

A survey on the use of antibacterial in orthopaedic surgery

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Key words

Survey • Antibacterial drugs • Orthopaedic surgery

Summary

The aim of this study is the comprehensive (pre-operative, operative and post-operative) evaluation of the use of antibacterial drugs on a group of patients subjected to orthopaedic surgery. The data regarding 1000 orthopaedic surgical operations, corresponding to 1000 non-urgent patients, have been examined.

This study reveals the incongruity in the use of antibacterial drugs in the orthopaedic surgical activity mainly in operative prophylaxis, but also the administration during the intra-operative period, and the use of the same drugs in the post operative period.

Introduction

Hospital infections represent a remarkable cause of morbidity and mortality. With regards to orthopaedic surgery, follow-up studies of 2 to 5 years, have pointed out a prevalence of post operation infections between 0.5% and 2% in hip prosthesis and between 1% to 4% in knee prosthesis. The prevalence of the infections in arthroscopic surgery resulted between 0.01% and 0.4% [1]. Most publications have focused attention on the operative antibacterial prophylaxis. This prophylaxis contributes to the diminution of the morbidity and the mortality, correlated to post operative infections on the whole, by reducing the microbial load to an easily controllable level for the immune system of the patient who had undergone surgery. Some years ago it was shown that the administration of antibacterial for operative prophylaxis can reduce the incidence of infections in prosthetic orthopaedic surgery [2] and similar results have been obtained with the fractures treated by internal fixation [3]. Many studies documented a wide misuse of antibacterial prophylaxis in this surgical field.

The lack of a national surveillance system or of wide-spread regional network, however, does not permit our country to quantify exactly the consequences in terms of prevalence and costs. On the another hand the circulation of infective agents which have critical resistance patterns to antibacterial substances contributes greatly. In order to explain the development and the starting up of the resistance mechanisms, two hypothesis have been formulated: the first is based on the connection of the particular interaction between the drug and the bacterium; the second is based on the interrelation among the drugs, the bacterium and the environment [4, 5]. Both hypothesis share the concept of threshold of duration or quantity-duration, that, transferred on an applicative level depends on the appropriateness and on the congruity of the use.

The general purpose of this study is the comprehensive evaluation of the use of antibacterial drugs on a group of patients subjected to orthopaedic surgery. The study distinguishes between pre-operative hospitalisation, operative prophylaxis and post-operative hospitalisation. According to the operative prophylaxis the specific targets are: to evaluate the prevalence of improperly applied procedures; to differentiate between the single problems that can exist within the context of different stages of the procedure itself; to evaluate some elements associated with incorrect procedures.

Therefore, a survey has been conducted on a group of patients subjected to orthopaedic surgery at Pistoia hospital. Other studies aimed to assess the use of antibacterial substances in the orthopaedic surgery, on the whole, have not been found.

Materials and methods

The hospital of Pistoia is endowed with 491 beds. The data regarding 1000 orthopaedic surgical operations, corresponding to 1000 non-urgent patients and during their hospitalisation, between January and October 2003, have been examined. The sources of the information used were: the surgical register, to recompile a list of orthopaedic surgical patients; a clinical chart with particular attention to the operation report, in order to examine the kind of surgery carried out: initial diagnosis, type of surgery, description; the anaesthesiology report regarding the administration of the operative antibacterial prophylaxis; the clinical diary for the eventual use of antibacterial drugs during the post-operative period. Using a software EpiInfo 6.4 [6], a recording report composed of 55 variables was created and organized into six sections:

1. personal data of the patient;
2. identity of the surgeon and the anaesthetist;

3. classification of the types of operations;
4. the use of antibacterial drugs during the pre-operative hospitalisation;
5. operative prophylaxis;
6. the use of antibacterial drugs during the post-operative period.

The correct administration of the antibacterial therapy was evaluated during the following periods:

- a) pre-operative hospitalisation: period between patients entry into the hospital and operation;
- b) operative period;
- c) post-operative hospitalisation: period included between the 24 hours following the operation and the removal.

Criteria for analysing the use of antibacterial drugs was as follows: during the first period the administration of the therapy was considered correct if the clinical documentation evidenced: the presence of infection in progress documented with signs and symptoms together with laboratory data; the presence of new traumatic infected wounds; the presence of open fractures; the presence of retention of foreign bodies; the presence of necrotic tissue.

The administration of the operative antibiotic prophylaxis was evaluated correct if applied to endoprosthesis and artroprosthesis with internal fixers (screws, nails, plaques, etc.) and to amputation, 30 minutes before surgical cut, using Cefazoline (2 g intravenous) in the first case and Cefoxitine (2 g intravenous) in the second case. The types of surgical operations carried out were as follow:

1. Reconstruction of the anterior cruciate ligament (ACL) of the knee.
Surgical replacement of damaged ligament (total or partially-insufficient) with new ligament made with tendons and/or bone variously fixed to the tibia or to

the femur (using nails, screws, cramps, threads).

2. Amputation
Total or partial amputation of the whole bony segment (bones, muscles, tendons, blood vessels).
3. Prosthesis
Endoprosthesis and artroprosthesis, consisting respectively in: the replacement of one or both of the articular heads of a joint using metal prosthesis, acrylic prosthesis, meta-acrylic prosthesis, or other material. System of internal or external fixers (screws, nails, plaques, etc.).

Regarding the post-operative hospitalisation, the continuation of the administration of the same antibacterial drugs used for the prophylaxis, without an interruption of, at least one day, was considered incorrect. The criteria adopted are related to guidelines of protocol elaborated by Committee for Hospital Infections of Local Health Unit (LHU) 3 in 2002.

STATISTICS METHODS

The single sample proportion, were estimated by calculating a 95% confidence interval (95% C.I.). In order to compare the proportions, the chi-squared test was applied with significance level fixed at 5%. Odds Ratios and corresponding 95% CI have been calculated in order to measure the association related to the probability of correct procedure for chosen operators. Data have been elaborated by Stata 6 [7].

Results

The composition of the sample examined with reference to the kind of operation, together with the mean age, was reported in Table I.

Tab. I. Distribution of operated patients according to sex, kind of operation and mean age of the study population.

Sex	Kind of operation							
	Susceptible of prophylaxis						Not susceptible of prophylaxis	
	Prosthesis		Amputation		ACL		N.	%
N.	%	N.	%	N.	%			
Male	183	32.6	11	78.6	64	82.0	207	59.6
Female	378	67.4	3	21.4	14	18.0	140	40.4
Total	561	100.0	14	100.0	78	100.0	347	100.0
Total	1000/1000 (100.0%)							
Mean age	55.6 (± 22.043)							

Tab. II. Antibacterial therapy during pre-operative hospitalisation.

	Effected				Not effected			
	Correct		Incorrect		Correct		Incorrect	
	N.	(%)	N.	(%)	N.	(%)	N.	(%)
Total	71/73	(97.3)	2/73	(2.7)	925/927	(99.8)	2/927	(0.2)
Total	73/1000 (7.3%)				927/1000 (92.7%)			
Total	1000/1000 (100.0%)							

Tab. III. Use of antibacterial in operative phase (653 operations) in surgical procedures for which the use of prophylaxis subsisted: distinction for kind of operation, correctness of the used options and kind of mistake within incorrect options.

Kind of operation	Correct			Option regarding antibacterial prophylaxis						TOTAL					
	n	%	95% C.I.	Timing			Incorrect			Not effectuated					
				n	%	95% C.I.	N	%	95% C.I.	n	%	95% C.I.	n	%	95% C.I.
Amputation	0	0.0	---	4	1.3	0.1;2.5	0	0.0	---	10	4.6	1.9;7.3	14	2.2	1.0;3.4
Prosthesis	97	77.6	70.3; 84.8	266	86.9	83.2; 90.6	6	100.0	---	192	88.9	84.8; 93.0	561	85.9	83.2; 88.6
ACL	28	22.4	15.1; 29.7	36	11.8	8.3; 15.3	0	0.0	---	14	6.5	3.2; 9.8	78	11.9	9.3; 14.4
Total (%)	125	100.0		306	100.0		6	100.0		216	100.0		653	100.0	
Total (%)	---	---		306 (58.0)			6 (1.2)			216 (40.8)			---		
TOTAL (%)		125 (19.1)					528 (80.9)						653 (100.0)		

THE USE OF ANTIBACTERIAL DRUGS DURING PRE-OPERATIVE HOSPITALISATION

73 patients (7.3%) were subjected to administration of antibacterial drugs during pre-operative hospitalisation. Among those patients in 71 of the cases (97.3%) the therapeutical option corresponded with the criteria previously explained but in 2 (2.7%) it resulted incorrect (Tab. II).

THE USE OF ANTIBACTERIAL DRUGS DURING OPERATION

Of the 1000 orthopaedical operations examined in order to conduct an analysis related to the operative period, in 653 (65.3%) the administration of antibacterial drugs was indicated to reduce the risk of infection related to the specific surgical procedure and in 347 (34.7%) cases prophylaxis was not indicated.

The first subgroup of 561 (85.9%) were prosthesis applications operations, the second 14 (2.1%) were amputations and 78 (12.0%) were reconstructions of the anterior cruciate ligament. In 125 operations from the subgroup, where the antibacterial prophylaxis procedure was indicated (19.1%), the procedures resulted correct: among these, 97 (77.6%) were prosthesis operations and 28 (22.4%) were reconstruction operations of the anterior cruciate ligament. In the remaining 528 (80.9%) the procedure was incorrectly applied: in 306 cases (58.0%) due to "timing" errors in the administration of the drug. Among these 266 (86.9%) were prosthesis operations; 36 (11.8%) were reconstruction of the anterior cruciate ligament operations; 4 (1.3%) were amputations. In 6

cases (1.1%), which were all prosthetic implants, due to "timing" errors together with the administration of different substances not indicated in the protocol, the procedure was incorrectly applied. In the remaining 216 cases (40.9%) where the procedure was not effected: 192 (88.9%) prosthesis; 14 (6.5%) replacement of the anterior cruciate ligament; 10 (4.6%) amputations (Tab. III). In 214 cases (61.7%), from the subgroup for which the antibacterial prophylaxis was not indicated, the procedure was carried out while in 133 cases (38.3%) no antibacterial drugs was administrated. In all cases the way of administration was incorrect (Tab. IV).

In the cases' histories examined the procedures was correctly carried out, in 258 operations (25.8%), while in 742 (74.2%) it was not possible to ascertain that the procedure had been correctly applied. With regards to the kind of substance, cefazoline was more widely used: respectively in 97.7% of prosthesis operations, in 100% of amputation operations, in 96.8% of replacement of the anterior cruciate ligament operations (Tab. V).

The administration of antibacterial drugs during the intra-operative phase was repeated in one case and this option corresponded to what was indicated in the protocol. Differently, the administration was not repeated in 18 cases (1.8%) even tough it was indicated (Tab. VI).

USE OF ANTIBACTERIAL DURING POST-OPERATIVE PERIOD

Table VII illustrates the use of antibacterial drugs during the post-operative period. In 126 patients (12.6%) the administration was repeated and in 874 (87.4%) it

Tab. IV. Use of antibacterial in operative phase (347 operations) in surgical procedures for which the indication of using the prophylaxis subsisted.

Option regarding antibacterial prophylaxis	Total - (%) - 95% C.I.
Correct	133 - (38.3) - 33.2, 43.7
Incorrect	214 - (61.7) - 56.3, 66.8
Total (%)	347 (100.0)

Tab. V. Used antibacterial drugs in operative prophylaxis, for kind of operation.

Kind of antibacterial	Kind of operation						Not susceptible of prophylaxis	
	Susceptible of prophylaxis				LCA		N.	%
	Prosthesis		Amputations					
N.	%	N.	%	N.	%	N.	%	
Cefazolin	362/369	(97.9)	4/4	(100.0)	62/64	(96.8)	214/214	(100.0)
Gentamicina	---	---	---	---	1/64	(1.6)	---	---
Claritromicina	1/369	(0.3)	---	---	---	---	---	---
Ciprofloxacina	1/369	(0.3)	---	---	---	---	---	---
Levofloxacina	1/369	(0.3)	---	---	---	---	---	---
Teicoplanin	2/369	(0.6)	---	---	1/64	(1.6)	---	---
Vancomicina	2/369	(0.6)	---	---	---	---	---	---
Total	369/651	(56.8)	4/651	(0.5)	64/651	(9.8%)		
Total			437/651 (67.1%)				214/651 (32.9)	
TOTAL			651/651 (100.0%)					

Tab. VI. Use of antibacterial drugs in intra-operative period.

	Repeated administration				Not repeated administration			
	Correct		Incorrect		Correct		Incorrect	
	N.	(%)	N.	(%)	N.	(%)	N.	(%)
Total	1/1	(100.0)	---	---	981/999	(98.2)	18/999	1.8%
TOTAL	1/1000 (0.1%)		1000/1000 (100.0%)		999/1000 (99.9%)			

Tab. VII. Use of antibacterial drugs in post-operative period.

	Repeated administration				Not repeated administration			
	Correct		Incorrect		Correct		Incorrect	
	N.	(%)	N.	(%)	N.	(%)	N.	(%)
Total	53/126	(42.1)	73/126	(57.9)	874/874	(100.0)	---	---
TOTAL	126/1000 (12.6%)		1000/1000 (100.0%)		874/1000 (87.4%)			

was not. In the first subgroup the choice was correct in 53 of the cases (42.1%) and incorrect in the remaining 73 cases (57.9%). In the subgroup regarding the patients whose treatment was discontinued, the choice of not proceeding with an additional administration of antibacterial drug, resulted correct in 100% of the cases. For each orthopaedic surgeon and for each anaesthetists who decided the procedure, as it was verified in the operative register, we calculated the percentage of correct options regarding the operative antibacterial prophylaxis (Tab. VIII).

The higher percentages in both cases, correspond to low volumes of activity. For the orthopaedic surgeons and anaesthetists who performed the most operations we attributed the respective percentages: 28.2% in Ort.10; 32.1% in Ort.11; 29.8% in Ort.14; 23.1% in Ort.18; 27.8% in Anae.6; 16.9% in Anae.12; 32.3% in Anae.13; 25.0% in Anae.18. The estimates obtained using Odds Ratio as the measure of association relative to the probability of correct procedure for every chosen operator specified the following values: Ort.10 O.R. 0.98 (0.58, 1.65); Ort.11 O.R. 1.22 (0.84, 1.78); Ort.14 O.R. 1.08 (0.76, 1.53); Ort.18 O.R. 0.71 (0.47, 1.08); Anae.6 O.R. 0.96 (0.57, 1.59); Anae.12 O.R. 0.48 (0.25, 0.92); Anae.13 O.R. 1.21 (0.75, 1.96); Anae.18 O.R. 0.82 (0.48, 1.39).

Discussion

This study reveals the incongruity in the use of antibacterial drugs in the orthopaedic surgical activity mainly in operative prophylaxis, the administration during the intra-operative period, and the use of the same drugs in the post-operative period. The implications derived from these two conditions are different.

The first implication regards the protection of each patient from the risk of infective complications. The second regarding the ecological aspects of the bacteria found in the hospital environment which together with the types of substances used are strictly connected to the possibility of emerging bacterial resistance. This last item can be combined with some critical aspects either from "side effect" point of view or from an "economic" point of view.

All the studies identified in bibliographical analysis only considered the use of antibacterial drugs in operative prophylaxis. Significant attention to this last aspect of the efficacy of antibacterial prophylaxis in orthopaedic surgery, is documented by many studies differently designed regarding to the prophylaxis which had already been carried out, using different substances [8-12]. Other studies have principally emphasized the role of different materials for prosthetic surgery (which were more or less soaked in antiseptic substances or antibacterial drugs) in order to hinder bacterial adhesivity, but only a few authors were doubtful regarding the use of the antibacterial operative prophylaxis [13-15]. Others consider the matter to be controversial and therefore it would be necessary to carry out controlled studies [16, 17]. Therefore the prevalent opinion, gravitates towards a correct operative prophylaxis; particularly in the short course type as indicated in most of protocols.

On the other hand, the risk of infection does not appear to be homogeneous in orthopaedic surgery patients. Old age, previous operations particularly of arthroplasty, illnesses which favour the infections, the presence of tumors, the coexistence of infections of the lower urinary tract and a low "risk index score", are relevant factors in those subjects who developed post-operative infections [18, 19].

Tab. VIII. Correct procedures on the total of done procedures for every operator: legal ownership of the procedure assigned to the orthopaedic and anaesthetist.

Legal ownership assigned to the orthopaedic				Legal ownership assigned to the anaesthetist			
Orthopaedic	N. correct procedure	N. total procedures	Percentage	Anaesthetist	N. correct procedure	N. total procedures	Percentage
Ort.1	0	4	0.0	Anae.1	1	6	16.7
Ort.2	22	65	33.8	Anae.2	1	1	100.0
Ort.3	2	2	100.0	Anae.3	8	11	72.7
Ort.4	19	64	29.7	Anae.4	2	12	16.7
Ort.5	13	47	27.7	Anae.5	5	17	29.4
Ort.6	12	26	46.2	Anae.6	25	90	27.8
Ort.7	6	31	19.4	Anae.7	8	41	19.5
Ort.8	5	22	22.7	Anae.8	7	10	70.0
Ort.9	1	3	33.3	Anae.9	23	67	34.3
Ort.10	24	85	28.2	Anae.10	16	67	23.9
Ort.11	52	162	32.1	Anae.11	9	52	17.3
Ort.12	17	54	31.5	Anae.12	13	77	16.9
Ort.13	7	31	22.6	Anae.13	30	93	32.3
Ort.14	62	208	29.8	Anae.14	12	53	22.6
Ort.15	3	15	20.0	Anae.15	22	63	34.9
Ort.16	4	20	20.0	Anae.16	16	58	27.6
Ort.17	0	1	0.0	Anae.17	2	5	40.0
Ort.18	37	160	23.1	Anae.18	22	88	25.0
				Anae.19	8	20	40.0
				Anae.20	2	6	33.3
				Anae.21	20	66	30.3
				Anae.22	8	12	66.7
				Anae.23	7	23	30.4
				Anae.24	6	31	19.4
				Anae.25	13	28	46.4
				Anae.26	0	2	0.0
				Anae.27	0	1	0.0
Total	286	1000	28.6		286	1000	28.6

Similarly to what was reported in other scientific papers regarding the use of antibacterial drugs during the operative period, it was possible to establish very high percentages of incorrectly adopted options with high frequencies both in the choice of the time of administration and in the same absence of administration. Both the conditions rendered the procedures ineffective; either because they were incorrectly conducted or because they were not applied, resulting in a critical low level of protection of the patients (Tab. III). A retrospective Canadian study regarding 438 random patients from 22 general hospitals, including community and university ones, revealed that 70% of the patients with the prophylaxis were incorrectly carried out with respect to the time of administration, while in the 94% of the cases, the choice of the substance and the way of the administration (an intravenously injected first generation cephalosporin) resulted correct [20]. A more recent analysis conducted at the “C. Poma” hospital in Mantova, documented the lack of uniformity regarding the choice of antibiotic, “timing”, posology, the method and the number of administrations; both among the different specialties or/and within the same surgical specialty. With special reference to orthopaedic surgery,

the choice of the time of administration resulted incorrect, in every examined case [21].

With regards to the use of the antibacterial drugs in the post-operative period, we have no useful comparative data from other studies. The survey emphasises the need to study the entire surgical activity for the possible impact in terms of resistance to antibacterial and in terms of economic cost. On the other hand, since the analysis conducted by the operators who effected the most operation (possible responsible for the application of the protocol) does not furnish significant statistics values, it is possible that the procedure was incorrectly managed. A research conducted from this view point aims at meeting different requirements:

- a. to create conditions in order to make pharmaco-economic systematic evaluations to optimise costs;
- b. to organize a surveillance system where data regarding the use of antibacterial is crossed with data regarding the prevalence of the circulation of bacteria characterised by critical patterns of resistance;
- c. to rationalize the use of antibacterial drugs in order to improve the correct use. These three elements are closely connected by functional reciprocity and in a general prospective of administration of the hospital

structures, they are inseparable. This study is innovative for previously mentioned reasons, and it is aided by the number of sample cases but it presents some

limits which are: the limiting of the study to a single hospital; the limiting to only one surgical area of specialization; it is limited to a descriptive analysis.

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■ Received on June 6, 2005. Accepted on January 10, 2006.

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