Original Article

The Prognosis of Surgical Site Infection Post Osteosynthesis of Long Tubular Bones

Ehsan ul Haq, Shafqat Wasim Ch. Maryam Jamill and Ali Raza Hashmi

Objective: To identify risk factors for the development of SSI post osteosynthesis of long tubular bones with diaphyseal fractures, assess them in quantitative terms to form a risk group.

Methods: Cohort retrospective-prospective study. Inclusion criteria: patients with fracture of long tubular bone (LTB) post metalosteosynthesis (MOS), duration (2011-2016), location in our department*. Exclusion criteria: death or loss of communication with the patient in less than 12 months post intervention. A retrospective analysis of data on 179 patients who underwent MOS of LTB with diaphyseal fractures was performed. Data on 144 patients who underwent MOS without surgical site infection (SSI) were compared with data of 35 patients who had SSI within one year post operation. The method of sequential analysis was applied.

Results: When studying the data on the retrospective group, a database was created that became the basis for the development of a mathematical prognosis for the development of local infectious complications in patients who underwent MOS of LTB with diaphyseal fractures. 18 criteria for the prognosis of the development of SSI were determined. Sensitivity 94.29%.

Conclusions: In the prospective study (117 cases), the established prognosis program have been tested. As a result of monitoring patients, the incidence of SSI decreased from 19.6% to 9.4%.

Keywords: long tubular bones, diaphyseal fracture, metalosteosynthesis, surgical site infection, prognosis.

Introduction

Post traumatic fractures of long bones of extremities take the leading place in trauma in the last decades. According to different authors, it varies between 16.7% to 49.8% among all musculoskeletal injuries.[1] At the same time open fractures have been found in 10 - 18% of among all fractures of the long tubular bones (LTB).[2] Local infection rate in the early post-operative period post metalosteosynthesis (MOS) of long bones is 2 - 12%, reaching 55.9% in case of open fracture of tibia/fibula.[3,4] The deep infection rate at surgical site has been observed between 1.3% - 4.0%, at the same time it has reached 22.6% in victims with open fractures of a tibia.[4,5] In recent years there were a significant amount of the publications addressed to the question of prognosis in trauma and orthopedics.[6,7] In literature data can be found concerning infection at surgical site in treatment of fractures of long bones of extremities.[8-10] At the same time, authors have no single point of view at the type and ponder ability of prognostic criteria, and data on the capacity of such a prognosis are contradictory. In this regard, the study of aspects related to the development of methods for predicting SSI post MOS of LTB can be considered an actual topic of scientific medical research. The aim of the study was to identify the risk factors for the development of SSI occurred post MOS of LTB in diaphyseal fractures, assessing them in quantitative equivalent for the formation of a risk group.

Methods

The study was carried out with permission of the Bioethics Committee. Metallosteosynthesis with diaphyseal fractures of long tubular bones at the Department of Orthopedics* (herein after referred to as «the clinic») was conducted in 2011-2016 in 347 patients. Patients were divided into two study groups: a retrospective (230 patients who underwent MOS in 2011-2014) and a prospective (117 patients who underwent MOS in 2015-2016). In retrospective group average age of patients was 56.8 ± 18,2 (from 18 to 90 years),mortality rate 2.6% (6 cases). 224 patients were discharged from the clinic. Within one year, long-term results were evaluated in 179 (79.9%) patients. In 45 (20.1%) patients 12 months post intervention the results could not be assessed due to loss of communication with them or in case of their death.` Preoperative preparation and prevention of infection at the surgical site was carried out in retrospective group as a standard procedure. In these 179 patients,

Dynamic compression plate (DCP) was performed in 90 (50.3%) cases, IM nail - in 52 (29.1%) patients. External fixator was performed in 32 cases (17.8%). In 5 (2.8%) cases, other types of MOS were used (K-Wires, cerclage, screws, etc.) (**Table-1**). Within one year after the operation, local infectious complications were detected in 35 (19.6%) cases, with a deep infection noted in 10 patients (5.6%). Both superficial and deep infection in the field of surgical intervention were considered.[11]

In retrospective group allocated 2 subgroups: I patients who had no infection in the operation area (144 patients) within 12 months after the intervention and II - patients with superficial and deep infection in the operation area (35 patients).A comparative analysis of the data on these two subgroups of the retrospective study was carried out using the method of A. Wald (1960)[12]. At the same time, both the risk factors for the infection at the operation site and their quantitative equivalent were determined. Based on these values the risk of development of infection, identified retrospectively, a model was developed for predicting the course of the postoperative period in patients after MOS of long tubular bones. To assess the diagnostic effectiveness of the model (according to the data of the retrospective group), the sensitivity (Se) and specificity (Sp) were determined, and the positive and negative predictive value of the test was assessed using the program: Medcalc.org/calc/diagnostic-test.php. Prospective group received preoperative preparation taking into account the prognosis and the developed algorithms. Clinical implementation of the prognosis of infection in the wound area after MOS of long tubular bones was performed in 117 patients from the prospective group. The method of sequential analysis allows to carry out the forecast at all stages of treatment, including an incomplete set of characteristics. According to this method, in the presence of A and B states characterized by the same symptoms, by sequentially summing the logarithms (l) of the probability of occurrence of individual symptoms in state A and the probability of their occurrence in state B, information can gradually be accumulated that allows one to differentiate with a given accuracy these states. If the value of the error in diagnosing the state A is taken as d, and for the error value when diagnosing the state B - b, then for a sum of the logarithms of the indicated ratios greater than in (l - d / b), with the established reliability level, for a sum of logarithms smaller than ln (/l-b) - state B, with the sum of the logarithms within the specified range, a conclusion is made about an uncertain estimate for a given level of reliability.

Results

85 parameters were analyzed, reflecting the patient's condition, data of his clinical status, laboratory and radiological examination. These included information about the general and local status of the patient (sex, age, concomitant pathology, body mass index, etc.), data on surgical intervention (duration of operation, amount of intra-operative blood loss, type of intervention, etc.). Separately, a number of indicators of laboratory and instrumental research were analyzed. The risk factorsused to predict infection at surgical site include parameters that have significant differences ($p<0.05$) in the study groups, as well as prognostic criteria for which the p-level error probability exceeded the generally accepted norm, but was identified the trend of manifestations of differences (at least, 1.5 times in percentage terms). However, there was an expert evaluation of other researchers, where the p-level of the analyzed risk factor was statistically confirmed. Thus, 18 prognostic criteria were selected for the program. Among them, 12 were used in the preoperative period, 4 - during the intervention and one - in the early postoperative period. As an example, we give data on the distribution of patients, taking into account the localization of the fracture, as one of the risk factors for infection at surgical site **(Table-2).**

As follows from the data of **(Table-1)**, in the group with uncomplicated course of the postoperative period of patients with fractures of the humerus was 39.6%, and among patients with the later developed at the surgical site cases of fracture of the humerus was 17.1%, i.e. 2.3 times less. The opposite situation is observed with a fracture of the tibia/fibula. Among patients with a favorable postoperative period of such observations was 24.3%, and among patients with infectious complications 40%.In statistical analysis, it is determined that the number of degrees of freedom is 3. The value of the criterion $\chi 2$ is 14.206. The critical value of $\chi 2$ at a significance level of $p <0.01$ is 11.345. The relationship between the factor and the outcome is statistically significant at a significance level of $p <0.01$. Thus, the localization of the fracture was taken into account when developing a mathematical model for the prediction of the surgical site infection. Similarly, other criteria for predicting the development of local complications were selected. After the formation of a complete list of prognostic factors, the correlation index and the coefficient of prognosis

Were calculated. The ratio index was a quotient between the frequency of occurrence of the symptom in the group of patients with a favorable course of the postoperative period and the frequency of its occurrence among patients with infections at surgical site. The coefficient of prognosis was a natural logarithm (ln) of the ratio index increased, for convenience of calculations, by a factor of 10. As a result, the prognosis factor for fracture of the humerus was "+8.5", fractures of the forearm bones "- 0.5", femur "- 3.0", shin bones "- 5.1". This allowed to draw a conclusion about the degree of increase in the risk of surgical site infection in the localization of a fracture in the lower extremity. Subsequently, all coefficients of prognosis known at the time of the examination were summarized. The result is a summary index of prognosis (PI). This parameter is determined at different stages of the study and treatment of the patient. Before the operation - 13 items, taking into account intra-operative data - 17 items, in the early postoperative - taking into account all 18 points with confidence interval from "-14" to "+14" conventional unit(c.u).

If the total IP was at the level of "+14 c.u. "and more, then, with a probability of more than 80%, a favorable course of the postoperative period was predicted, without the development of local purulent complications. With the IP parameters less than "-14 c.u.", with the same probability it was possible to expect the development of infection at surgical site. If the IP indicators were in the range of "- 14 c.u.", up to "+14 c.u." the prognosis was considered uncertain. A complete list of prognostic criteria with calculation of the prognosis for the development of local purulent complications is presented in **(Table 3).**

Table-1: Patient groups whose data were analyzed.

Option Comparisons		No of Obs in study groups (%) Retrospective (n=179)	Prospective (n=117)
Average Age		56.8±18.2	542±14.4
Sex	Male	74 (41.3)	48 (41.0)
	Female	105 (58.7)	69 (59.0)
Location	Humerus	57 (39.6)	43 (36.7)
	Radius/Ulna	28 (19.4)	16 (13.7)
	Femur	24 (16.7)	20 (17.1)
	Tibia/Fibula	35 (24.3)	36 (32.5)
Type of MOS	DCP	90 (50.3)	55 (47.1)
	IM nail	52(29.1)	39 (33.3)
	External Fixator	32 (17.8)	21 (17.9)
	Others	5 (2.8)	2 (1.7)
SSI in 12 months time		35 (19.6)	11 (9.4)
	Superficial	25 (6.8)	8 6.8)
	Deep	10 (5.6)	3 (2.6)

Table-2: Distribution of patients with fractures.

Location of Fracture	No of Obs during the post-op period Without SSI (n=144) No	%	With SSI (n=35) No	%
Humerus	57	39.6	6	17.1
Ulna/Radius	28	19.4	7	20.0
Femur	24	16.7	18	22.9
Tibial/fibula	35	24.3	14	40.0
Total	144	100.0	35	100.0

Table-3: Patient groups whose data were analyzed.

Prognostic Criteria 1		The frequency of observations (%) Without Complications 2	With SSI 3	The ratio index 4	P-level 5	Coefficient of prognosis 6
		PRE-OPERATION				
1: Sex	Male	39	51	0.765	0.044	2.2
	Female	61	49	1.245	61	-2.2
2: Age in Years	18-29	9	6	1.500	0.210	4.1
	30-44	14	14	1.000	0.500	0
	45-59	26	23	1.130	0.311	1.2
	60-74	35	34	1.029	0.411	0.3
	75-89	16	23	0.696	0.106	-3.6
3: CVS	IHD, HTN Present	40	69	0.580	0.0001	-5.4
	IHD, HTN absent	60	31	1.935		6.6

4:Digestive System	Present	19	29	0.655	0.049	-4.2
	Absent	81	71	1.141		1.3
5: Edocrine System	DM Present	13	20	0.650	0.091	-4.3
	DM Absent	87	80	1.088		0.8
6: Excretory System	Chronic pyelonephritis present	4	11	0.364	0.030	-10.1
	Chronic pyelonephritis Absent	96	89	1.079		0.8
7: Osteoporosis	Present	21	37	0.568	0.006	-5.7
	Absent	79	63	1.206		1.9
8: Kind of Fracture	Open	4	14	0.429	0.030	-8.4
	Close	94	86	1.093		0.9
9: Location of Prognosis	Humerus	40	17	2.353	0.0002	8.5
	Ulna/Radius	19	20	0.950	0.459	-0.5
	Femur	17	23	0.739	0.145	-3.0
	Tibia/Fibula	24	40	0.300	0.008	-5.1
10:Type of fracture	Transverse	33.5	23	1.453	0.058	3.7
	Spiral	24.5	20	1.225	0.199	2.0
	Communicated	38	51	0.745	0.032	-2.9
	Impacted	4	6	0.667	0.258	-4.0
11:Season of year the	Winter	45	34	1.324	0.190	2.8
Operation has been done	Spring	20	37	0.541	0.004	-6.1
	Summer	12	14.5	0.828	0.267	-1.9
	Autumn	23	14.5	1.586	0.051	4.6
12: Pre-operative length	1	40	23	1.739	0.005	5.5
Of the stay (in days)	2-3	30	37	0.811	0.148	-2.1
	4-15	12	17	0.7.6	0.159	-3.5
	16+	18	23	0.783	0.191	-2.4
13: Operation risk,	ASA 2	56	34	1.647	0.0009	5.0
	ASA3	44	66	0.667		-4.0
14: Kind of MOS	DCP	51	49	1.041	0.389	0.4
	IM nail	28	34	0.824	0.180	-1.9
	External Fixator	19	14	1.357	0.170	3.1
	Others	3	3	1.000	0.500	0
15: Queue in Operation	**I**	8	16	1.333	0.290	2.9
Theater	**II**	54	46	1.174	0.130	1.6
	III	31	34	0.912	0.325	-0.0
	After Hours	7	14	0.500	0.053	-6.9
16 Duration of surgery	Upto to 1 h.	16	11	1.455	0.151	3.8
	From 1 to 2 H.	59	49	1.204	0.078	1.9
	More than 2 h.	25	40	0.625	0.012	-4.7
17: Intra operative	Up to 500ml	83	63	1.317	0.0007	2.8
Blood Loss	500ml. To 1000ml	12	26	0.462	0.006	-7.7
	More than 100ml.	5	11	0.455	0.059	-7.9
18: Post-operative	Strict bed rest (I)	25	49	0.510	0.0002	-6.7
Regime	Mobile (II-III)	75	51	1.471		3.9

Discussion

In the recent years in literature different methods has been widely used for predicting infection after MOS of long bones. At the same time, there is no single generally accepted method. When analyzing prognostic criteria for the development of local infectious complications after surgical intervention for trauma, including fractures of long tubular bones, many authors consider the time to be the main factor since the time of injury before surgery.[13,14] Some authors believe that the incidence of infection at surgery site depends on the type of MOS. So, Ippolitov I.Y. with co- authors (2016) reported that the frequency of infectious complications (11.5%) is higher in the case of bone MOS with DCP of long tubular bones, than with IM nailing (3.1%).[15] A. Miromanov with co-authors (2017), in a study covering 163 cases of long tubular bones fractures and their infectious complications, suggest a prognosis for infection in the field of surgical intervention (including chronic posttraumatic osteomyelitis) in MI in both early and late period of traumatic disease on the basis of genetic predisposition . These authors consider the identification of the genotype-589T/T of the IL-4 gene and the -308A / A genotype of the TNFα gene as an informative indicator of the development of SSI in fractures of long bones of extremities[8] .Some experts believe that several factors contribute to the development of local purulent complications in the treatment of long tubular bones fractures: the age of the affected (over 60 years old), obesity, concomitant diseases (diabetes mellitus, decompensated pathology of cardiovascular and respiratory systems, the presence of foci of dormant infection), alimentary protein deficiency, localization fracture in the distal parts of the lower limb, dysfunction of the immune systam etc[9,10,15]. However, these authors do not report the importance of each of the listed prognostic criteria. Most of the factors described by these researchers characterize either the general condition of the patient or the organizational parameters that reflect the availability of specialized orthopedic and trauma care. The main shortcomings of these works are the following: the authors do not provide recommendations on how to apply in practice information about the presence of a particular criterion in a patient. In some studies, experts attempt to assess the risk of infection at surgical site development according to the developed scoring system that takes into account the quantitative equivalent of each risk factor and, accordingly, the total indicator that allows to distinguish among patients a risk group with respect to the development of local infectious complications. However, information about the introduction of the proposed systems and algorithms on the material of their own prospective studies is not always met. When assessing the diagnostic effectiveness of the model (according to the data of the retrospective group), it was revealed that the sensitivity (Se) was 94.29%, and specificity (Sp) 97.92%. The positive predictive value of the test was 91.67% (78.16% - 97.13%), the negative predictive value was 98.60% (94.83% - 99.63%). The method of prognosis of infection at surgical site development, proposed by us, allows to identify a risk group among patients. The results were evaluated in the prospective study group, which included 117 clinical observations. This risk was virtually assumed in 22 (18.8%) of 117 patients. All these 22 patients (from the high risk group for surgical site infection) and 31(26.5%) patients, whose risk was assessed as uncertain, conducted a set of special preventive measures (local, general and antibiotic prophylaxis). Preventive measures in general: prognosis of the development of infection at the surgical site at the stage of preoperative examination; refinement of prognosis of infection at surgical site development taking into account intra-operative data; assessment of cardiovascular system: correction of water-electrolyte balance, heart rhythm disturbances; carbohydrate metabolism disorders; intracellular homeostasis; respiratory assessment; optimization of traffic in the operating room. Local prophylaxis measures included: ultrasound of the operation zone, aspiration of hematoma formation (according to ultrasound data), control over the amount of drainage, culture of drainage and puncture material, magnetic and laser therapy in the operationarea. After the implementation of these measures, out of 22 cases with a high risk of purulent-inflammatory complications in the surgical intervention area predicted mathematically, surgical site infection was actually detected in 11 (9.4%) patients who underwent MOS operations due to a fracture of long tubular bones. In this case, deep infection at surgical site developed in 3 (2.6%) patients.

Conclusion

Thus, the use of the technique of a mathematical prognosis for the development of infection at surgical site in practice and the use of preventive measures in patients at risk have made it possible to reduce the incidence of SSI after MOS of LTB from 19.6% to 9.4%, i.e. twice. At the same time, the frequency

of deep infection also decreased by half: from 5.6% to 2.6%. Clinical introduction of the prognosis and prophylaxis program in patients of the prospective group confirms the correct choice of the risk factors for the infection in the area of operation in the MOS of LTB. The most significant criteria were those that had the maximum range between the positive and negative values of the prognosis factor: the localization of the fracture, its appearance (open or closed), the duration of the operation, and the amount of intra-operative blood loss. The frequency of fractures of LTB does not have a steady tendency to decrease. There is also a risk of developing infectious complications in the surgical treatment of patients with fractures of LTB. In this regard, it is obvious that the allocation among the affected group of high risk of SSI and the use of preventive measures allows in half the cases to prevent the development of purulent complications in the surgical intervention zone. The practical application of the proposed method for determining the index of the prognosis of infection in the area of surgical intervention in the MOS of LTB consists in the summation of the prognosis coefficients and does not require special training or equipment. The obtained data demonstrate that the use of modern organizational approaches in patients who need surgical treatment of long bone fractures allows in some cases to prevent the development of infectious complications.

Department of Orthopaedics
SIMS/Services Hospital, Lahore
www.esculapio.pk

References

1. Agadzhanyan VV, Shatalin AV, Kravtcov SA, Skopincev DA. Criteria for assessing the severity of patients with polytrauma during the inter hospital transportation. Polytravma 2011;№1:5-11.
2. Van den Berg J, Osei D, Boyer MI, Gardner MJ, Ricci WM. Open tibia shaft fractures and soft-tissue coverage: the effects of management by an orthopaedic microsurgical team. J. Orthop. Trauma2017;31:339-344.
3. Popov VP, Zdrel'ko VP, Truhachev IG, Popov AV. Plate osteosynthesis complications in patients with long bones fractures. Genijortopedii 2014; №2:5-9.
4. Scharfenberger A, Alabassi K, Smith S, Weber D, Dulai S et al. Primary wound closure after open fracture: a prospective cohort study examining nonunion and deep infection. J. Orthop. Trauma 2017;31:121-126.
5. Westgeest J, Weber D, Dulai SK, Bergman JW, Buckley R, Beaupre LA. Factors associated with development of nonunion or delayed healing after an open long bone fracture: A prospective cohort study of 736 subjects. J. Orthop. Trauma 2016;30:149-155.
6. Tkachenko AN, Bahtin MYu, Zharovskih OS, Shcherbakov AA, Topchij PA. Possibilities for infectious complications predicting in hip joint replacement in patients of older age groups. Travmatologiyaiortopediya Rossii 2012; № 2:48-53.
7. Dorofeev YuL, Ptashnikov DA, Tkachenko AN, Bahtin MYu, Kalimullina AF. Prognosis of deep infectious complications in hip replacement. Vestn. khirurgiiim. I.I.Grekova 2015;174:40-44.
8. Miromanov AM, Trubicyn MV, Mironova OB, Miromanova NA Personalized aspects of inflammatory complications development in limb bones fractures. Polytravma 2017;№2:37-41.
9. Hernigou J, Schuind F. Smoking as a predictor of negative outcome in diaphyseal fracture healing. Int. Orthop. 2013;37:883-887.
10. Kempegowda H, Richard R, Borade A, Tawari A, Graham J, Suk M et al. Obesity is associated with high perioperative complications among surgically treated intertrochanteric fracture of the femur. J. Orthop. Trauma 2017;31:352- 357.
11. Bachoura, Guitton TG, Malcolm Smith R, Vrahas MS, Zurakowski D, Ring DA. Infirmity and injury complexity are risk factors for surgical-site infection after operative fracture care. Clin. Orthop. Relat. Res. 2011;469: 2621 2630. Doi:10.1007 /s11999-010-1737-2
12. Wald A. Sequential Tests of Statistical Hypotheses. Annals of Mathematical Statistics 1945;16(2):117186.
13. Yokoyama K, Uchino M, Nakamura K. Risk factors for deep infection in secondary intramedullary nailing after external fixation for open tibial fractures. Injury2006;37:554560.
14. Nahm NJ, Moore TA, Vallier HA. Use of two grading systems in determining risks associated with timing of fracture fixation. J. Trauma Acute Care Surg.2014; 77:268-279.
15. IppolitovIYu, Kistkin AI, Shirokov II. Results of using locking osteosynthesis in long bones fractures in urgent traumatology. Nauch. Al'manah 2016;№6:351-357.