

Mirzatolooei F. Comparison between operative and nonoperative treatment methods in the management of comminuted fractures of the clavicle. Acta Orthop Traumatol Turc 2011;45(1):34-40.

Design: Randomized clinical trial

Study question: In patients with fresh comminuted clavicular fractures, are the outcomes of open reduction better than those of nonoperative treatment?

Population/sample size/setting:

- 50 patients (41 men, 9 women, mean age 33) treated for comminuted fractures of the clavicle in the orthopedic ward of a hospital in Iran
- Eligibility criteria were age 18 to 65, a comminuted (3 or more fragments), displaced midshaft clavicular fracture, and no medical contraindication for general anesthesia
- Exclusion criteria were any fracture in an upper extremity distal to the shoulder, concomitant fracture in the distal or medial third of the clavicle, any weakness in the upper extremity from a head or neurovascular injury, any pathological fracture, an old fracture more than three weeks old, and inability to complete followup

Main outcome measures:

- Randomization was to open reduction with internal fixation (ORIF, n=26) or closed treatment (n=24)
 - o ORIF entailed reduction of fragments with lag screws or sutures, secured by a number 3.5 reconstruction plate, and postoperative fixation of the arm to the body with adhesive tape and a simple sling; passive ROM exercises were started after 10 days, and progressive exercises began three weeks after the operation
 - o Closed treatment entailed a commercial sling in the casting room, with an elastic cotton band wrapped around the patient's chest and arm to limit abduction and internal rotation; no attempt was made for closed reduction
- Followup was done one month, three months, and one year after treatment
- Radiographic outcomes were defined as nonunion (lack of cortical bridging of the clavicle 6 months after treatment), shortening (more than a 10 mm difference in the length of the clavicle compared to the opposite side), and malunion (an abnormal radiographic contour with symptoms of pain, weakness, or neurovascular symptoms)
- Non-radiographic outcomes were the DASH score, the Constant shoulder score, patient satisfaction, and range of motion in abduction, forward flexion and external rotation
- In the ORIF group, one patient developed a nonunion, and in the closed group, one patient had nonunion
- In the ORIF group, 4 patients had malunion, compared to 19 in the closed group

- In the ORIF group, the mean Constant and DASH scores were 89.8 and 8.6 one year after the operation, compared to Constant and DASH scores in the closed group of 78.8 and 21.3
- The mean clavicular shortening in the ORIF group was 4 mm, compared to 26.5 mm in the closed group
- In the ORIF group, 3 patients were completely dissatisfied with the outcome of treatment, compared to 18 in the closed group
- Some complications did occur in the ORIF group; 2 patients had skin dysesthesia, 1 had an infection, and 2 had hypertrophic scars, but in 4 ORIF patients, the surgeons were not able to achieve an anatomic open reduction due to the severity of comminution

Author's comments:

- Compared to closed treatment of comminuted midshaft clavicle fractures, ORIF reduces pain at one year after the fracture and its treatment
- ORIF should be considered for comminuted fractures of the clavicle; it is the practice of the author to inform women of the possibility for scar formation

Comments:

- There was only one author, but others may have been involved in some way with the execution of the study; in any case, the assessment of outcome appears not to have been blinded
 - o The radiographic assessment cannot be blinded because of the hardware in ORIF; the clavicle shortening and nonunion, however, are resistant to bias in these measures, and the greater shortening of the clavicle in the closed treatment group is likely to be valid
 - o Similarly, the difference in DASH scores, which are completed by the patients, are great enough such to make it unlikely that bias can account for all of the differences between groups
- Three patients in the ORIF group did not accept surgery and were excluded from the analysis; however, this is not likely to lead to a bias in the direction of better outcomes for ORIF, since it is likely that patients who refuse surgery would be less severely symptomatic than those who accept surgery (also, there were 12 patients in the ORIF group with more than three fracture fragments, but only 8 in the closed treatment groups)
- The results are consistent with other studies showing that surgical treatment of displaced midshaft fractures tends to be better than closed treatment

Assessment: Adequate for some evidence that open reduction and internal fixation of comminuted midshaft clavicle fractures leads to less pain and disability at one year than closed treatment of the same fractures