## Original Research

# Figure-of-eight versus Velpeau bandage for treating: results of a randomized controlled trial

Elham Pishbin[1], Mahdi Foroughian[1], Babak Saadatfar[2], Bahram Zarmehri[1], Mona Najaf Najafi[3], Sayyed Reza Ahmadi[1*]

1. Department of Emergency Medicine, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
2. Department of Emergency Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
3. Clinical Research Unit, Mashhad University of Medical sciences, Mashhad, Iran.

**Corresponding author: Sayyed Reza Ahmadi**. Department of Emergency Medicine, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran. Email: AhmadiKoupaeiR@mums.ac.ir. https://orcid.org/0000-0001-6053-5689 .

**Abstract:**

**Background**: Although clavicle fracture is the most common fracture in children, the best method of its treatment is still a challenge.

**Objective**: The purpose of this study is comparing the clinical outcomes in Velpeau bandage and figure of eight in treatment of pediatric mid-clavicle fracture.

**Method**: This randomized clinical trial was conducted on 74 children presented to our emergency department with mid clavicle fracture. Patients were randomly divided into two groups (the Velpeau bandage and the figure of eight). Patients were followed by telephone two weeks after presentation, regarding general satisfaction and comfort and severity of pain. Second follow up was performed six weeks after the initial presentation through an outpatient visit for evaluation of shoulder range of movement, any limitations of daily activity, bone shortening and probable complications.

**Results**: There was no significant difference between two groups in term of limitation of shoulder range of movement (P = 0.69) after 6 weeks and pain (P = 0.46), general satisfaction of treatment process (P = 0.13), and satisfaction with the comfort of the bandage (P = 0.28) after 2 weeks. The mean of bone shortening was 5.15 ± 3.18 and 7.67 ± 3.14 in figure if figure of eight and Velpeau bandage respectively.

**Conclusion**: There are no clinical differences between Velpeau bandage and figure of eight in treatment of mid clavicle fracture in children.

**Keywords:** Pediatric, Clavicle fracture, Figure of eight, Velpeau bandage

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## Introduction:

Clavicle fracture is the most common bone fracture in children and middle shaft clavicle (mid-clavicle) accounts for about 80% of all fractures of this bone. (1-2). The most prevalent mechanism of clavicle fracture in toddlers is falling from a height or child abuse injuries, and in school age children typically occurs as a result of same-level falls in playgrounds and during sport activities (3). Despite in adults, direct injury to the clavicle is a less common mechanism of fracture in children (4). Mechanism of fracture in adolescents is similar to the school age children but high energy

mechanisms such as motor vehicle accidents are also common in this age group (4,5). Clavicle fractures are generally classified based on the location of the fracture (medial, middle shaft, lateral) and degree of displacement (6,7). Despite the high prevalence of this fracture, there is still no consensus about the treatment of choice (8). Non-surgical treatment is the mainstay of treatment for mid-shift pediatric clavicle fractures. Based on the low incidence of non-union after nonsurgical treatment of non-displaced or minimally displaced fractures (fractures with less than 1.5 to 2 cm displacement), conservative no-operative treatment is generally recommended for these fractures. (8,9) The most common conservative treatment options are figure of-eight bandage and Velpeau bandage, applied for two to six weeks, but there is no consensus on the method of choice and the optimal duration of immobilization (10).

There are few studies which compared Velpeau and figure of eight bandage for treatment of clavicle fracture in terms of the clinical outcomes and patient's satisfaction and there is still no conclusive evidence on the preferred method of immobilization (10-12).

We conducted this randomized clinical trial to investigate and compare the clinical benefits of Velpeau versus figure of eight bandage in treatment of pediatric middle clavicle fractures

## Methods

### Participants

This randomized controlled clinical trial was conducted from August 2018 to February 2019, in the ED of Emam Reza hospital, affiliated with Mashhad University of Medical Sciences. The study was approved by the university ethics committee and registered on Clinical Trials Registry (IRCT20141115019962N2).

All pediatric patients aged between 2-15 years old, presented to the ED with mid-shaft clavicle fracture were enrolled in the study when one of the investigators was available. Patients were excluded if they had open fractures, pathological fractures, delayed presentation (after 24 hours post-injury), more than 2 cm dislocation between 2 parts of fracture, neuro-vascular injury.

### -Study protocol

On presentation to the ED, all pediatric patients (2-15 years) with the initial diagnosis of mid-shat clavicle fracture (based on the radiographic verification), were assessed for eligibility and Written informed consent was obtained from all parents before the enrollment. Patients were randomly allocated to either figure of 8 group or Velpeau group. We used non-stratified randomization in blocks of two using the sealed envelope method, so when one envelope was given to a patient, the next patient would be allocated to a group according to the remaining envelope of the pair. In both groups, bandage was performed by one of the investigators who was available. All the patients received the same recommendations and pain relief protocol by using acetaminophen according to their age. A visual analog scale (VAS) Rulers (Wong-Baker faces) was given to the parents at the time of initial with full explanation about it. Then, after 2 weeks, patients were followed up by phone call regarding their pain severity and comfortability of the bandage .Patients had an outpatient visit after six weeks and shoulder range of motion was assessed based on Constant score. A control radiography was performed and the bone shortening was measured as shown in figure (2).

### -Statistical analysis

The primary outcome variables were pain score and comfortability of bandage for the patient during the two weeks of treatment. Secondary outcome variable was shoulder range of motion based on Constant Score after six weeks of treatment

The data entered into SPSS-20 software and descriptive statistics by the use of indicators presented in the form of frequency, tables and

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charts. The data analyzed by using Mann-Whitney, T-test and Chi-square tests when applicable. The significance level was considered 0.05.

**Result**

This study performed on 88 patients that 44 of them were in figure of eight group and 44 patients in Velpeau bandage group. After two weeks, patients were evaluated through their pain rate, total satisfaction of treatment process and effectiveness, and comfort of bandages which due to the unresponsive of parents, 42 children stayed in figure of eight group and 41 patients in Velpeau group. After 6 weeks, 36 patients in the in figure of eight-bandage group and 38 patients in the Velpeau group were referred to Hospital for an outpatient visit. The limitation of shoulder movements, daily activity, bone shortening and complications in patients evaluated.

The mean age of the patients was 6.64 ± 4.25 years (range below the age of 15 years) and the mean of bone shortening was 6.39 ± 6.3 mm. Among patients in the figure of eight, 16 patients (44.4%) were in the range of 1-5 years, 10 (27.8%) were in the range of 10-6 years old and 10 (27.8%) were between the ages of 15 and 11 years. The patients in the Velpeau group, 18 (47.4%) were in the range of 1-5 years, 11 (28.9%) were in the age range of 6-10 years and 9 (23.7%) Were between the ages of 15 and 11 years. There was no significant difference between the two groups regarding age distribution (P = 0.92).

Patients in figure of eight-bandage group, 18 (50.0%) were male and 18 (50.0%) were female. There were 24 (63.2%) male and 14 (36.8%) girls in Velpeau group. There were no significant differences between the two groups from the viewpoint of sex (P = 0.18).

The results showed that there was no significant correlation between the type of bandage used for patients and pain rate after two weeks (P = 0.46), overall patient satisfaction from the whole process of treatment after two weeks (P = 0.13), satisfaction with the comfort of bandage after two weeks (P = 0.28), limitation of shoulder movement after six weeks (P = 0.69), and the mean of bone shortening after 6 weeks (P = 0.069) (Table 1 and 2).

It should be noted that patients who had the outpatient after 6 weeks examined for complications such as displacement, malunion and etc. and there were no complications in any of the patients.

**Discussion**

Clavicle bone fracture is one of the most common bone injuries (13) that included 35 to 43% of fractures in the middle part of the body (14). In most of the patients who suffer from Clavicle bone fracture, especially adults, there is a history of falling straight on shoulders, falling from height, and during exercise or an accident with motorcycles (13, 15-16). Also, in adults, the incidence of fractures decreases at the age of 20 to 50 years and increases again at the age of 70 years. For the treatment of Clavicle fractures, a large number of physicians recommended in figure eight and Velpeau methods of bandaging for 6 weeks (13, 15, 17). The purpose of this study is comparing the clinical outcomes in Velpeau bandage and figure of eight in treatment of child's Clavicle bone fracture. The mean age of the patients was 64.6 ± 4.6 years (range below the age of 15 years). The results showed that there is no significant correlation between shoulder movement restriction after six weeks (P = 0.69) and pain rate after two weeks (P = 0.46) and type of the bandage used for patients. Lenza and Faloppa (2016) in a study compared the figure of eight and sling in treatments of Clavicle fracture in middle third. They evaluated 110 patients over the age of 18 with acute damage in Clavicle fracture of middle third (less than 10 days of the incident). The results showed that there were no significant differences between two methods in performance, disability, and pain rate,

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treatment failure, complications and ability to return to previous activities (18). The results of their study consist with the result of the present study which there is no significant difference between the figure of eight and Velpeau bandage regarding the shoulder movement and pain rate. In order to confirm the results of our study, we can mention the study of Andersen et al. In their study, the clinical outcome of the treatment was similar in the two groups of bandage and simple sling, and all fractures improved after follow up. In both groups, improved fracture alignment was unchanged from the beginning of treatment (12). In the study of Pandey and Gupta (2015), the clinical outcomes of the treatment were similar in both methods of figure of eight and simple sling (19), and the result of their study consist of ours. In the study of Lenza et al. (2016), the systematic review of shoulder function was similar in both in figure of eight and sling groups. In two studies, there was no difference in pain rate in two groups of in figure of eight and sling after 2 weeks, but in one study, there was a greater pain and unpleasantness in the in figure of eight-bandage group (20). In our study, the shoulder function and pain rate were similar in both groups in figure eight and Velpeau. The mean of bone shortening was 6.93 ± 6.39 mm. The mean of shortening in patients using in figure of eight bandage was 5.15 ± 3.18 and in the patients using Velpeau was 7.67 ± 3.14. However, there was no significant relationship between the mean of bone shortening in the present study after 6 weeks and the type of bandage used for them (P = 0.069). In the study of Ersen et al. (2015), the average shortening rate in figure of eight-bandage was 9 mm (range of 17-3 mm) and in sling was 7.5 mm (range 0-24 mm) (21). Considering that their study performed on patients between 15-75 years old, and the present study performed on children below the age of 15 years, the mean of the shortening is different and raises the issue of discrepancy. Other results showed that there was no significant relationship between total satisfaction from treatment and effectiveness (P = 0.13) and satisfaction with comfort of use (P = 0.28) after 2 weeks with the type of bandage used for patients, and both groups were consent of their bandages. Andersen et al. found that the comfort of children with simple sling was more than the figure of eight-bandage (12). Also, the study of Pandey and Gupta (2015) that compared the figure of eight and the sling on the treatment of Clavicle bone fracture in adults, showed the highest level of dissatisfaction reported in figure of eight group due to the disruption of personal hygiene, sleep disorder, and loosen the bandage (19). The results of both studies do not confirm with the present study in similar satisfaction of comfort, effectiveness in the group of figure of eight and Velpeau. One of the issues parents mentioned during their visit was fixing the bandage at the time of loosening. Therefore, in different studies it can be seen the satisfaction of the type of bandage used for patients is different, and there are still contradictory findings and different opinions about the type of bandage we use for patients, so further studies are needed in this field. It should be noted that patients who had the outpatient after 6 weeks examined for complications such as displacement, malunion and etc. and there was no complications in any of the patients.

**Limitation**

Considering to the fact that there are few studies which compared the clinical outcomes between Velpeau bandage and figure of eight-bandage in treatment of child's Clavicle bone fracture worldwide especially in children. And there were no similar studies in Iran to confirm our study with it. This study performed in one center and had low sample size which reduce the generalizability of results. It is also possible to mention the patients who did not refer to Hospital to follow up after six weeks.

**Conclusion**

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Overall, regarding the results of this study on comparing it with similar studies, it seems that there are no clinically differences in treatment of child's Clavicle fracture by Velpeau bandage and figure of eight and the use of each bandage depended on the diagnosis. However, due to the lack of similar studies in this field, we require extensive, more precise and comprehensive studies to determine the type of bandage.

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**Conflict of interest**

There are no conflicts of interest in this study.

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**Tables and Charts:**

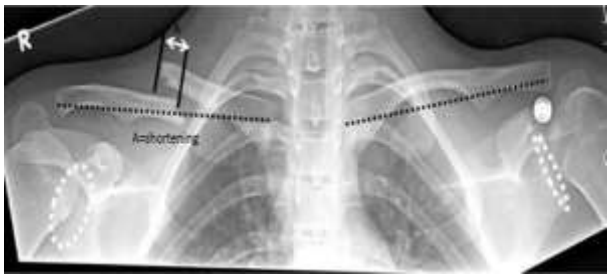



**Figure 2 - How to calculate bone shortening in the case of an overlap.**

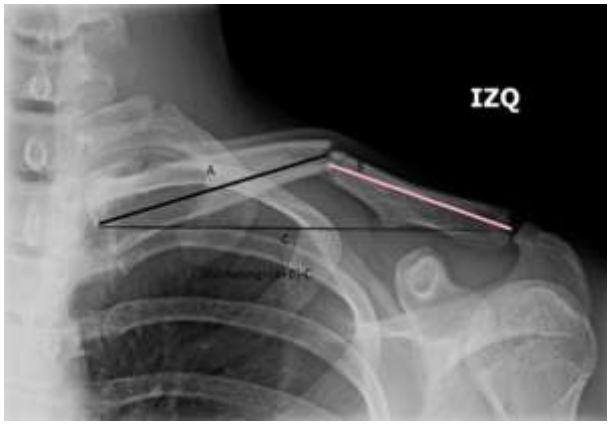



**Figure 3 - How to calculate bone shortening in the form of bulging.**

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**Table1- Frequency distribution of pain rate, total satisfaction and comfort of bandages and the limitation of shoulder movements depending on the type of bandage used.**

| | | figure of eight Frequency (percent) | Velpeau Frequency (percent) | P * |
|---|---|---|---|---|
| **Pain rate (after 2 weeks)** | Low | (69) 29 | (61/0) 25 | 0.46 |
| | Medium | (26.2) 11 | (34/1) 14 | |
| | Much | (4.8) 2 | (4/9) 2 | |
| | Total | (100) 42 | (100/0) 41 | |
| **Total satisfaction (after 2 weeks)** | Low | (2.4) 1 | (4/9) 2 | 0.13 |
| | Medium | (23.8) 10 | (36/6) 15 | |
| | Much | (73.8) 31 | (58/5) 24 | |
| | Total | (100) 42 | (100/0) 41 | |
| **Comfort of bandages (after 2 weeks)** | Low | (4.7) 2 | (9/8) 4 | 0.28 |
| | Medium | (28.6) 12 | (34/1) 14 | |
| | Much | (66.7) 28 | (56/1) 23 | |
| | Total | (100) 42 | (100/0) 41 | |
| **The limitation of shoulder movements (after 6 weeks)** | Low | (69.4) 25 | (73/7) 28 | 0.69 |
| | Medium | (27.8) 10 | (23/7) 9 | |
| | Much | (2.8) 1 | (2/6) 1 | |
| | Total | (100)36 | (100/0) 38 | |

**Table2- Evaluation of bone shortening in patients present in the study by type of bandage after 6 weeks.**

| Bandage type | Number | Mean | Standard deviation | P-Value |
|---|---|---|---|---|
| **figure of eight** | 36 | 6.15 | 3.81 | 0.069 |
| **Velpeau** | 38 | 7.67 | 3.24 | |

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