital stay. Also it's appropriate to avoid social, physical, psychological stress and complications that may increase with conservative management due to prolonged immobilizations.[30]

The advantages of closed reduction internal fixation technique with flexible intramedullary nails are less invasive, less blood loss, shortening operative time, with no need for muscle and soft tissue dissection or periosteal striping, early mobilization and weight bearing. And relatively rapid union due to hematoma and periosteum preservation that may increase the rate of bone healing, also the micro motion due to relative stability of the flexible nail may help in union.[30]–[32] In 2017 (Pandey, et al) reported a prospective study of 60 patients were fixed with ESIN showed that weight of patient was the most affecting factor on the final outcomes. According to Flynn criteria score, the reported outcome was up to 92% excellent outcome in patient weight < 40kg, while 80% of patient's weight > 40kg showed good to poor outcomes. Also the outcomes regardless to weight of patient (Pandey, et al) reported 48 patients with excellent outcomes, 10 patients with good (satisfactory) outcomes and 2 patients with poor outcomes.[31]

The plate fixation provides an anatomical fixation for any type of fractures, and doesn't affected by patient weight or fracture location proximal or distal to physis, with less malalignment in plating due to the rigid fixation. [33], [34]In 2013, Abdelgawad and his colleagues reported a retrospective study of 58 patients (60 femoral fractures) fixed with sub muscular plating for femoral diaphyseal fractures where 40 fractures out of 60 were diagnosed as unstable fractures. They showed that no difference in results between fracture location and patient weight. All patients returned to full functional activity, fractures healed with no clinically significant malalignment or malrotation and minimal leg length discrepancy with 2 implant failure recorded.[33] This meta-analysis reviewed 8 different studies [20]–[27], six prospective studies three of them randomized prospective clinical trial and two retrospective studies, were performed in contribution to found a solution for this controversy. After analyzing the included studies we had pooled the available data about operative/postoperative, follow up and complications, to define the appropriate method of fixation.

ESIN has shown less operative time than plate fixation with high statistical significant difference reported by [20], [22], [23], [25]–[27] (P value 0.007) that is due to less invasive technique of closed reduction internal fixation. Also ESIN had less estimated blood loss (EBL) than plate fixation with a highly significant difference reported in three studies [20], [25], [27] of them (P value 0.00001). Our analysis showed statistical insignificant data about hospital staying between both groups that reported by 4 different studies [20], [21], [25], [27]. But the pooled data from these different studies showed high heterogeneity and this may be due to the different protocols and strategies used in management in these patients.

Different data was used to estimate the success of the method of management for fracture femur in children. The most common reported follow up data were the estimated fracture union time and Flynn scoring system, which is a clinical and radiological scoring system based on 4 parameters to estimate the patient satisfaction from the femoral shaft fracture management. The reported data obviously showed that the healing power is in favor to ESIN over the plating [23], [25]–[27] that's most probably due to the preservation of fracture hematoma, periosteum and soft tissue integrity by the percutaneous technique. Also the micro motion that occurs at the fracture site with using of ESIN may strength the formation of callus and these factors could accelerate the fracture union. But this was not the case when we considered the poor outcomes that were demonstrated by Flynn criteria in four studies for both groups [20], [21], [25], [26]. Were it showed a statistical insignificant difference between the pooled data, although the chart was in favor to ESIN over the plate. This may be due to the small number of studies and with only two prospective studies (Reddy et al. Said et al.) that reported outcomes by Flynn criteria.

Leg length discrepancy is a condition where the lengths of both legs are unequal. Some studies reported events of shortening of fracture femur, other reported lengthening and both were considered as reported event in leg length discrepancy in these studies. One of the major problems in the five studies reporting LLD, that the cut off value of the LLD was not clear. According to Flynn scoring system <1cm LLD is considered one of the parameters of excellent group. While

Said et al. [26] reported that there was 18 events in LLD in the ESIN group with values <1cm. Although of this, the pooled data of these five studies [20], [21], [24]–[26] showed insignificant difference between the plate and nail for leg length discrepancy. Also Knee joint ROM has no statistically significant difference between both groups after pooling the data [20], [21], [24]–[26], (P value = 0.67). Nevertheless, the surgeon should be in caution to protrusion of nail at the entry point site that may cause pain, bursa irritation and limitation of movement at knee joint in case of ESIN fixation.

Fracture malalignment is defined as more than 5 degrees of deformity in any plane. The femoral shaft fracture union malalignment may occur in any planes of directions. Anterior, posterior angulation, varus, valgus angulation and rotational malalignment, all were reported as an incidence of angulation in the 8 studies of this meta-analysis (Ahmed et al. Allen et al. Caglar et al. Milligan et al. Olivo et al. Reddy et al. said et al. Wang et al). [20]–[27] The analysis of the pooled data showed statistical significant difference (P value = 0.006) and goes in favor to plate fixation over the ESIN. That may return to the anatomical fixation of the plates which is more stable than relative fixation of the ESIN. Postoperative infection rate has been described only by three studies [25]–[27] with statistical insignificant difference between plate and ESIN. The demonstrated data showed that deep infection occurred in 2 cases within plate group, which reported by (Said et al). The first case was at 6 week postoperative, resolved by antibiotic, waiting until union then plate removal and debridement, the second case came with severe infection extended to bone, and treated by plate removal, debridement and external fixator. The other two studies reported superficial infection and resolved by antibiotic treatment and regular dressing. According to what was mentioned above, it's clearly that infection especially the deep infection has less occurrence with ESIN, because of small incisions and the less invasive technique. Possibly the cause of insignificant statistical results are due to small number of studies that reported infection data with only one study was RCT.

The implant failure was the last pooled data in our meta-analysis; the data goes in favor to ESIN. Although the analysis was statistically insignificant but the data showed only 1 event of implant failure in ESIN group reported by Caglar et al. conversely 8 events reported by the other studies beside these study, [23]–[26]Caglar et al. reported that the cause of ESIN implant failure maybe hypertrophic nonunion as the patient weights > 45kg but he did not report the cause of 4 implant failure in plate group in his study.Olivo et al. and his colleagues had reported 1 implant failure (peri-implant fracture) in plate group after one year by accident. Also Reddy et al has reported 1 implant re-fracture at end of 10 week was due to fall from his bed. Finally Said et al. has reported two implant failures, the first case was due to deep infection and the second case was re-fractured after implant removal.

STUDY LIMITATIONS

It is known that meta-analyses require detailed and explained mechanisms for determining which studies to include or exclude. These eligibility criteria are explained by a combination of relevance and considerations of bias and are typically decided before the search for the studies. Although of this, we could not gather many RCTs or studies with appropriate allocation of patients in large sample size studies. The quality of the included study was not remarkably high. Two of the eight studies were retrospective studies, three randomized clinical trial, and the allocation concealment was clarified in one study only.

Radiation exposure is considered one of the main problems in orthopedics pediatric patients, especially if percutaneous techniques are considered. Estimating the radiation dose to a patient is complex. From the sensitive tissues to radiation are the gonads and bone marrow, both are vulnerable to radiation in the fixation of femoral fracture. We think this is one of the major limitations of the studies in this meta-analysis, as the radiation exposure was not discussed in these studies and the procedures safety in this pediatric population.[35]

CONCLUSION

According to the collected data from the included studies showed that operative time, estimated blood loss and union time goes in favor to flexible nails. In the other side, using plate fixation is more stable and has lower rate of fracture angulation more than flexible nails. And based on the pooled data results we suggest the use of flexible nails with the stable fractures, due to the minimally invasive technique, early union and weight bearing. And only use of plates for the unstable fractures due to the rigid fixation, to avoid the angulation that maybe caused by flexible nails.

More RCTs with large sample size, about fracture shaft femur in school age group is needed, for more assessment.

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