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Research Paper

RANDOMIZED CONTROLLED TRIAL COMPARING OUTCOME OF LIMITED CONTACT LOCKING COMPRESSION PLATE WITH LIMITED CONTACT DYNAMIC COMPRESSION PLATE FOR BOTH BONE FOREARM FRACTURES IN ADULTS

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ABSTRACT

OBJECTIVES: Forearm shaft fractures are often referred to as being frequent fractures. It comprises of 0.8 % of all fractures. The chances for the occurrence of malunion and non-union are greater. Cortical porosis and refractures were considered secondary to excessive plate-bone contact in DCPs that interfered with cortical perfusion has not been completely resolved by LC-DCP. This study compares the outcomes of limited contact locking compression plate (LC-LCP) with limited contact dynamic compression plate (LC-DCP) for the treatment of adult diaphyseal both bone forearm fractures.

METHODS: The study was conducted in the Department of Orthopedics, B.P. Koirala Institute of Health Sciences, a tertiary care hospital in Eastern Nepal, over a period of fifteen months from June 2015 to August 2016. Ethical clearance was taken from the Institutional Review committee (IRC). Study design was randomized controlled. Patients in group A treated with ORIF with LC-LCP and in group B treated with ORIF with LC-DCP.

RESULTS: Mean union time did not differ significantly in the LC-LCP and LC-DCP group (8.40 and 10.00 days respectively, p-value 0.292). There was no difference in functional outcome as per Anderson criteria between two groups. Patient rated outcome as per DASH score did not differ significantly between both the groups (p-value 0.69). One patient in the LC-DCP group developed deep surgical site infection.

CONCLUSION: our study showed that there was no significant difference between two groups in terms of reduction technique, mean operating time, union time and final functional outcomes.

KEYWORDS

diaphyseal, forearm, limited contact locking compression plate, limited contact dynamic compression plate.

INTRODUCTION

Forearm shaft fractures are often referred to as being frequent fractures. It comprises of 0.8 % of all fractures. The average yearly incidence in adult's male (16-35yrs) and adults' female (16-35 yrs.) have been reported to be 1.2 % (20.9 per 10, 0000 populations) and 0.6 % (4.2 per 1, 00,000 population) respectively.[5]

Treatment by closed reduction and cast immobilization results in a poor functional outcome with unsatisfactory results reported in up to 92% of cases, usually caused by malunion, nonunion or synostosis.[13] Open reduction and internal fixation (ORIF) with plates and screws is considered the gold standard of operative treatment of forearm fractures which allows removal of soft tissue interposed at the fracture site and anatomic reduction of the fracture, thereby allowing restoration of the radial bow and the normal spatial arrangement of the ulna and radius and if required, bone grafting can be performed.[23]

In conventional plating (DCP), the actual stability results from the friction between the plate and the bone, which in turn may prevent periosteal perfusion resulting in cortical porosis and refractures. [17,20]

The limited contact dynamic compression plates (LC-DCP) is said to reduce the bone-plate contact by approximately 50% to minimize the disruption of periosteal blood vessels beneath the plate but it still relied on the plate-bone interface for stability and the problem of confluent contact areas was not completely resolved.[6,10]

Locking compression plate (LCP) in which concepts of DCP, PC-Fix and LISS were merged offers advantages over other plate system such as minimal surgical incision, preservation of blood supply to bone and adjacent soft tissue, angular stability, better fixation of osteoporotic bone, contouring of plate is not required to fit the bone. [13] However, LCPs have some disadvantages, including difficulties during removal and a higher cost.[2]

LCP has many advantages over LC-DCP for fixation of both bone forearm fracture in adult but reports on the results of clinical application of LCP are few. The aim of this study was to compare the advantage of LCP over LC-DCP for treatment of adult diphysial forearm fracture in terms of union time, functional outcome, patient outcome, complications amongst patients treated with locking compression plate and limited contact dynamic compression plate.

MATERIALS AND METHODS

SETTING:

The study was conducted in the Department of Orthopedics, B.P. Koirala Institute of Health Sciences, a tertiary care hospital in eastern Nepal, over a period of fifteen months from June 2015 to August 2016. Ethical approval was taken from the Institutional Review committee (IRC) of BPKIHS prior to conduction of the study.

INCLUSION CRITERIA:

- All Adult diaphyseal fracture both bone forearm fracture
- Closed and Gustilo grade I Open fracture

EXCLUSION CRITERIA:

- Pathological fracture
- Polytrauma
- Compartment syndrome
- presence of distal neurovascular deficit
- Unfit and unwillingness to participate in surgery

SAMPLE SIZE:

By taking account of this study where primary outcome is union time,

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we could not find any literature having union time providing standard deviation at the time conducting this study. Based on medical record of year 2014 at BPKIHS where total number of cases of both bone forearm fracture in adult were approximately 30 patients. Hence expecting same number of case in 2015 sample size were estimated 15 cases in each group which were allocated using www.randomization.com using two blocks were included in this study.

Group- A (ORIF WITH LCP) - 15 cases.
Group- B (ORIF WITH LC-DCP) – 15 cases.

INTERVENTIONS;
Adults patients with both bone forearm fracture presented to BPKIHS were evaluated through general physical and systemic examination, plain X-ray of forearm including wrist and elbow joint (AP and Lateral view) was obtained. Injured limb was splinted. Once the general condition of the patient was stabilized, definitive treatment was planned after Pre anesthetic evaluation was done by anesthetist.

IN GROUP A:
Surgery was performed under general or regional anesthesia. Patients were set up in the supine position on the operating table. Prophylactic antibiotic IV 2nd generation cephalosporin and amino glycosides was given. A tourniquet was used to diminish blood loss and was deflated after no more than 90 minutes. The radius was exposed through the anterior Henry approach when the fracture was on the lower two-third or through the dorsal Thompson approach when the fracture was on upper third. The ulna was exposed through the postero–medial subcutaneous surface. Fracture reduction achieved and in the simple transverse fractures a conventional screw was inserted to secure the plate on to the bone temporarily followed by another conventional screw in the opposite fragment proximal and distal to fracture fragment respectively to achieve compression, locking head screws were used for the rest of the screw holes. In the oblique fractures, fracture reduction achieved and lag screw technique was used to achieve interfragmentary compression using the hole on the plate, the locking screw was placed in the other holes. In the comminuted fractures length and alignment was obtained followed by appropriate length of plate was selected and only locking screw is used to bridge the fracture. When fracture was on distal third level LCP applied on volar aspect and when fracture was on proximal third LCP applied on dorsal aspect. During the operation, the fracture reduction was visualized. After fracture fixation wound closure, wound dressing was done and upper limb was kept on above elbow plaster of Paris slab. Post op antibiotic for seven days and adequate analgesia was considered.

GROUP B:
Surgery was performed under general or regional anesthesia. Patients were set up in the supine position on the operating table. Prophylactic antibiotic IV 2nd generation cephalosporin and amino glycosides was given. A tourniquet was used to diminish blood loss and was deflated after no more than 90 minutes. The radius was exposed through the Anterior Henry approach when the fracture was on upper third or through the dorsal Thompson approach when the fracture was on upper third. The ulna was exposed through the postero – medial subcutaneous surface. Fracture reduction achieved and two compression screws were inserted proximal and distal to the fracture,followed by the insertion of other conventional screws. When fracture was on distal third level LC-DCP applied on volar aspect and when fracture was on proximal third LC-DCP applied on dorsal aspect. During the operation, the fracture reduction was visualized. After fracture fixation wound closure, wound dressing was done and upper limb was kept on above elbow plaster of Paris slab. Post op antibiotic for seven days and adequate analgesia was considered.

Patients were discharged on second post op day depending upon the condition of the patient. Then patients were followed on fourteen post-OP day, wound were assessed for local feature of infection, suture removal were done, range of motion (elbow, supination-pronation of forearm and wrist) were assessed and were advised for continuing active and passive mobilization of joints and fingers. Then patients were then followed up at sixth weeks, twelve weeks, eighteen weeks and at twenty-four weeks. Union and functional outcome were assessed using Anderson criteria. The patient rated outcomes were assessed using the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Complications were evaluated in terms of infections (superficial or deep or chronic osteomyelitis), synostosis, implant loosening, secondary loss of reduction, implant breakage, re-fracture, and fracture at the end of the plate and fracture through the compression hole.

STATISTICAL ANALYSIS:
Consecutive sampling technique was applied. The data was collected in Microsoft EXCEL 2012 and analysis done in SPSS data sheet Version 11.5. Proportion, measure of central tendency and dispersion of continuous variables like age, sex, involved limb, mode of Injury, interval between injury and surgery was tested by appropriate parametric and non-parametric statistical technique (e.g. t-test or Mann-Whitney test. Chi-square test was used for categorical data like socio-demographical variable with graphs. Outcome at various follow up intervals were compared between two groups and both magnitude and significance of difference was measured using appropriate tests. The results were compared with other relevant studies in the literature and consensus view presented comparing cost and complication rate between the two groups.

Table. 1 showing pre-operative variables

Variable		Group		P-value
		LCP	LC-DCP	
Gender	Male	9	4	0.65
	Female	6	11	
Age (Mean ±S.D.) yrs.	35±15.29	35±16.39	0.98	0.70
Side	Right	5	6	
	Left	10	9	
Mode of injury	Fall from height	7	2	0.02
	RTA	6	4	
	Fall on ground	2	9	
Nature of fracture	closed	13	11	0.65
	open	2	4	
Level of fracture	proximal	1	3	0.33
	Middle	11	10	
	Distal	1	2	
	Different level	2	0	

RESULTS
Initially 38 patients were assessed for eligibility for our study. Eight patients were excluded from our study not meeting inclusion criteria. Total 30 number of patients were randomised into two groups LCP and LC-DCP group ,each group consisting of 15 patients.

Table. 1 showing pre-operative variablesThe time required for LCP fixation (fig. 4) (Mean ±SD; 80.67±12.22 min.) in comparison to LCDCP fixation (fig.2) (Mean ±SD; 80.33±15.17 min.) was found to be not significant (Independent Sample T -test, p value 0.94).

Table. 2 showing union time

Variable	Group		P -value
	LCP	LC-DCP	
Union time (Mean± SD) in weeks	13.20±2.48	16.00±4.89	0.058

Table.3 showing functional outcome

Functional outcome	LCP	LC-DCP	P -value
Excellent	15	14	NA
Unsatisfactory	0	1	

The mean ranges of elbow, forearm supination-pronation, wrist joint movements in the LCP groups were 141.33, 151.33, 147.33, respectively, while they were 142.00, 150, 150.33 , respectively at six months follow up. But this time difference was not significant (Independent Sample T -test, p value 0.60).

We had excellent functional outcome in 29 patients, one patient in LC-DCP group had unsatisfactory functional outcome due to deep surgical site infection but the difference between the two groups as per Anderson et al (1975) criteria is not significant (Fisher's exact test, p value 1.00).

fig. 1 both bone forearm fracture

fig. 2 both bone forearm fracture fixed with LC-DCP

fig. 3 both bone forearm fracture

fig. 4 both bone forearm fracture fixed with LC-LCP

The Quick Dash score at sixth month was considered to assess the outcome subjectively. The raw score ranged from 0 to 32.5 in LCP group and 0 to 32.40 in LC-DCP group. The difference between the two groups was statistically not significant (P > 0.05).

One patient in LC-DCP group has developed deep surgical site infection at fourteen day follow up and was treated with wound debridement and IV antibiotics and wound persisted for three months' post-op and was resolved on subsequent follow up with local wound care. The difference between both groups was statistically not significant (P>0.05).

DISCUSSION

Open reduction and internal fixation (ORIF) with plates and screws is considered the gold standard treatment for forearm fractures.[23] In conventional plating (DCP), the actual stability results from the friction between the plate and the bone, which in turn may prevent periosteal perfusion.[20] Locking compression plate (LCP) offers advantages over other plate system such as minimal surgical incision, preservation of blood supply to bone and adjacent soft tissue, angular stability, better fixation of osteoporotic bone, contouring of plate is not required to fit the bone.[13] But there is few literatures comparing LCP with LC-DCP.

In current study, the mean age of fracture at time of surgery in LCP group was 4.67 days, range being one to 21 days while it was 4.87 days in LC-DCP group, range being one to 16 days. This data is similar to study of Meena et al.[14]

In current study the mean operative time was 80.67 minutes (S.D.±12.288, range 60-90 minutes) in LCP group, while in LC-DCP group mean operative time was 80.33 minutes (S.D.± 15.17, range 60 – 105 minutes). The difference between both groups was statistically not significant (P>0.05). This data is similar to reported literatures.[14,20]

In current study mean union time for the forearms fixed with LCP was found to be 13.2 weeks (S.D.±2.48, range 12–18 weeks) in comparison to 16 weeks (S. D±4.899, range 12-24 weeks) for the LC-DCP group. The difference between the two groups was statistically not significant (P >0.05). This data is similar to study of Meena et al[14] where they have reported mean time for union for the forearms fixed with LCP was 13.90 weeks (range 8 – 18 weeks) in comparison to 16.80 weeks (range 14-24 weeks) for the LC-DCP group, Saikia et al[20] reported the mean time for union for the forearms fixed with LCP was 14.16 weeks (range 8-21 weeks) in comparison to 16.27 weeks (range 10-29weeks) in the LC-DCP groups, Sharma et al[22] in their study of forearm bone fractures fixed by locking compression plate (LCP) reported mean union time of 12.6 weeks (range 8-24 weeks).

The mean ranges of elbow, wrist joint and pronation–supination movements in the LCP group were 141.33, 147.33 and 151.33° respectively, while they were 142, 150.33 and 150°, respectively, for the LC-DCP group. The difference between two group was statistically not significant (P >0.05). This data is similar to study of Saikia et al[20] where they have reported mean ranges of elbow, wrist joint and pronation–supination movements in the LCP group were 146.9, 147.77 and 145°, respectively, while they were 141.4, 140.55 and 141.66°, respectively, for the LC-DCP group. Leung and chow[11] in their study reported full ROM in 74 % of cases and slightly affected in 26 % of cases.

In current study, one patient (6.7%) in LC-DCP group has developed deep surgical site infection at fourteen day follow up and was treated with wound debridement and IV antibiotics and wound persisted for three months' post-op and was resolved on subsequent follow up. This data is similar to study of Saikia et al[20] where they have reported superficial infection 11.11 % in LC-DCP group and deep infection 5.55% in LCP group, Azboy et al[2] reported superficial infection in 9.09% of patients in the LCP group and five percent of patients in the DCP group.

One patient (6.7%) in LC-DCP group had unsatisfactory functional outcome due to restricted wrist ROM, 14 patients have (93.3%) excellent functional outcome. However, all 15 patients (100%) in LCP group had excellent functional outcome. This data is similar to reported literatures .[4,14,20.]

The Quick Dash score at sixth month was considered to assess the outcome subjectively. The raw score ranged from 0 to 32.5 in LCP group and 0 to 32.40 in LC-DCP group. The difference between the two groups was statistically not significant (P > 0.05). This data is similar to study of Meena et al[14] where they have reported raw score ranged from 0 to 24.00 in LCP group and 0 to 33.40 in LC-DCP group. Saikai et al[20] observed that the raw score ranged from 0 to 22.32 in the LCP group and 0 to 44.44 in the LC-DCP group. Overall, the patients were satisfied with the outcomes in both the groups.

The strength of this study is that the follow up assessment of every patient was done by the same doctor during the entire study period.

The limitations of the study are small sample size study from a single center hence significant conclusions could not be drawn and shorter duration of follow up.[13]

CONCLUSION

Our study showed that there is no significant difference in terms of union time, ROM (elbow, supination-pronation and wrist), functional outcome, and patient rated outcome, infection between LCP and LC-DCP in treatment of adult diphysial forearm fracture. However, another RCT with larger sample size and longer follow-up will be needed to validate the findings of this study.

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