SYSTEMATIC REVIEW

Titanium Elastic Nails Versus Spica Cast in Pediatric Femoral Shaft Fractures: A Systematic Review and Meta-analysis of 1012 Patients

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Abstract

Background: There is a general consensus on the management of femoral fractures in children younger than two years and adolescents older than sixteen years. The best treatment for patients younger than sixteen years of age is still debatable. Titanium Elastic Nails (TEN), is widely used with some evidence, nonetheless, we undertook a systematic meta-analysis to assess the efficacy of TEN compared to Spica cast for the management of femoral shaft fracture in children aged between 2 to 16 years old.

Methods: A computer literature search of PubMed, Scopus, Web of Science, CINAHL and Cochrane Central was conducted using relevant keywords. We included clinical trials and observational studies that compared TEN versus Spica cast; Records were screened for eligible studies and data were extracted and synthesized using Review Manager version 5.3 for Windows. Our search found 573 unique articles. After screening the abstract and relevant full text, 12 studies with a total of 1012 patients were suitable for the final analysis.

Results: In terms of union (in weeks), the reported effect sizes favoured the TEN group in two included studies only. Moreover, the overall standardized mean difference in sagittal (SMD -0.48, 95% CI [-0.70 to -0.26], P<0.001) and coronal angulations (SMD -0.66, 95% CI [-1.00 to -0.31], P<0.001) favored TEN fixation in management of femoral fractures younger than 16 years. The reported length of hospital stay was not consistent across studies. The overall risk ratio of malalignment (RR=0.39, 95% CI [0.27 to 0.57], P<0.001) favored the TEN as well as walking independently. Based on our analysis, TEN treatment is superior to traction and hip spica for femoral fractures in patients younger than 16 years old.

Conclusion: Based on our analysis we recommend the use of TEN fixation in management of pediatric femoral fractures in patients younger than 16 years.

Level of evidence: II

Keywords: Femoral fractures, Flexible nails, Spica cast, Titanium elastic nails

Introduction

Fractures of the shaft of the femur represent 1.4% to 1.7% of all pediatric fractures (1). There is a bimodal pattern being more in early childhood and mid-adolescence and more common in males compared with females (2). The reported annual incidence is up to 1/5000- they represent the most

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frequently pediatric fracture requiring a hospital admission. There are different mechanisms of injury described; this includes but not limited to road traffic accidents, falls, Non-accidental injuries, incidental findings, sports related injuries and pathologic fractures (3, 4). In those younger than 4 years, non-accidental injuries constitute a major concern (5). In mid-adolescence motor vehicle accidents represent a common cause (6).

When choosing the treatment modality in this age group, several issues including the final outcome ought to be considered; as they have impact on psychological and developmental effects: on the child, family and social ramifications and financial implications (if a parent has to take time off work).

There is a global consensus on the management of these fractures in children younger than two years and adolescents aged 16 or more (7). The ideal treatment for patients between two and sixteen years of age is debatable (8, 9). Closed reduction and Spica cast (CRSC), external fixation, plate and screws, intramedullary nails and flexible intramedullary nails have been described for the treatment of these injuries (7, 10-32).

Titanium Elastic Nails (TEN) is used globally for the operative fixation of femoral fractures in those younger than 16 years old, despite the paucity of studies evaluating their risks and benefits (29-32). TEN have been used in Europe since the eighties and historically stainless-steel Ender nails have been used elsewhere (33, 34). The surge of TEN in North America has led to an over-spill in their use (35).

We undertook a systematic review and meta-analysis to analyse the evidence about the efficacy of flexible nails compared to Spica cast for the management of femoral shaft fracture in patients younger than 16 years old.

Materials and Methods

The quality of the Randomized Clinical Trials was evaluated as per the guidance of the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 (updated March 2011) utilizing the quality assessment table presented in that handbook (Part 2, Chapter 8.5). The Cochrane risk of bias assessment tool comprises the subsequent domains: sequence production (selection bias), allocation selection concealment (selection bias), blindfolding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), inadequate outcome data (attrition bias), selective outcome reporting (reporting bias) and additional possible causes of bias. The authors’ interpretation is graded as ‘Low risk’, ‘High risk’ or ‘Unclear risk’ of bias. The NOS comprises 8 items, classified into three dimensions including selection, comparability, and—based on the study category—outcome (cohort studies) or exposure (case-control reports). For each feature, a set of response potentialities is implemented. For observational investigations, we applied the Newcastle-Ottawa Scale (NOS) for quality appraisal (36). NOS is based on a star system and is utilized to permit a semi-quantitative assessment of the study quality; it ranges between 0 up to 9 stars.

Measures of treatment effect

The primary outcomes were the time to union, malunion rate, the length of stay, independent walking, angulations (Sagittal and coronal) in both groups. The secondary outcomes were: complications and parents’ satisfaction.
Dealing with missing data

In the event of the lack of Standard deviation (SD) of change from baseline, estimates were conducted employing the standard error or 95% confidence interval (CI), according to Altman (37).

Data Synthesis

Hospital stay, time to union, sagittal angulations, coronal angulations, malunion and walking independently were pooled as standardized mean difference (SMD) in the random effect model meta-analysis described by Der-Simonian and Laird (38). The incidence of malalignment in both groups was pooled as relative risk (RR) in the meta-analysis model using the Mantel-Haenszel (M-H) method. Statistical analyses were conducted using Review Manager 5.3 for Windows.

Assessment of heterogeneity

Heterogeneity was assessed by visual inspection of the forest plots and measured by I-squared and Chi-Squared tests. According to the Cochrane Handbook of Systematic Reviews and Meta-analysis of interventional studies, the Chi-squared test assesses whether observed differences in results are compatible with chance alone. According to Higgins 2002 and Higgins 2003, the heterogeneity test I-squared is calculated from the following equation: \(\frac{(Q-df)}{Q}\times100\%\) where Q is the chi-squared statistic and df is its degrees of freedom (39, 40). I-squared test can be interpreted as follows: 0% to 40%: might not be important; 30% to 60%: may represent moderate heterogeneity; 50% to 90%: may represent substantial heterogeneity; and 75% to 100%: considerable heterogeneity.

Publication bias

According to Egger et al. publication bias evaluation is not suitable for less than 10 pooled studies (41). Hence, in the current study, we could not assess the existence of publication bias by Egger’s test for funnel plot asymmetry.

Results

Search results

Our search retrieved 573 unique articles. After screening of the abstract and full-text, 12 studies with a sum of 1012 patients were included for the concluding analysis (See PRISMA flow diagram; Figure 1) (31, 35, 42-52). The reasons for study exclusion are shown in Supplementary File no.1.

Of the 12 included studies, two studies were randomized controlled studies; the summary of the
included studies and their main results are shown in [Table 1].

**Quality of included studies**
The quality of the included studies was from moderate to high quality according to the Cochrane risk of bias assessment tool and the NOS. Therefore; included studies have acceptable quality for inclusion in our review. The summary of quality assessment domains of included studies is shown in supplementary file.

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Design</th>
<th>Population</th>
<th>Sample size</th>
<th>Main finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heffernan, et al 2015 (39)</td>
<td>Retrospective observational study</td>
<td>Young Children Aged 2 to 6 Years with femur fractures</td>
<td>215</td>
<td>TENS is a reasonable option for treatment of femur fractures in young children when compared with spica casting with shorter time to independent ambulation and full activities. Fractures associated with a high-energy mechanism are especially appropriate for consideration of treatment with TENS.</td>
</tr>
<tr>
<td>Assaghir et al. 2013 (40)</td>
<td>Retrospective observational study</td>
<td>preschool children up to 6 years with femur fracture</td>
<td>104</td>
<td>TENS in preschool children is a safe choice but involves a scar, risk of infection, and the need for a second operation</td>
</tr>
<tr>
<td>Nascimento et al. 2013 (41)</td>
<td>Retrospective observational study</td>
<td>Children between the ages of 5 and 14 with femoral shaft fractures</td>
<td>60</td>
<td>The surgical method presented better results for children.</td>
</tr>
<tr>
<td>Sela et al. 2013 (42)</td>
<td>Retrospective observational study</td>
<td>Children with femur fractures</td>
<td>212</td>
<td>TENS treatment was superior to spica casting for children who had reached an average age of 4 years.</td>
</tr>
<tr>
<td>Say et al. 2013 (43)</td>
<td>Retrospective observational study</td>
<td>Children 6 to 16 years of age, with femur fractures</td>
<td>42</td>
<td>Both treatment options were similar with regard to complications and results. Although the complications are similar in two treatment methods, complications of elastic nail are more challenging and may require new surgical procedure. If the elastic nail is selected, surgical complications should not be underestimated</td>
</tr>
<tr>
<td>Buechsenschuetz et al. 2002 (44)</td>
<td>Retrospective observational study</td>
<td>Children admitted with femur fractures</td>
<td>68</td>
<td>Less cost and comparable clinical outcome make TENS a better option than traditional CRSC for femoral fracture care in the skeletally immature patient.</td>
</tr>
<tr>
<td>Flynn et al. 2004 (35)</td>
<td>Prospective observational study</td>
<td>Children 6 to 16 years of age, with femur fractures</td>
<td>83</td>
<td>The results of this prospective study support that a child in whom a femoral fracture is treated with titanium elastic nails achieves recovery milestones significantly faster than a child treated with traction and a spica cast. Hospital charges for the two treatment methods are similar. The complication rate associated with nailing compares favorably with that associated with traction and application of a spica cast.</td>
</tr>
<tr>
<td>Hsu et al. 2009 (45)</td>
<td>Prospective observational study</td>
<td>Children, five to twelve years of age, with femoral fractures</td>
<td>51</td>
<td>In resource-limited healthcare settings, Spica is an effective alternative to TENS with comparable post-op radiographic angulations, decreased hospital stays, and lower cost.</td>
</tr>
<tr>
<td>Kaiser et al. 2014 (31)</td>
<td>Prospective observational study</td>
<td>Patients ages 3–14 years</td>
<td>84</td>
<td>The initial experience of operative treatment of femoral shaft fractures in children using TENS was positive, with improved rates of treatment success and no surgical complications. Because of the high cost of implants, direct costs of treatment remained higher with ESIN despite reductions in length of hospital stay.</td>
</tr>
<tr>
<td>Saseendar et al. 2010 (46)</td>
<td>Prospective observational study</td>
<td>Children 5–15 years with femur fractures</td>
<td>17</td>
<td>Titanium elastic nailing led to better outcomes compared to hip spica casting in terms of earlier union, lower rates of malunion, shorter rehabilitation milestones, and better functional outcome scores.</td>
</tr>
<tr>
<td>Soleimanpour et al. 2013 (47)</td>
<td>Randomized controlled trial</td>
<td>Children, 6–12 years old, with one-sided femoral-shaft fractures</td>
<td>30</td>
<td>The results indicated that a child in whom a femoral fracture is treated with TENS achieves recovery milestones significantly faster than a child treated with traction and spica cast.</td>
</tr>
<tr>
<td>Shemshaki et al. 2011 (48)</td>
<td>Randomized controlled trial</td>
<td>Children, 6–12 years old, with simple femoral-shaft fractures</td>
<td>46</td>
<td>The results showed significant benefits of TENS compared with traction and hip spica cast in the treatment of femoral-shaft fractures in children. Further trials with longer follow-ups and comparison of TEN with other methods, such as external fixation, in children's femoral fractures are warranted.</td>
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</tbody>
</table>
Primary Outcomes

Duration to Union (in weeks)
In terms of duration till union (in weeks), reported effect sizes were heterogeneous and were not reliable for pooling in a meta-analysis model to give an overall effect estimate [Figure 2]. The duration till union was significantly less in the TEN group than the control group in two studies; while in the third study of (42-44).

Malunion
The pooled risk ratio of malunion showed less rate of malunion in the TEN group compared with the Spica group (RR 0.43, 95% CI [0.26, 0.71], P<0.001, [Figure 3]. Pooled studies were homogenous (P>0.1; I-square=0%).

Sagittal Angulations
The overall standardized mean difference in sagittal angulations favored TEN group than the control group (SMD -0.48, 95% CI [-0.70 to -0.26], P<0.001, [Figure 4]. Pooled studies were not heterogeneous (Chi square P=0.90; I-square=0%).
Coronal Angulations
The overall standardized mean difference in coronal angulations favored TEN group than the control group (SMD -0.66, 95% CI [-1.00 to -0.31], P<0.001, [Figure 5]). Pooled studies were not heterogeneous (Chi square P=0.14; I-square=48%).

Hospital stay (days)
Three retrospective studies favored the CRSC group over the TEN group. The remaining retrospective study did not favor either of the two groups. The two RCTs, reported a statistically significant difference favoring shorter hospital stay in the case of TEN than the CRSC group (Mean Difference = -13.60 days, 95% CI [-16.25 to -10.95], and Mean Difference = -12.28 days, 95% CI [-13.26 to -11.30], respectively) (42, 43). The overall effect estimates did not support superiority of any of the two groups (Mean Difference = -3.13, 95% CI [-7.44, 1.18], P=0.15, [Figure 6]); the pooled effect estimate was highly heterogeneous (Chi square P<0.001; I-square=99%).

Malalignment
The overall risk ratio of malalignment favored TEN group than control group (RR=0.39, 95% CI [0.27 to 0.57], P<0.001, [Figure 7]). Pooled studies were not
heterogeneous (Chi-square $P=0.40$ and I-square=0%).

**Walking independently**

Four studies (two retrospective studies and two RCTs) investigated the ability of patients to walk independently. All the four studies reported a statistically significant difference in walking independently favoring the TEN group than the control group (Figure 8).

**Secondary Outcomes**

**Parent Satisfaction**

Two studies reported parent satisfaction; both studies showed higher satisfaction rate following TEN than Spica. The pooled RR of parent satisfaction did not significantly favor the TEN group than the Spica group (RR 1.65, 95% CI [0.94, 2.88], $P=0.08$, [Figure 9]).

**Complications**

The complications of each procedure are mutually independent. Therefore, we cannot compare both procedures for the same complications. Therefore, the percentages could not be expressed as Risk Ratio between the two groups. Summary of complications is summarized in [Table 2] and [Table 3].
Discussion

Our analysis showed a statistically significant difference favoring the TEN group in the duration of union when compared with CRSC - as well as malunion, sagittal and coronal angulations in the management of femoral fractures in patients younger than 16 years old. We report a statistically significant difference favoring shorter hospital stay in the case of TEN when compared to the CRSC group. Likewise, the overall risk ratio of malalignment favored TEN group than CRSC. Similarly, we have observed a statistically significant difference in independent walking and parents’ satisfaction favoring the TEN group than the CRSC group. Subsequently, based on our observations, the results showed significant benefits of TEN compared to CRSC in the treatment of femoral-shaft fractures in children younger than 16 years old.

Traditionally, conservative treatment was the method of choice for diaphyseal fractures in children and adolescents, because it avoided surgical risks. However, spica use requires lengthy immobilisation and a higher risk for limb length discrepancy (LLD). TEN fixation subsequently replaced other surgical options in children, as it is an effective reproducible and minimally invasive option. It permits: a stable fixation, rapid healing and a prompt return to normal activity (35, 40, 44, 51).

Overall completeness of evidence

Shemshaki et al. compared spica cast with TEN in management of pediatric femoral fractures and reported superior results in the TEN group with earlier discharge from hospital ($P<0.001$), return to independent walking ($P<0.001$), return to school ($P<0.001$) and better parent satisfaction ($P=0.003$); the two groups were similar in baseline characteristics (45). The Range of knee motion was 138.7 ± 3.4 and 133.5 ± 13.4 degrees in the CRSC and the TEN groups respectively ($P=0.078$). Malunion was observed three patients (13.0%) in the CRSC group compared with none in the TEN group ($P=0.117$). The occurrence of infection was reported in three patients (13.0%) in the TEN group, after surgery. Similarly, Soleimanpour et al. reported superior results in the TEN group in regards to the absence time from school, duration of hospitalization, time required for return to normal walking and varus or valgus angular deviation were when compared with the CRSC group (46). They observed no statistically significant differences between the two groups in relation to malunion, wound complications and hospital charges.

Union

Heffernan et al. showed no statistical significant difference between the two groups in regards to the time to union (42). However, Sasseendar et al. and Flynn et al. showed a statistically significant difference favoring the TEN group than the control group (35, 44). Sela et al. reported 100% union rate, less than 8% rate of LLD and a complication rate of less than 5% with CRSC (47). Only one of the 151 patients treated with CRSC needed a re-operation. Assaghir et al. retrospectively evaluated 104 pediatric femoral fracture in children with a mean age of 4.5 years managed with wither TEN or spica cast followed up for a minimum of 3 years (43). TEN was statistically better in terms of union ($P<0.001$), and shortening ($P=0.016$) subsequently leading to earlier weight bearing ($P<0.001$). Saseendar et al. demonstrated that fracture union happens earlier in the TEN group (6 weeks) than in the spica group (8 weeks) ($P=0.001$) (44). Heffernan et al. performed a multicenter retrospective analysis of 215 patients aged 2 to 6 Years (42). Although there was no significant difference in healing times between TEN and the spica groups ($P=0.652$), they recommended that TEN is a sensible option for management of femur fractures in young children when compared with CRSC with shorter time to independent ambulation and full activities (P=0.023). They strongly recommended the utilization of TEN in high-energy mechanism fractures.

Complications

In our analysis, reported complications in TEN group

<table>
<thead>
<tr>
<th>Table 3. Complications for the Cast Group</th>
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<tbody>
<tr>
<td>Sore</td>
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<tr>
<td>Ulcer</td>
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<tr>
<td>Infected Traction pin</td>
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<tr>
<td>Wedging of the Spica</td>
</tr>
<tr>
<td>Removal and reinsertion of</td>
</tr>
<tr>
<td>a traction pin</td>
</tr>
<tr>
<td>Substantial loss of reduction</td>
</tr>
<tr>
<td>Revision under anesthesia</td>
</tr>
<tr>
<td>Revision under anesthesia</td>
</tr>
<tr>
<td>Painless limp</td>
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</tbody>
</table>
included: painful nail ends, pin migration, superficial infection, painful scar and painless limb. On the other hand, complications in CRSC group ranged from: sores, ulcers, infected pin, wedging of the spica, revision and limbing.

Sela et al. reported that CRSC were associated with increased risks of adverse events- mainly contact dermatitis (47). The main complication was the risk of revision of manipulation when the reduction is lost. Additionally, they also had 10.5% more LLDs (>2 cm shortening or <1 cm lengthening). Similarly, Flynn et al. published complications associated with TEN compared favorably with that associated with CRSC (32). In their cohort, none of the children treated with TEN had more than one cm of LLD compared to 2/35 (4%).

Say et al. detected no significant differences in the rate of occurrence of complications (48). Although the complications are statistically alike in both procedures, they highlighted that the complications of TEN are more challenging.

**Malunion, sagittal, and coronal angulation**

Our analysis showed lower rate of malunion in the TEN group compared with the CRSC group. Similarly, the overall standardized mean difference in sagittal angulation ($P=0.0001$) and coronal angulation ($P=0.0002$) favored TEN group than the CRSC group. Satisfactory angulation in femoral shaft fractures in children has been established by Kesser (53): angulation of 30° in sagittal and coronal planes in children aged 2 years of age, 20° (sagittal plane) and 15° (coronal plane) in children aged 2 and 5 years and 10° (coronal plane) and 15° (sagittal plane) in children aged between 5 and 10 years. When angulations during spica cast treatment occur beyond these ranges, different strategies must be considered - such as cast wedging (3). Loss of acceptable angulation after reduction of femoral fracture in children treated with spica casting has been reported (31, 35, 44). Assaghir et al. reported statistically significant differences in favor of TEN over CRSC in regards to shortening ($P=0.016$); sagittal angulation ($P=0.018$); coronal angulation ($P=0.022$); rotation ($P=0.014$) (43).

Heffernan et al. reported lingering angulation was higher in the CRSC vs (42). TEN group in both the sagittal plane ($P=0.002$) and coronal plane ($P=0.006$). Similarly, outcome success represented by coronal and sagittal angulation less than 10° and shortening less than 15 mm was attained in 92 % of the TEN group compared to 67% in the CRSC group (odds ratio for TEN group 9.28 (1.6–54.7); $P=0.0138$) (31). Saseendar et al. demonstrated that Spica casting was associated with more coronal plane angulation ($P=0.001$), increased rotational malalignment ($P=0.001$), increased limb length discrepancy at one year post surgery ($P<0.001$) when compared with the TEN group (44).

Shemshaki et al. reported a 13.0% of nonunion in the CRSC group whereas none occurred in the TEN group in their randomized controlled trial ($P=0.117$) (45). In the younger age groups. Assaghir et al. retrospectively evaluated femoral fracture in children with a mean age of 4.5 years (43). TEN was statistically better in terms of sagittal angulation ($P=0.018$), coronal angulation ($P=0.022$), rotation ($P=0.014$).

**Cost effectiveness**

Buechsenschuetz et al. retrospectively undertook a cost analysis comparing both modalities (49). They looked at different aspects including hospital, physicians, physiotherapy and facility costs. Hospital costs were higher in the TEN group including the overall surgeon’s and physiotherapy costs paid ($P<0.001$). The metalwork removal procedure was included as well in the TEN group. Nevertheless, hospitalization costs, were higher in the spica group ($P=0.015$). Subsequently, there is a slight difference in overall inpatient expenses between the two groups ($P=0.047$). Finally, they reported that the total overall costs of femoral shaft fractures with TEN was significantly less expensive (average, $11,077) than traditional CRSC approach (average, $13,490), with a value of $P<0.04$. On the other hand, Clinkscales and Peterson demonstrated that the costs for patients in the traction group were equal to the TEN group (51). Similarly, Flynn et al. and Soleimanpour et al. reported that costs for the two treatment options were similar (35, 46). Flynn et al. demonstrated that although the surgical costs is significantly higher in the TEN group ($P=0.0001$), the hospitalization cost was significantly higher in the CRSC group ($P<0.001$), yielding to insignificant total costs' differences between both groups (35).

**Parent satisfaction**

Two studies reported parent satisfaction (43, 49). Both studies showed higher satisfaction rate following TEN than Spica. Also comparable to our results, there was reduced parent satisfaction in the CRSC group, with superior parental acceptance of the TEN treatment. This was also reported by Clinkscales and Peterson (51). This observation could be attributed to the various community and psychological aspects of treating femoral fractures with spica casts that was highlighted by different studies (54-56).

Buechsenschuetz et al. reported that most children in the TEN group were reintegrated with their social environment quicker than their CRSC equivalents (49). Patients in the TEN group were capable to rejoin school within 2 to 3 weeks of their surgery, and in certain cases even before the CRSC group patients were discharged from hospital. They showed that two children in the CRSC group had to repeat a school grade. This led to parental dissatisfaction and had adverse implications on the child. One parent reported that their child was “emotionally scarred” during the cast period, and another patient ultimately needed psychiatric consultation after removal of the cast. Though these observations cannot be generalized, this is inferred as a direct consequence of the CRSC procedure, as was previously reported by Streissguth and Streissguth (57).

**Length of hospital stay**

Two RCTs reported a statistically significant difference favoring shorter hospital stay in the case of TEN than the CRSC group (45, 46). Shemshaki et al. reported a short length of stay in the TEN group when compared
with the CRSC group with a mean of 6.9 ± 2.9 days in the TEN group to 20.5 ± 5.8 days in the CRSC group \((P<0.001)\) (45). Likewise, Soleimanpour et al. and Flynn et al. reported a shorter hospitalization in the TEN group, when compared with CRSC group \((P=0.05)\) and \((P<0.0001)\) respectively (35, 46). Flynn et al. reported a mean of 5 days of hospitalization in the TEN group compared to 24 days in the CRSC group. Nonetheless, the reminder of the included studies demonstrated different results with reduced hospital stay in the CRSC group. Our pooled effect estimate did not favor any of the two groups.

Independent walking and return to school

Similar to our findings, Shemshaki et al. reported a short time interval to independent walking in the TEN group when compared with the CRSC group (45). They reported a mean 17.6 ± 10.2 days to supported walking in the TEN group compared to 65.6 ± 10.7 in the CRSC group \((P<0.001)\). Additionally, they demonstrated that the children in the TEN group took a shorter time to return to school sooner. It took the patients in the TEN group a mean of 31.5 ± 13.4 to return back to school compared to 64.3 ±19.6 days in the CRSC group \((P<0.001)\). Similarly, Flynn et al. reported an earlier return to supported walking and independent walking in children in the TEN group, and a quicker return to school and these differences were significant when compared with CRSC group \((48\,\text{days})\) in the TEN group compared to 103 days in the CRSC group \((P<0.0001)\) (35). The same observations were reported by Soleimanpour et al.; they demonstrated that mean non-attendance time from school, time needed for walking with and without help were significantly lower in the group treated by TEN \((P<0.05)\) (46). Assaghir et al. demonstrated TEN was statistically better in terms of earlier weight bearing \((P<0.001)\), and earlier return to nursery \((P=0.000)\) in children less than 6 years old (43).

Quality of the evidence

The quality of this evidence is reliable as it is based on high-quality investigations as shown by the quality assessment. Search designs and eligibility criteria were well established. We used the PRISMA checklist to plan this study and we completed all the steps following the guidance by the Cochrane Handbook for Systematic Reviews of Interventions. We should state that in our study, we mixed data from Randomised Controlled Trials and observational studies. Notwithstanding, most effect estimates were pooled without significant heterogeneity. Moreover, the effect estimates of Randomised Controlled Trials were not significantly different from those of observational studies except in terms of hospital stay. Accordingly, we conclude that evidence obtained from our analysis is robust.

Based on our analysis we recommend the use of TEN fixation in management of pediatric femoral fractures in patients younger than 16 years old. The results imply that a child with a femoral fracture when treated with a TEN, achieves recovery milestones significantly faster than a child treated with traction and spica cast. Further studies with longer follow-ups and comparison of TEN with other surgical methods, such as external fixation, in children’s femoral fractures are required.

All authors confirm no financial or personal relationship with a third party whose interests could be positively or negatively influenced by the article’s content.

Limitations

This meta-analysis included retrospective and observational studies together with two RCTs. It is well established that RCTs are the gold standard comparative studies providing class one evidence. Given this, we recommend further RCTs comparing the TEN with Spica hip. Additionally, the included studies did not study comprehensively different aspects of femoral shaft fractures and subsequently, this has been under-reported in our meta-analysis. These include factors like fracture type, patients' skeletal maturity and associated co-morbidities in those children. As these are important factors that should be considered when choosing the preferred treatment method.

Acknowledgements

We would like to thank Ali M. Hammad for his help in the literature search and selection of studies.

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