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Research Article

Relationship between Antibiotic duration and Superficial Surgical Site Infection in Arthroplasty surgery, Khartoum, Sudan

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Abstract

The study aims to study the difference in using antimicrobial prophylaxis for different durations in joints replacement operations and developing superficial surgical site infection.

A retrospective cohort study carried out in a well-equipped hospital, data collected from the record files of in-patient's medical record unit and the outcome data was collected from consultant's out- patient records and telephone calls.

Total sample size was 101, incidence of superficial site infection from the cohort was found to be 6.9% overall, (8.89% and 5.36% among those who took the antimicrobial for 24 hours and a week respectively). No association was found between the different duration of antimicrobial prophylaxis and having superficial surgical site infections (The risk ratio was 1.66 {confidence interval = 0.39 to 7.04}).

These results are consistent with the international results and current knowledge about the duration of administration of antimicrobial prophylaxis in joints replacement operation and clean surgical operations in general, as the 24 Hours use duration is supported by most of current results.

Keywords: Surgical Site; Infection; Sudan; Prophylaxis

Introduction

Arthroplasty is a form of orthopedic surgery where the articular surface of a musculoskeletal joint is replaced, remodeled, or realigned by osteotomy or some other procedure. It is an elective procedure that is done to relieve pain and restore function to the joint after damage by arthritis or some other type of trauma. Replacement orthopedic operations developed in the twentieth century, and it's not an evolution in orthopedicsurgery only but in Medicine as a whole, as it improves the quality of life more than coronary bypass surgery and renal transplant [1].

Induction of antimicrobial prophylaxis (first generation cephalosporin) is usually done as a part of the anesthetic preparation of the patient at least one hour before skin incision. Following international guidelines, the antimicrobial prophylaxis should continue for less than 24hours, but sometimes that is not the case. Surgical site infection (SSI) is major and well-known complication in surgery, and infections have beendocumented for the past 4000-5000 years [2].

The term surgical site infection is used to describe any infected wound following surgical incisions (iatrogenic) to any body tissue and SSI also encompass surgical implants and prosthetic device if they got infected. According to the national health work criteria of wound, UnitedStates, SSI classified to Superficial incisional SSI, Deep incisional SSI and Organ/space SSI, the clearest and easily detected early is the superficial incisional SSI [3].

For that, certain guidelines have been developed to prevent post-operative infection with many measures and one of the important measures being antimicrobial prophylaxis. Prophylaxis refers to the prevention of disease occurrence, it could be primary prophylaxis for prevention the initial infection, secondary prophylaxis for prevention the reactivation of infection or eradication referring to the elimination of colonizing microbes to prevent infection [3,4]. The duration of antimicrobial prophylaxis is a very controversial area for that many research have been done to know the exact duration with the maximumefficacy. On the other hand, the overuse of antimicrobials and the development of resistant strains among them has resulted in losing the antimicrobials as a guard during our operations, making the challenge more difficult.

The absence of guidelines for daily practice in medical procedures like operations is a real problem that all medical staff should stand for and initiate an action toward the benefit not only patients and community but also doctors (medico-legal aspect), and special consideration should be addressed to health problems which have huge health and economic impact like SSI. The joint replacement is a common procedure in Sudan, unfortunately no research has been carried out to assess the incidence or the outcome of those operation. In this study we aim to study the effectof the duration of administration of antimicrobial prophylaxis (for 24hours and extending it for a week) in joint replacement orthopedic surgery on the development of Superficial SSI, at private hospital, Khartoum, Sudan.

Patients and Methods

- **Study Design:** Retrospective cohort study, hospital based.
- **Study Population:** Data records of patients underwent total kneereplacement or total hip replacement.
- **Inclusion Criteria:** All patients aged more than 45 underwent total kneeor hip replacement operation with no frank clinical inflamed joint and Completed 30 days from the operation were included in the study.
- **Exclusion criteria:** Patients on corticosteroid therapy and patients forwhom outcome data was not available were excluded.
- **Sample size:** Sample size as calculated online by openepi website wasfound to be 146.

  Unfortunately, the number of patients who underwent the replacement orthopedic operations in the hospital were only 110. Five cases didn't fulfill the criteria of the research and four cases had been lost on followup., so the final sample was 101.
- **Method of data collection:** The cohort cases inspected retrospectively through the medical records, all cases have file (hard and soft scanned one) in medical record unit, file have many forms (clinical assessment forms) from admission and general demographic and contact data forms to discharge note form which inform the patient the follow up appointment. Suitable cohort sheet was designed to collect all data needed for the research. Data was collected in two steps the first step from patient planned for operation to discharge and second step to knowtheir outcome.

To facilitate the collection for the first step, the operation room monthly report for all operations carried out at the hospital was collected. This is along excel sheet with a lot of information from his MRN (special code foreach patient enter the hospital) like the time spent in site the theater reported there, from the operation room monthly all cases have the criteria of the cohort selected, their MRNs, names and operations.

Then through the medical record unit all scanned files of the selected cohort group collected, those cases where no scanned files found the original hard files took from their store.

Through each file (cohort index) for each selected cases then fulfilled the designed cohort sheet, all variables identified in the hospital record forms.

For the second step to collect the outcome, first patient should be 30 days post-operative then identified Superficial SSI's as Purulent drainage from the superficial incision or Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision, or at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon and is culture-positive or not cultured (a culture-negative finding does not meet this criterion) and Diagnosis of superficial incision SSI is made by the surgeon or attending physician [3]. Lastly the outcome identified through the consultant record at out-patient department (soft material at programmed software and through telephone calls.

Data analysis

Data was entered and analyzed using SPSS and computer program software version 21st. Risk ratio and their confidence interval, Fisher'sexact test and Time to event ratios (hazard ratio) were uses to analyze data and test associations.

Ethical consideration

Approval of this study was taken from both department of Community Medicine University of Khartoum board and the medical directors of thehospital and medical records unit.

Results

The total number of cases entered in the study was 101, 35.6% ofthem were males, with a mean age of 64.4 years old (SE 1.09). Most ofthem were diagnosed as osteoarthritis 80% and about 19% operated because of fracture at joint side to which replacement were indicated (Table 1). All the cases had a clean surgical site before the operation which was checked clinically in the records.

Characteristic	Frequency (%)
Age (years):	
(45-55)	26 (25.7)
(55-65)	25 (24.7)
(75-85)	33 (32.7)
(85-95)	15 (14.8)
More than 95	2 (1.99)
Gender:	
Male	36 (35.6 %)
Female	65 (64.4)
Cause of the operation:	
Osteoarthritis	…. (80.2)
Fracture neck of femur	….. (18.8)
Others	…… (0.99)
Duration of antimicrobial prophylaxis:	
24 hours	…… (55.45)
One week	……. (44.55)
Diabetes mellitus status:	
Not diabetic	……. (76.33)
Controlled diabetes	…….. (21.78)
Uncontrolled diabetes	……. (10.89)
length of pre-operative admission:	
Less than 24 hours	…….. (37.62)
24 hours	……. (46.53)
More than 24 hours	…… (15.84)
Length of the operation (In minutes):	
Less than 60	….. (0.99)
60-89	….. (10.8)
90-120	…… (33.6)
120-180	…. (45.5)
More than 180	…… (8.9)
Drain Insertion:	
Not inserted	27 (26.7)
Inserted	74 (73.3)

Table 1: Distribution of socio-demographic and health status characteristics of Study participants (n = 101)

Incidence of superficial site infection for the cohort is 6.9%, incidenceamong those who had antimicrobial prophylaxis for 24 hours is 8.89% and the incidence for those who took it for a week is 5.36% with a risk ratio of 1.66 {CI = 0.39 to 7.04} table 2, 3}, fisher's exact test is 0.697 table 4 and risk estimate for those who didn't develop Superficial SSI is 1.039 (CI = 0.93 to 1.16).

Factor	Relative Risk (RR)	Confidence Interval (CI)
Age		
(45-55)	-----	------
(55-65)	0.35	0.039 - 3.012
(75-85)	0.53	0.095 - 2.92
(85-95)	0.58	0.066 - 5.07
>95	1.29	0.085 - 19.37
Duration of Antimicrobial Prophylaxis		
One week	------	------
24 hours	1.66	0.39 - 7.04
Diabetes status		
Not diabetic	-----	-----
Controlled diabetes	0.61	0.076 - 5.011
Uncontrolled diabetes	1.24	0.16 - 9.6
Length of pre-operative admission		
24 hours	----	-----
Less than 24 hours	1.86	0.33 - 10.54
More than 24 hours	2.9	0.45 to 19.18
Drain Insertion		
Not Inserted	-----	----
Inserted	0.9	0.19 - 4.43
Duration of admission		
Less than or for 6 days	----	----
7 days or more	0.23	0.014 - 3.9

Table 2: Factors affecting occurrence of Superficial SSI for the participants in a study about Superficial SSI. n = 101.

Time to event ratios {hazard ratio} were calculated for time spentat the operation room using < 60 min as reference are 0.17 {CI = 0.005 to6.24}, 0.29 {CI = 0.0196 to 4.17}, 0.38 {CI = 0.0297 to 4.94} and 0.6 {CI = 0.036 to 10.04} for those their operation took 60-90 minutes, 90-120 minutes, 120-180 minutes and > 180 minutes respectively, table (3).

Length of the operation	Superficial SSI No/Yes		Total	RR	CI
< 60	1	0	1	-	-
60-89	11	0	11	0.17	0.005 - 6.24
90-120	32	2	34	0.29	0.0196 - 4.17
120-180	42	4	46	0.38	0.0297 - 4.94
> 180	8	1	9	0.6	0.036 - 10.04
Total	94	7	101	-	-

Table 3: Length of the operation and developing Superficial SSI.

Also, time to event ratios {hazard ratio} were calculated for the day of drain removal (using no drain insertion as reference) and were found to be 0.64 {CI = 0.062 to 6.62}, 1.45 {CI = 0.26 to 7.99}, 0.75 {CI = 0.073 to 7.67} and 0.7 {CI = 0.037 to 13.15} for those whom their drain was removed on the first day, second day, third day and fourth daypost-operatively respectively, table (4).

Drain removal	Superficial SSI No Yes		Total	RR	CI
No drain	25	2	27	-	-
Removed first day post-operative	20	1	21	0.64	0.062 - 6.62
Removal second day post-operative	25	3	28	1.45	0.26 - 7.99
Removal third day post-operative	17	1	18	0.75	0.073 - 7.67
Removed fourth day post-operative	7	0	7	0.7	0.037 - 13.15
Total	94	7	101	-	-

Table 4: Day of drain removal and developing Superficial SSI.

Discussion

The research was intended to address if there is a significant deferencebetween using antimicrobial prophylaxis for 24 hour and a week in ourqualified local hospital circumstances, In the study female (65 cases) was almost twice male number (36 cases) which can be explained by the high incidence of osteoarthritis among female due to estrogen loss, and age of the cases range from 45 – 98 yearsold with mean age group 64.4 years old (SE = 1.09), which is less than mean age group among those underwent same operations (65.5 – 67.5 years old) in other research [5], furthermore most of case were diagnosed as osteoarthritis (almost 80%) which similar to other study described osteoarthritis as major cause of orthopedic replacement surgeries [6] and can be explained by the demography (gender and sex) within the study.

As addressed in methodology all those cases were traced retrospectively, there general clinical conditions and local operation sites were clear from infection through inspect their signs, symptoms and investigations, and all of them took their antimicrobial prophylaxis started with induction of anesthesia. Incidence of superficial site infection form the cohort is 6.9%which within the range of most researches (0.67% - 12%), although this is higher than most reported figure (less than 2%), but most of those researches they didn't clarified if their incidence among all types of SSI's or just superficial one and the statistical method that they sum it, furthermore the incidence of superficial SSI's in these research (6.9%) is smaller than previous local (Sudan) incidence rate 13.8% and 7% in twodeferent studies and far smaller than the reported African (Tanzania) incidence rate which was 26% [3,7-12].

Incidence of Superficial SSI's among those who had antimicrobial prophylaxis is 8.89% and the incidence for those who took it for a week is 5.36%, although it looks with a risk ratio of 1.66 as the duration affect result, but with confidence interval of 0.39 to 7.04 that crossing the null which suggests that the data are consistent with the lack of an association,although the wide confidence interval most likely due to small sample size which may affect the result, the fisher's exact test is 0.697 which is also insignifican, and as Fisher's exact test is less affected with small sample size unlike chi- square test, in addition the risk estimate for cohort how didn't develop Superficial SSI is 1.039 (CI = 0.93 to 1.16) although its mildly cross the null with these narrow confidence interval indicate even with increasing the sample size the association will be insignificant all those results support the lack of association between the exposure (duration of antimicrobial) and the outcome (superficial SSI's), furthermore these result are consistent with both international results which failed also to find significant between these different duration [3,7,12].

Although I couldn't do matching to remove the confounding that may happen, due to weakness of stoical software, but cross

tabulates for the possible measurable risk done. The cohort comparison study wasn't design to measure the effect of those risk factors, but ensure that none ofthem were associated with the outcome an act as a confounder in this research.

Stratification of age group in an ordinal way using age group of 45 – 55 years old as reference group, although the risk ratio increase with age groups as 0.35{CI = 0.039 to 3012}, 0.53 {CI = 0.095 to 2.92}, 0.58 {CI = 0.066 to 5.07} and 1.29 {CI = 0.085 to 19.37} for 55-65 years old, 65-75 years old, 75-85 years old and above 85 years old age groups respectively, which consistent with senility as risk factor for SSI's but in all of them the confidence intervals were crossing the null which meanthat no association between the age and getting the Superficial SSI's inthis research.

As diabetic status of patient is known risk factor for Superficial SSI's I classified the cases into non –diabetic, control diabetic and non-control diabetic, using the non-diabetic group as reference the risk ratio for controlled diabetics was 0.61 {CI = 0.076 to 5.011} and for non- controlled diabetics is 1.24 {CI = 0.16 to 9.6} which also suggest lack of association in this research for the diabetic status. The same result with arisk ratio of 2.1 {CI = 0.45 to 10.02}, 0.23 {CI = 0.014 to 3.9} and 0.9 {CI = 0.19 to 4.43} for those admitted more than 2 days pre-operatively,those who were admitted for more than 6 days {hospital stay} and thosewho had drain insertion respectively, making none of these risk factors affecting the research result.

As both time spending in operation room and day of removal for an inserted drain are known risk factor, time to event ratios {hazard ratio}were measured and hazard ratio for time spent at the operation room using < 60 min as reference are 0.17 {CI = 0.005 to 6.24}, 0.29 {CI = 0.0196 to 4.17}, 0.38 {CI = 0.0297 to 4.94} and 0.6 {CI = 0.036 to 10.04} for those their operation took 60-90 minutes, 90-120 minutes, 120-180 minutes and > 180 minutes respectively, which reveal an increase with risk with time spending there, but all of the have lack of association to Superficial SSI's in this research. Also time to event ratios calculate for the day of drain removal (using no drain insertion as reference) and we found it to be 0.64 {CI = 0.062 to 6.62}, 1.45 {CI = 0.26 to 7.99}, 0.75 {CI = 0.073 to 7.67} and 0.7 {CI = 0.037 to 13.15} for those whom their drain was removed on the first day, second day,third day and fourth day post-operatively respectively, higher risk for those whom their drain removed in the second day is found, but againwithout association with SSI's in this research.

Other risk factor like obesity, smoking, gloves perforation was deficientin the record, immeasurable risks aren't encounter, and un applicable measures like decolonization of nasal staphylococcus aureus aren't encounter in the research.

Conclusion

We found that the incidence of superficial site infection forms the cohort fall within the same incidence rate of international reported incidence rates, although it is higher than the most reported incidence rate, but it is less than local previously reported incidence rates.

The risk ratio suggests no significant statistical different between the twocomparison groups, those results are consistent with the international results and current knowledge of the unnecessary extension of the antimicrobial prophylaxis.

Recommendation

- More research in SSI's risk factors with the proper sample size tostrength the knowledge in our local circumstance is the hoping steps toward building our local guidelines.
- New research in different hospitals to compare between them tomake the results representable for all working hospitals in joints replacement surgeries.
- More strength to the hospitals infection control protocols todecrease the current incidence rate.
- To increase the awareness of health cadres about SSI's and theirhuge impact financially for both patients and hospitals.
- To have a joint replacement research unit to improve data recordsfor these operations to have more research and to facilitate datatransfers between surgeons.

Limitation of Study

Many of those risk factors are immeasurable like degree of tissue loss during surgery, traffic and conversation in site the theater, some are not recorded in file like if gloves perforation occurs, degree of fluid loss, BMI of the patients, and smoking cigar and some are not applicable yetin Sudan like percentage of staphylococcus aureus colonization and decolonization with nasal antibiotic drugs.

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