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RESEARCH ARTICLE

FUNCTIONAL OUTCOME OF DISPLACED CLAVICLE FRACTURE TREATED BY INTRAMEDULLARY NAILING: A PROSPECTIVE STUDY

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Abstract

Background: Clavicle fracture is one of the most common injury.Despite the high incidence, the choice of proper treatment is still controversial. This prospective study was done to evaluate functional outcome of displaced clavicle fracture treated by intramedullary nailing.

Material and methods: The study was conducted on 30 patients(25 males and 5 females) with displaced/comminuted clavicle fracture treated by either elastic intramedullary nails or elastic intramedullary nails with endcap.Followupexamination for functional and radiological evaluationwas done at 1 month,3 months and 6 months.

Results: Mean duration of clinical union in comminuted and transverse/oblique fracture was 6.41 weeks and 6.89 weeks respectively while the mean duration of radiological union in comminuted and transverse/oblique fracture was 8 weeks and 8.5 weeks respectively.In co-relation between functional outcome and fracture pattern we obtained P-value 0.418,0.842 and 0.453 for Constant shoulder,DASH and VAS scores respectively which was statically not significant that means there was no relation between fracture pattern and functional outcome.

Conclusion:- The intramedullary fixation of displaced clavicle fracture is a safe minimally invasive technique. The intramedullary nailing holds advantages of high union rate, minimal periosteal stripping and soft tissue damage, minimal blood loss and relatively less complications. This technique provides faster return to daily and professional activities with excellent functional results. Implant removal is easier and can be done as day care procedure under local anesthesia.

Introduction:-

Fracture of clavicle represent about 2-10% of all fractures in adults with almost 80% of these fractures located within the middle one third occuring predominantly from high energy trauma and being displaced.(1,2).Though the healing and functional outcomes are better with conservative treatment for midshaft

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clavicular fracturesbut poor cosmetic results due to shortening and angulation are concern(3,4).Non-union rate is about 5% with conservative treatment (4,5). Surgical fixation is now increasingly utilized for the management of displaced midshaft clavicle fractures as a result of growing incidence of non-union, malunion,impaired shoulder function, cosmetic deformity and residual pain with non-operative treatment (2,6).There are various methods of surgical fixation of displaced clavicle fracture have gained the attention and mainly can be divided into two:plating and intramedullary nailing techniques but the indications for both for a particular type of fractures is still a debate.Currently plating is considered the mainstay of treatment among surgical management of clavicle fracture but higher complication rates have been described with this technique(7). Recently more studies have been favouring minimally invasive intramedullary nails as a better alternative to plate fixation(8-12). The aim of our study is to evaluate the functional, clinical, radiological outcomes and complications in clavicle fracture treated by intramedullary nailing.

Material and Method:-

This was a prospective study of 30 cases that were admitted and operated in the department of orthopaedics, NSCB medical College, Jabalpur from December 2019 to August 2021 and followed up at 1month,3 months and 6 months and all patients with Clavicle fracture were treated by TENS nail or TENS nail with endcap.This study was approved by the ethical committee of our institution and informed consent was obtained from all patients.The functional outcome was assessed using CONSTANT,DASH and VAS scoring system during follow-up.

Inclusion criteria

A total of 30 patients who meet the following criterias included in the study:-
1.Fully displaced fracture (no fracture side contact of distal and proximal fragments).
2.Age between 22 years and above.
3.No medical contra-indications to general/regional anaesthesia.
4.Signed informed consent by the patient or a legal representative.

Exclusion criteria

1. Fracture in the medial $1/3^{rd}$ and latera $1/3^{rd}$ l end of the clavicle.
2. Pathologic fracture (bony abnormalities at the side of the fracture) or an open fracture.
3. Neurovascular injury.
4. Associated head injury (Glasgow Coma Scale < 12).
5. An ipsilateral humerus or scapula fracture that would delay the functional recovery of the arm.
6. A clavicular fracture more than 3 weeks old.
7. Inability to comply with follow-up.
8. Prior surgery to the shoulder or pre-existing shoulder complaints with subsequent loss of function.
9. Contralateral clavicle fracture.

Preoperative evaluation

All the patients were admitted and required skeletal survey were done and other injuries ruled out. The patient were initially immobilized by Arm sling, Until the patient gets assessed for surgery.

1. History taking and physical examination.
2. Radiological: Plain x-ray of the affected shoulder AnteroPosterior view and 45 degree cephalic tilt view if needed.
3. Complete hemogram,Renal function test
4. Bleeding time and clotting time .
5. Screening for HIV, Hepatitis B & C.
6. Chest X-ray and Electrocardiogram.
7. Parts preperation for surgery.

If the patients had any other comorbidities, concerned specialist opinion are obtained prior to surgery.

Surgical procedure

After pre-anesthetic check up and fitness and fasting of 8 hours, patient was taken in operation theatre.The surgery was performed under general anaesthesia or interscleneblocks.The patient was placed on a radiolucent operating table in beach chair position with a bolster placed under interscapular region to

provide an extension of the shoulder girdle and prominence of clavicle so that the sternoclavicular joint is accessible for the entery point. The entire upper limb from midline chest to base of neck, axilla, shoulder,arm,forearmupto hand was scrubbed, painted and draped to allow free manipulation of arm and shoulder during surgery.An image intensifier was used during surgery and its camera and collimator was covered with sterile sheets. A small skin incision of around 1-2 cm was made just medial to the sternoclavicular joint and then the underlying soft tissue,fascia along with platysma was dissected. The medullary canal of the clavicle was opened using a bone awl about 1-2cm lateral to the sternoclavicular joint under image intensifier and the size of entery point was increased with an artery forceps then the awl was pointed laterally in line with the clavicle and angled at around 30° to the coronal plane. Once the medullary cavity was opened, an appropriate sized TENS nail or TENS nail with endcap (appropriate diameter and length of nail was taken by placing it over contralateral un-fractured clavicle and seeing under image intensifier) was loaded in T-handle and inserted into entery point carefully under c-arm guidance and advanced with ocillating movements till it reached the fracture site. In case of TENS with endcap the nail was advanced with 3.5mm screw driver by gentle hammering over screw driver. The curved lateral end of nail was slightly straighten before inserting into entery point. Now closed reduction achieved by direct pressure on the fragments combined with manipulations of the arm was performed or in some cases,small pointed reduction clamps/towel clips were used percutaneously to facilitate reduction.If the closed reduction was not achieved then a small nick was given either around medial or lateral fragment of fracture and a small curved artery or spike was inserted inside nick either to depress medial fragment inferiorly and anteriorly or to elevate lateral fragment superiorly and posteriorly with manipulations of arm and shoulder to achieve reduction . If still reduction was not achieved then a small skin incision (2 to 3 cm) was directly given over the fracture site for direct manipulation of fracture.Once the reduction was achieved, the nail was then passed across the fracture site until it reached just 2 cm medial to the acromioclavicular joint. The medial end of nail was cut close to the entery point leaving enough length to facilitate easy extraction.In case of TENS with endcap the endcap was screwed into medial metaphyseal end of clavicle with 3.5mm screw driver. The wound wash given, closure was done in layers and sterile dressing was done.

Postoperative protocols

Postoperatively all patients were kept NBM for 6 hours, IV fluids and IV antibiotics were given for 3 days. Above head shoulder mobilisation started from next day of surgery. Arm pouch sling was given for 2 weeks. First check dressing of wounds were done on 2nd post-op day and if found healthy, patients were discharged on same day on oral antibiotics, antacids, analgesics, calcium. Suture removal was done on 11th post op day. Rehabilitation of affected upper limb was explained to all patients.All the patients were counselled for regular follow up at 1 month, 3 months and 6 months. All the patients were examined clinically and Radiologically for implant position,fracture union and complications.Functional outcome was assessed by Constant,DASH and VAS scores.

Results:-

A total of 30 patients(25 males,5 females) included in study.The mean age was 38.06 years(18 to 60 years).In our study major mode of trauma was RTA in 22 patients(73.3%), fall from stairs in 5 patients (16.7%),fall from height in 2 patients (6.7%) and fall on ground in 1 patient (3.3%).

We classified and distributed our patients according to AO classification of clavicle fracture. Out of 30 patients,18 patientshad simple transverse/oblique fractures(15-B1) and 12 patients had wedge Comminuted fractures(15-B2).In transverse fracture out of 18 patients,16 caseswere done by CRIF and 2 cases were done by ORIF while for comminuted fracture out of 12 patients, 9 patients were operated by CRIF and 3 patients were operated by ORIF.So Out of 30 patients 25 patients were operated by closed method or mini open technique while 5 patients were operated by open method since closed reduction was not possible.Although the ORIF is quite common in comminuted fracture than transverse fracture but on comparing fracture type with reduction method using Fisher's exact test we obtained P-value 0.364 which was statically non-significant.

In 24 patients we used simple TENS and in 6 patients we used TENS with endcap.In all patients same diameter nail 2.5mm was used.

Though the mean duration of clinical union for comminuted fracture (6.41 weeks) is less than the mean duration for transverse fracture (6.89 weeks) that means the comminuted fractures clinically unite earliar

than the transverse fracture but on comparing fracture type and duration of clinical union using paired t-test we obtained P-value 0.09 which was statically not significant . On comparing fracture type and duration of radiological union we obtained P-value 0.037 which was statically significant which means **the comminuted fractures radiologically unite earlier than transverse fractures.**

Type of fracture	**Average time of clinical union (mean ±SD)(weeks)**	**Average time of radiological union (mean ±SD)(weeks)**
Transverse / oblique fracture	6.89 ± 0.76	8.50 ± 0.62
Wedge / Comminuted fracture	6.41 ± 0.67	8.00 ± 0.60
t Value	1.75	2.20
p Value	0.09	0.037
Result	Non-significant	Significant

Table1:- Co-relation of duration of union and fracture pattern.

Post operatively 23 patients had no shortening and 7 patients had shortening of 0.2 to 0.3cm with average shortening of 0.2cm. Out of 18 patients of transverse fracture, one patient had clavicular shortening and out of 12 patients of comminuted fracture 6 patients(50%)had shortening.On comparing fracture type and postoperative shortening using Z-test we obtained P-value 0.004 which was statically significant that means **postoperative shortening is more frequent in comminuted fractures.**

Out of 30 patients,implant removal was done in total 9 patients due to prominence and irritation at medial end of nail (8 patients) and infection at medial end of nail(1 patient). Implant removal was done after clinical and radiological union of fracture. Mean time for implant removal was 101 days(>3 months). Out of 18 patients of transverse fracture, two patients had nail migration and out of 12 patients of comminuted fracture,7 patients had nail migration.On comparing fracture pattern and nail migration using Z-test we obtained P-value 0.005 which was statically significant which indicates that **nail migration is more common in comminuted fractures than transverse fractures.**

Type of fracture	**No. of patients with Nail migration**	**Percent**	**Z Value**	**P value**	**Result**
Transverse / oblique fracture (18)	2	11.11%	2.76	0.005	Significant
Wedge / Comminuted fracture (12)	7	58.3%			

Table 2:– Co-relation of Nail Migration and fracture pattern.

On Comparing final Constant,DASH and VAS scores at 6 months with fracture type(transverse/oblique vs comminuted)using paired t-test we obtained P-values 0.418, 0.842 and 0.453 respectively which were statically not significant which means **statically there is no relation between fracture pattern and function outcome so we recommend TENS nail for comminuted fracture as well.**

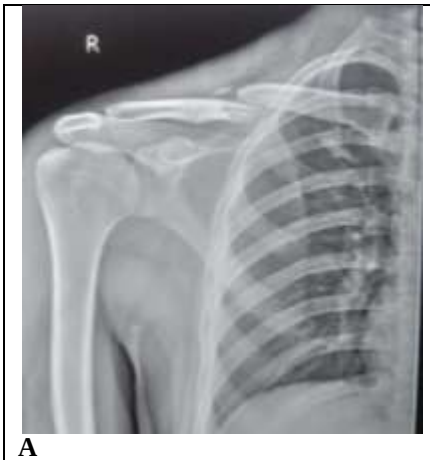
Score	**Fracture type**	**No. of patients**	**Mean**	**SD**	**t value**	**p value**
Final Constant Score	Transverse / oblique fracture	18	90.44	3.97	0.822	0.418
	Wedge / Comminuted fracture	12	91.83	5.29		
Final DASH score	Transverse / oblique fracture	18	12.39	2.75	0.201	0.842

	Wedge / Comminuted fracture	12	12.17	3.27		
Final VAS core	Transverse / oblique fracture	18	3.67	1.14	0.671	0.4
	Wedge / Comminuted fract	12	3.33	1.23		

Table 3:- Co-relation of functional outcome score and fracture pattern.

Score	Results	Constant Score	No of Patients	Percen
Constant score at 1 Months	Excellent	86 - 100	0	0%
	Good	71-85	17.00	56.67%
	Fair	56-70	13.00	43.33%
	Poor	1 - 55	0	0%
Constant score at 3 Months	Excellent	86 - 100	9.00	0%
	Good	71-85	21.00	30.00%
	Fair	56-70	0	70.00%
	Poor	1 - 55	0	0%
Constant score at 6 Months	Excellent	86 - 100	26.00	0%
	Good	71-85	4.00	86.67%
	Fair	56-70	0	13.33%
	Poor	1 - 55	0	0%

Table 4:- Results of constant score at 1 month, 3 months and 6 months.



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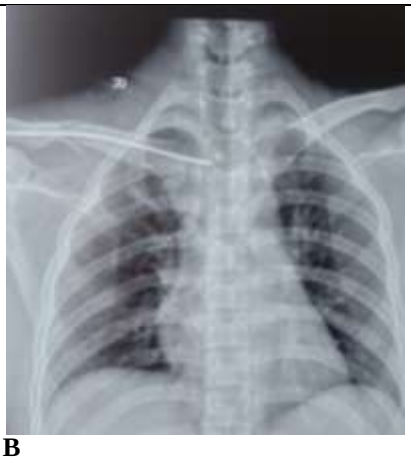

B

C

D

E

F

Fig- 1:- Radiographs A- Pre op X-ray, B-Immediate post op x-ray fracture fixed with 2.5 mm TENS , C-1 month follow up X- ray , D- 3 months follow up X- ray ,E-4 months follow up X- ray showing medial nail migration, F- After Implant removal.

S.No.	Complications	No. of patients	Management
1	Hardware Prominence or Painful hardware or Irritation at medial end	8	Implant removal under local anesthesia
8	Clavicular shortening / Malunion	7	Even with shortening of clavical patient had excellent outcome at serial followup
2	Numbess over the antromedial aspect of shoulder over operated side	5	Partially improved with oral pregabalin + methyl cobalamine
3	Infection at medial end	1	Setteled with implant removal and oral antibiotics
4	Non union (Atrophic type)	1	Under observation.
6	Skin erosion	None	-
7	Hardware breakage	None	-
8	Lateral migration of nail	None	-
9	Hypertrophic scar	None	-

Table 5:- Post- op Complications.

Discussion:-

We compared our study variables with **Genena et al.**(13) , **Idris et al.**(14), **Kenan et al**(15)., **Boktor MS et al**(16) and **khare et al**(17) studies.All five studies including our study, are prospective studies, done for management of clavicle fractures with TENS.

In our study of 30 patients, 25 were males and 5 were females, mean age was 38.06 years(ranged 22 to 60) and 16 patients had right sided while 14 patients had left sided clavicle fracture. In **Genena et al.** study of 60 patients,51 patients were males and 9 patients were females with mean age of 26.40±8.91 years.In**Idris et al** study of 30 pateints there was a male preponderance seen with the left side being more

commonly affected.Mean age was 41.3 years In **kenan AE et al.** study of 20 patients, 17 patients were males and 3 patients were females with a mean age of 26.4 years. In khare et al. Study of 33 patients,23 patients were males and 10 were females and mean age was 34 years.In**Boktor MS et al.** study of 20 patients,70% patients were males and 30% patients were females with mean age of 37.5 years.

In our study major mode of trauma was Road traffic accident(RTA)in 22 patients,fall from stairs in 5 patients,fall from height in 2 patients and fall on ground in 1 patient.InGenena et al study commonest mechanism of injury was RTA in 36 patients,followed by falling from standing height in 15 patients and direct trauma in 9 patients.In Idris et al study most common mode of injury were RTA followed by fall from height and slip and fall.In**khare et al.** study the mechanism of injury was a simple fall 23 patients,3 patients fell from height, 5 from RTA, 2 by direct trauma and 1 by sports activity.In**Boktor et al.** study 60% patients were polytraumatized and 40% isolated.

In our study close reduction/MIS was possible in 25 patients (83.3%) and in 5 patients(16.7%) we done open reduction.In**Genena et al.** study open reduction was done in 18(30%) cases out of the 60 cases after failed close reduction of the fracture.In**Boktor et al**. study intraoperatively 60% of patients had closed reduction and 40% needed open reduction.In**Khare et al.** study closed reduction was possible in 21 cases and a short incision of about 2cm above the fracture site was necessary to obtain fracture reduction in 09 patients.

In our study mean duration of surgery was 31.67 minutes (Range: 20 to 50 min). Mean duration of surgery for ORIF was more than CRIF .In **Idris et al.** study the average surgical time was 57 minutes ranging from 45 to 65 minutes.In**Boktor et al.** study mean Operative time was 32.4 minutes with min-max 27-40 minutes.In**khare et al** study mean operation time was 38 minutes (Ranges 30 min to 90 min.). Operation time was much shorter when closed reduction was successfully compared with the open technique 39 minutes (Range 20 to 60) vs 84 minutes (Range 37to90).

In our study mean duration of clinical union was 6.7 weeks and radiological union was 6.93 weeks.In**Genena et al.** study time of union in the patients ranged from 8 weeks to 12 weeks with a mean 10.0±1.33 weeks with an exception of 3 cases which presented with hypertrophic non-union.In**Idris et al.** study the mean time to fracture union was 12.16 weeks ranging from 9 to 14 weeks and 100% union was achieved in their series.In**Boktoret al.** study mean time to union was 13.4 months with mi.-max 10-16 months.Inkenan AE et al. study time of union in studied patients ranged from 8 to 12 weeks with a mean 10.0±1.33 weeks with an exception of one case presentation with hypertrophic non-union. In **khare et al.** study time to union was 7.7 weeks (range:4 to 12) determined by visible osseous callus formation on the radiographs.

In our study mean duration of return to daily activities was 3.38 weeks and professional activities was 6.93 weeks. In **khare et al.** study all patients returned to their activities within 4 weeks after the procedure.

In our study 7 patients(23.3%) had shortening of 1 to 3mm with average shortening of 2mm. Although intramedullary nailing in comminuted fractures can lead to telescoping of the clavicle and fracture heals with shortening of clavicle and this shortening doesn't impaire the functional outcome of the patient hence we recommend intramedullary nailing in comminuted clavicle fracture as well. In **khare et al.** Clavicular Shortening was 1.7mm (range 0 to 7mm) campared with the contralateral side measured after fracture healing.

In our study final constant score was 91±4.51 and 26 patient had an excellent result and 4 patient had good result.In**Genena et al.** study final constant score was 95.70±13.55 and 54 patients had an excellent result, 3 patient had an adequate result and 3 patients had poor result.In **Idris et al.** study average Oxford shoulder score was 46.4 ranging from 36 to 49 while quickDASH score was 6.9 ranging from 2 to 14.2.In **Boktor MS et** al. study the mean Quick DASH score was 8.6 and mean Oxford score was 41.8.In **kenan AE et al.** study final constant score after 6 months was 95.70±13.55. 14 patients had excellent results,4 patients had good results.In**khare et al.** study the mean constant score was 96(Range 85 to 100) after 4 months, all patients presented with basically normal shoulder function (Mean :98,range 93 to 100).

In our study implant removal was done in 8 patients due to excessive prominence and irritation at medial end of nail and in 1 patient implant removal was done due to infection at medial end of nail which resolved with oral antibiotics and 1 patient presented with nonunion.InGenena et al. study 6 patients (10%) developed medial end skin irritation,one patient had to have the nail removed and in another the nail had to be shortened while the others resolved within 2 weeks of medical treatment,6 patients (10%) presented with dorsolateral migration of the nail which was followed up until removal of nail and 3 patients presented with nonunion which was revised with plate.In**Idris et al**. study nail removal was performed for 28 patients 6 months after clinical and radiological union of the fracture while 2 patients refused metal exit.One patient developed a superficial infection which resolved with antibiotics and one patient developed hypertrophic scar. In **Kenan AE et al.** Study one(5%) patient developed an incisional infection and 2 patients (10%) developed medial end skin irritation,one of them had to remove the nail,while the other improved within 2 weeks of medical treatment.Furthermore, 2 patients (10%) presented with dorsolateral migration of nail,which was followed up until nail removal.One patient (5%) presented with hypertrophic nonunion and had to revised by plating. In **khare et al.** study two infection and no migration of the nail was observed.Both case of infection were treated by surgical site debridement but in one case infection was not controlled and treated by early implant removal at 5^{th} weeks at that time fracture was united.Hardware prominence at medial aspect was noted in 9 cases that is due to fracture site collapse and managed by trimming of protrubentpart.Two cases observed with hypertrophic callus formation that were managed by proper assurance.

Conclusion:-

The intramedullary fixation of displaced clavicle fracture is a safe minimally invasive technique. The intramedullary nailing holds advantages of high union rate, minimal periosteal stripping and soft tissue damage, minimal blood loss and relatively less complications. This technique provides faster return to daily and professional activities with comparable functional results. Implant removal is easier and can be done as day care procedure under local anesthesia.

The most common complication of intramedullary nailing is hardware prominence/irritation at medial end either due to an insufficient cut of the TENS or due to secondary shortening/telescoping of the clavicle especially in comminuted fracture. Use of our designed TENS with endcap is devoid of this complication. Endcap also stops the movement of the nail in the entry point (rotatory stability) especially in the backing out direction. Sensory loss or numbness over anteromedial aspect of shoulder over operated side is quite common complication if we do open reduction internal fixation of clavicle fracture. It is due to injury to the branches of supraclavicular nerves.Open reduction internal fixation of fracture is quite common in comminuted clavicle fracture.

The results of intramedullary nailing in transverse or oblique clavicle fracture are excellent hence we highly recommend intramedullary nailing in these fractures.Although intramedullary nailing in comminuted clavicle fracture can lead to nail migration, telescoping and shortening of clavicle and increase need of open reduction but the final outcome of the patient is excellent at serial follow up hence we recommend intramedullary nailing in comminuted clavicle fracture as well. Endcap elastic nail is better in most closed clavical fractures as it has no implant prominance like plate or tip irritation like k-wires and other nails.

Limitation

The primary limitation of our study was that it was a small prospective study including a small number of patients due to Covid-19 pandemic and done at a single center.Larger randomized controlled trials are needed to further evaluate and validate the outcomes and complications of intramedullary nailing in displaced clavicle fracture.

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