Original Article

Complications of NA External Fixator and Related Factors: A Retrospective Cohort Analysis in Tibial Non-union Patients

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Objective: To determine the complications of NA external fixator and their predictors/related factors in tibial non-union patients in a tertiary care hospital, Lahore, Pakistan.

Methods: This was retrospective cohort analysis conducted in the Department of Orthopedics, Mayo hospital, Lahore on the data of the patients who followed from July 2002 till June 2012. Patients with tibial non-union of any age groups with both open and closed fractures were included.

Results: Out of total of 144 patients, 61.8% had complications of external fixator: 44.8% (n=39) had loosening of pin, 34.5% (n=30) had loosening of clamp, 17.2% (n=15) had breaking of pin, and 3.4% (n=3) had breaking of clamp. The occurrence of the complications had statistically significant association with age groups (p=0.009), presence of skin lesion (p=0.000), bone grafting (0.031), no leg length discrepancy (p=0.000), and skin reactions to pins (p=0.000). The occurrence of the complications had no significant association with gender (p=0.440), presence of comorbid disease (p=0.728), side involved in fracture (p=1.000), and mode of reduction of fracture (p=0.074).

Conclusions: Fixator complications were seen commonly in tibial non-union patients managed with NA external fixator. Among different complications, loosening of pin was most prevalent followed by loosening of clamp, breaking of pin, and breaking of clamp. Middle age group of patients was more prone to the complications of fixator. Co-existing skin trauma and bone grafting predict the subsequent occurrence of complications of external fixator. Similarly, no leg length discrepancy and skin reactions to pins also had a positive statistical correlation with complications of fixator. However, gender, coexisting systemic diseases, site of fracture, and mode of reduction of fracture had no statistically significant association with occurrence of the complications of the fixator.

Keywords: external fixation, NA fixator, tibial non-union, complications of fixator, SPSS

Introduction

External fixation[1] is a surgical treatment used to stabilize bone and soft tissues at a distance from the operative or injury focus. In an external fixator, metal pins and clamps are placed into the bone through small incisions into the skin and muscle. The pins and clamps are attached to a bar outside the skin.[2] Tibial nonunion[3] is an arrest in the fracture repair process, where fracture still is unable to unite usually by 6-9 months post-injury. It occurs most commonly due to inadequate fracture stabilization and poor blood supply.[4] Cigarette smoking is a known risk factor.[5] In a large series, the prevalence of tibia shaft nonunion was 12%.[6] Nonunion can be classified as atrophic, hypertrophic or infected depending upon its pathophysiology.[7] External Fixators are frequently used in the management of non-union tibial fractures especially infected nonunions.[8] Naseer Awais (NA) external fixator was invented by Professor Muhammad Awais in 1980 and is common in practice in our hospitals. There are multiple complications associated with the use of external fixators, where pin track sepsis is most common one.[9,10] Our study will discuss prevalence of the different complications of NA external fixator like pin loosening, clamp loosening, pin breaking and clamp breaking, about which nationally and internationally data was scarce. Our study will also provide the predictors of these complications in tibial nonunion patients among Pakistani population.

Methods

This retrospective cohort11 study was conducted in the Department of Orthopedics, Mayo hospital, Lahore on the data of the patients from July 2002 till June 2012. Patients with tibial non-union of any age

groups with both open and closed fractures were included. The data of the patients without complete follow up was excluded. Non-union was defined by non-healing at 9 months of management of the fracture.3 The complications of the external fixation including pin loose, pin break, clamp loose and clamp break were noted till the time healing achieved or persistent nonunion was documented. The age of the patients was categorized into childhood if < 13 years, adolescence if 13-18 years, young adults if 19-44years, middle aged adults if 45-65 years, and older adults if >65 years.12,13 Gender of the patients, comorbid systemic disease like hypertension, diabetes and ischemic heart disease, side of fracture, coexisting skin trauma, mode of reduction of fracture, bone grafting, leg length discrepancy (LLD), and skin reaction to pins of fixator like erythema and purulent discharge were also noted.

Statistical analysis was completed using the Statistical Package for Social Science (SPSS), version 25. Age of the patients was the only quantitative variable, while gender, age groups, coexisting systemic disease, side of the fracture, coexisting skin trauma, mode of reduction of fracture, bone grafting, LLD, and skin reaction to pins were the qualitative variables. Frequencies and percentages were computed for qualitative variables, while mean and standard deviation was calculated for quantitative variable. The chi-square test14 was applied on the data and p-values were considered as statistically significant if < 0.05. Odds ratios15 with 95% confidence interval for predictors of complications of external fixator were also calculated.

Results

Out of total of 144 patients, 61.8% had complications of external fixator: 44.8% (n=39) had loosening of pin, 34.5% (n=30) had loosening of clamp, 17.2% (n=15) had breaking of pin, and 3.4% (n=3) had breaking of clamp **(Fig-I)**. The age of patients ranged from 2-80 years, with a mean value of 35.06 + 17.89 years. 61.9% (78 out of 126) males & 50% (9 out of 18) females suffered complications of the fixator. The association between gender and the occurrence of the complications of fixator was not statistically significant (p=0.440). Amongst different age groups, fixator complications were most prevalent in middle aged adults. 20% children, 50% adolescents, 64.3% young adults, 72.7% middle aged adults, and 50% older adults suffered complications of the fixator. The association between age groups and the occurrence of the complications of fixator was statistically significant (p=0.009). 68.4% (78 out of 114) patients who had coexisting skin trauma (i.e. open fracture) and only 30% (9 out of 30) patients without coexisting skin trauma (i.e. closed fracture) faced the complications of fixator. The association between coexisting skin trauma and the occurrence of the complications of fixator was statistically significant (p = 0.000). 77.8% (21 out of 27) in which bone grafting was performed and 56.4% (66 out of 117) patients without bone grafting faced the complications of fixator. The association between bone grafting and the occurrence of the complications of fixator was statistically significant (p=0.031). 43.5% (30 out of 69) patients with LLD and 76% (57 out of 75) patients with no LLD suffered complications of the fixator. LLD had a statistically significant negative association with the occurrence of the complications of fixator (p=0.000). 74.3% (78 out of 105) patients with skin reactions to pins of fixator and 23.1% (9 out of 39) patients with no skin reactions to pins suffered complications of the fixator. The skin reactions to pins had a statistically significant positive association with the occurrence of the complications of fixator (p=0.000). However, the associations between the complications of fixator and coexisting systemic disease (p=0.728), side involved in fracture (p=1.000), and mode of reduction (p=0.074). were statistically insignificant. **(Table 1)**

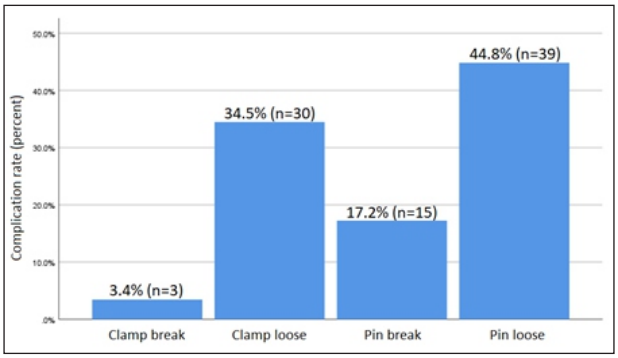

Fig-1: Complication of external fixator in non-union tibial patients (n=87/144).

Discussion

External fixation was widely used in the early part of the 20th century[16] but fell into disregard later with advent of new internal fixation devices. Its use is popular again, however there were several questions

Table-1: *Statistical correlation between Predictors and complications of external fixator in tibial nonunion patients (n = 144)*

Predictors/Factors		Complications No.	No.	Total	P-value	Odd ration with 65 confidence interval
Alternatess	Male	78 (61.9%)	48 (38.1%)	126	0.440	1.625 (0.6.3-4.38)
	Female	9 (50.0%)	9 (50.0%)	18		
Cyanosis	Childhood	3 (20.0%)	12 (80.0%)	15		
	Adolescence	53 (50.0%)	3 (50.0%)	06		
	Young adults	54 (64.3%)	30 (27.3%)	84		*
	Middle age adults	24 (72.7%)	9 (27.3%)	33		
	Olders adults	3 (50.0%)	3 (50.0%)	06		
Comorbid systemic disease	Yes	33 (57.9%)	24 (42.1%)	575	0.728	0.840 (0.4425-1.661)
	No	54 (62.0%)	33 (37.9%)	87		
Side of lesion	Right	60 (60.6%)	18 (40.0%)	99	1.000	1.026 (0.499-2.107)
	Left	27 (60.0%)	18 (40.0%)	45		
Skin trauma	Yes	78 (68.4%)	36 (31.6%)	114	0.000	5.056 (2.107-12.128)
	No	9 (30.0%)	21 (70.0%)	30		
Mode of reduction	Open	66 (64.7%)	36 (35.3%)	102	0.074	1.833 (0.885-3.0799
	Closed	21 (50.0%)	21 (50.0%)	42		
Bone graft	Yes	21 (77.8%)	6 (22.2%)	27	0.031	2.705 (1.017-7.1193)
	No	66 (56.4%)	21 (43.6%)	117		
Leg lenght discreppancy	Yes	30 (43.5%)	39 (56.5%)	69	0.000	0.243 (0.119-0.495)
	No	57 (76.0%)	18 (14.0%)	75		
Skin reaction to pin	Yes	78 (74.3%)	27(25.7%)	105	0.000	(4.059-22846)
	No	9 (23.1%)	30 (76.9%)	39		

** Odd ratio can only be computed for 2 X 2 tables*

and problems with its use. International review suggests that pin loosening is a major concern in external fixation of fractures.[17] Pin loosening is usually the sequalae of the pin site infection.[18] In our study, pin loosening was the commonest complication, seen in and breaking of clamp. In our study, we divided the age of the patients in 5 groups,[12,13] and the complications of fixator were most prevalent in middle age group of patients. Such comparison was not performed ever before, so larger studies are required to validate the findings.

A fracture in which there is an open wound or break in the skin near the site of the broken bone is called an open fracture.[19] Studies shows that skin trauma increases risk of external fixators complication in tibia fracture.[20] Similarly, in our data, it was seen that co-existing skin trauma increases 5 times the risk of complications of external fixator (Odd ratio= 5.056). When, we compared the bone grafting with the occurrence of complications of external fixator, the Odd ratio with 95% Confidence interval was 2.705 (1.017-7.193). Hence, bone grafting increases the chance of the complications of external fixator approximately 2.7% in our population. This finding is of importance that the need of the grafting should be minimized to avoid the complications of the fixator. Our data also showed a positive correlation between the complications of external fixator and LLD and skin reactions to pins.

On the other hand, no correlation was seen between the complications of the fixator and multiple other factors/predictors like gender, coexisting systemic diseases, side of fracture, and mode of reduction of fracture. However, it is suggested that studies with larger data should be planned to validate all these findings.

Conclusion

Fixator complications were seen commonly in non-union tibia patients managed with NA external fixator. Among different complications, loosening of pin was most prevalent followed by loosening of clamp, breaking of pin, and breaking of clamp. Middle age group of patients was more prone to the complications of fixator. Co-existing skin trauma and bone grafting predict the subsequent occurrence of complications of external fixator. Similarly, no leg length discrepancy and skin reactions to pins also had a positive statistical correlation with complications of fixator. However, gender, coexisting systemic diseases, side of fracture, and mode of reduction of fracture had no statistically significant association with occurrence of the complications of the fixator.

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