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RESEARCH ARTICLE

The Comparsion of Piperacillin / Tazobactem with Clindamycin in Diabetic Foot Ulcers

B. Anil kumar[1], T. Adiveni[1], N. Charan[1], P. Padmini[1], K. Ashwini[1], K. Haritha [1], *D. Surya Chandra[1] , Dr. N. Junior Sundresh[2]

[1]Department of pharmacy practice, Annamalai University, Annamalai nagar, Tamilnadu.

[2]Department of surgery, Asst. medical superintendent, RMMCH, Annamalai University, Annamalai nagar, Tamilnadu.

ABSTRACT

To evaluate and compare the study and efficacy of piperacillin/tazobactem with clindamycin in diabetic foot ulcer according to Wagner's different grades of classification of diabetic foot ulcer. The study was conducted in department of surgery, Rajah Muthai Medical College and Hospital, Annamalai University, Chidambaram. The study period is from August 2011-January 2012.A total of 100 patients were included in the study were divided in to two groups first group includes the patients treated with piperaciilin/ tazobactem and second group treated with clindamycin. The safety and efficacy outcome was described according to Wagners classification of diabetic foot ulcer. The patients with complaints of diabetic foot ulcer in between the age 20 and 80 and belonging to ulcer grade 2,3,&4 are included in the study and with an ulcer grade 0,1&5 and age below 20 and above 80 were excluded. The study shows that 38% of patients suffering with diabetes mellitus over 10 years and maximum number of patients attended with the ulcer foot were in the age group with 51-60 years followed by 61-70 years. Male population is predominant in the study than female. Piperacillin/tazobactem is more effective than clindamycin for the stabilization of infection in diabetic foot ulcer for supporting the result statistical analysis on 't' test was done

INTRODUCTION:

Diabetic foot ulcers are common and estimated to affect 15% of all diabetic individuals during their life time. It is now estimated that 15-20% of patients with such ulcers go on to need an amputation. Almost 85% of amputations are preceded by Diabetic foot ulcers[1].the risk of lower extremity amputations is 15-46 times higher in diabetic than in persons who do not have Diabetes mellitus[2].lower limb disease is the most common source of complications and hospitalization in the Diabetic population[3].Diabetes(7-10%) develop chronic foot ulcers, a severe and expensive complication with life and/or life threating conditions[4].Two main risk factors that cause Diabetic foot ulcers are Diabetic Neuropathy and micro as well as macro Ischemia[5].the global lower extremity amputation study group estimates that 25-90% of all amputations were associated with diabetes[6].Diabetic foot amputations tends to be concomitant with a rise in mortality rates over time. The concomitant mortality is believed to be 13-40% at 1 year,35-65% after 3 years and 39-80% after 5 years[7].Diabetic foot is classified in two major types:1.the neuropathic foot, where neuropathy dominates.2.the Neuroischemic foot, where occlusive vascular disease is the main factor, although neuropathy is present. Differentiating between their entities is essential because their complications are different and they require different therapeutic strategies[8].Identification of localized infections in diabetic foot ulcer is essential in order to prevent complications; such as amputation[9].Wagner's classification of diabetic foot ulcers are grade-0:no ulcer in high risk foot,grade-1:superficial ulcer,grade-2:deep ulcer, penetrating down to ligaments and muscle,grade-3:deep ulcer with cellulitis often with osteomvelitis,grade-4:localized gangrene,grade-5:extensive gangrene involving the whole foot[10].

METHODOLOGY:

The study was conducted in department of surgery, Rajah Muthaih Medical College and Hospital, Annamalai university, Annamalai Nagar which is a tertiary teaching hospital,as well as Multispecialty hospital having 1600 beds. The study duration period is august 2011-jan 2012.The study procedure includes the designing the collection form which includes Age, sex, type of diabetes and duration of diabetes. The inclusion criteria of the study was patients suffering from ulcers due to diabetes mellitus, patients having ulcers from grade 2,3,&4,diabetic foot ulcer patients aged between 20 and 80 and those who are willing to participate in the study. The exclusion criterion of the study was patients below 20 years of age, geriatric patients aged above 80 years old. A total of 100 diabetic foot patients were include in the study which was divided in to two groups,group-1 includes the patients treated with piperacillin/tazobactem inj. 4.5g as IV.group-2 includes the patients treated with clindamycin inj. 300mg as IV. Each of the group was sub-divided according to Wagner's classification grade and we visit to the patients on alternative days and will be observed for rate of wound healing and side effects.

*Corresponding author: D. Surya Chandra / Email: suryachandra888@gmail.com

RESULTS:

Table No. 1: Age wise distribution of patients:

Age	Group-1	Group-2	Total	Percentage (%)
20-40	0	4	4	4.0%
41-50	10	13	23	23%
51-60	20	12	32	32%
61-70	10	15	25	25%
71-80	12	4	16	16%

The present study shows that maximum number was cases in group-1 were between the age group1of 51-60 years where in group 2 between the age group 61-70 years. while considering the total no. of patients included in the study, The maximum number of cases were between the age group of 51-60 years followed by 61-70 years.

2. Sex wise distribution of patients:

Table No. 2:

Gender	Group-1	Group-2	Total	Percentage (%)
Male	34	34	68	68%
Female	15	17	32	32%

There was a male predominance in our study population while considering group-1 or group-2.The overall sex distribution of the study describes male were 68% and female were 32%.The ratio of male: female was 1:0.441.

3. TYPE OF DIABETES:

Table No 3:

Type	Group-1	Group-2	Total	Percentage (%)
Type-1	5	4	9	9%
Type-2	45	46	91	91%

In our study population,45 patients(90%) in group-1 and 46 patients(92%) in group-2 are having type-2 diabetes.91% 0f the patients having type-2 diabetes in this study.

4. **DURATION OF DIABETES:**

Table No. 4:

Year	Group-1	Group-2	Total	Percentage (%)
0-5	16	14	30	30%
6-10	14	18	32	32%
Above10	20	18	38	38%

While considering the total number of patients in this study, 38% of the patients suffering with diabetes mellitus over 10 years.

5. ULCER GRADE:

Grade	Group-1	Group-2	Total	Percentage (%)
2	20	20	40	40%
3	16	18	34	34%
4	14	12	26	26%

The present study shows the maximum number of patients in group-1 were the ulcer grade- 2(40%) followed by grade 3(32%) and grade-4(28%).

It shows that in the group-2 patients, maximum no. of patients were belongs to grade-2(40%) followed by grade-3(36%) and grade-4(24%).

In this study, majority of the patients (40%) presented with ulcer grde-2.

6. (A) Time taken for stabilizing infection (without considering ulcer grade)

Day	Group 1	Group 2
4	10	4
5	4	5
6	7	6
7	3	5
8	3	4
9	2	7
10	4	3
11	6	4
12	3	5
13	3	2
14	3	3
15	2	2
Total	50	50

The complete eradication of the present microorganism from the wound was the tool for finding the stabilization of infection.

6. (B) Time taken for stabilizing infection-grade 2 patients:

Day	Group 1	Group 2
4	8	2
5	2	2
6	4	5
7	2	3
8	2	2
9	-	3
10	2	-
11	-	3
Total	20	20

6. (c) Time taken for stabilizing-grade 3 patients:

Day	Group 1	Group 2
5	3	0
6	2	2
7	2	2
8	2	2
9	2	4
10	2	2
11	2	2
12	-	2
13	2	1
Total	16	18

6(d).Time taken for stabilizing infection-grade 4 patients:

Day	Group-1	Group-2
9	2	2
10	2	-
11	3	-
12	2	2
13	3	3
14	2	3
15	-	2
Total	14	12

7. Therapeutic Efficacy and 0utcome:

(a) Efficacy without considering ulcer grade:

Grade	No. of patients	Mean days	SD
Piperacillin/tazobactem	50	8.08	3.34
Clindamycin	50	8.78	2.98

T value : 3.34
Degree of freedom : 98
Significant level : 0.05
Table value : 1.658

Comparison of piperacillin/tazobactem versus clindamycin:

There is significant difference between the therapies. Statistical analysis (t distribution) showed piperacillin /tazobactem injection has better than clindamycin injection.

(b)Efficacy in grade 2 foot ulcer:

Group	No. of patients	Mean days	SD
Piperacillin/tazobactem	20	5.25	4.125
Clindamycin	20	5.9	3.124

T value : 1.80
Degree of freedom : 38
Significant level : 0.05
Table value : 1.684

Comparison of piperacillin/tazobactam versus clindamycin:

There is significant difference between the therapies.

(c)Efficacy in grade 3 ulcer:

Group	No. of patients	Mean days	SD
Piperacillin/tazobactem	14	11.57	2.09
Clindamycin	12	12.75	2.66

T value : 1.97
Degree of freedom : 32
Significant level : 0.05
Table value : 1.684

Comparison of piperacillin/tazobactem versus clindamycin:

There is significant difference between the therapies.

(d)Efficacy in grade 4 ulcer:

Group	No. of patients	Mean days	SD
Piperacillin/tazobactem	14	11.57	2.09
Clindamycin	12	12.75	2.66

T value : 2.521
Degree of freedom : 24
Significant level : 0.05
Table value : 1.711

Comparison of piperacillin/tazobactem versus clindamycin:

There is significant difference between the therapies. Statistical analysis (t distribution) showed piperacillin /tazobactem injection has better action than clindamycin injection.

DISCUSSION:

The study was carried out from the period of august 2011-january 2012 in the surgery department of Rajah Muthai medical college and Hospital, Annamalai university, Chidambaram.In this study an attempt was made to the evaluation of safety and efficacy of piperacillin/tazobactem and clindamycin. A total of 100 patients were enrolled in the study. The patients with the complaint of diabetic ulcer foot in between the age 20 and 80 and belonging to ulcer grade 2,3,4 were included in the study and patients with ulcer grade 0,1&5 and age below 20 and 80 were excluded.It was found that maximum number of patients attended with ulcer foot were in the age group 51-60 years followed by 61-70 years. Male population was predominant in the study(68%) and female were (32%),and majority of the patients in the study present with type-2 diabetes(91%).According to Wagner's

ulcer grade Cclassification majority of the patients in this study presented with grade-2 ulcer(52%).

EFFICACY AND SAFETY OUTCOME:

In this study, it was observed that piperacillin/tazobactem was more effective than clindamycin for the stabilization of infection in diabetic foot ulcer. For further supporting the result statistical analysis on't' test was done.

Efficacy without considering the ulcer grade: The't' test shows there is a significant difference between piperacillin/tazobactem group and clindamycin group. For piperacillin/tazobactem group, taken mean days 8.08+/-3.34 for the stabilization of infection, whereas clindamycin takes 8.78+/-2.98 mean days.it shows a higher t value 3.34 than table value (1.658) at significant level 0.05.it indicates comparatively higher effect of piperacillin/tazobactem group.

Efficacy in grade-2 foot ulcer: for piperacillin /tazobactem group, taken mean days 5.25+/-4.125 for the stabilization of infection, whereas clindamycin takes 5.9+/-3.124 mean days.it shows a higher 't' value (1.80) than the table value(1.684) at significant level 0.05.it indicates piperacillin/tazobactem has better action than the clindamycin for the stabilization of infection in foot ulcer.

Efficacy in grade-3 foot ulcer: It takes mean days 8.56+/-3.859 to piperacillin/tazobactem group and 9.33+/-3.88 to clindamycin for the stabilization of ulcer grade.It shows a higher't' value(1.97) than table value(1.684) at significant level 0.05.It indicates piperacillin/tazobactem has better action than the clindamycin for the stabilization of infect in foot ulcer.

Efficacy in grade-4 foot ulcer: piperaciili /tazobactem group has mean days 11.57+/-2.09 for the stabilization of infection and clindamycin group has mean days 12.75+/-2.66.it shows a higher 't' value (2.529)than table value(1.711) at significant level 0.05.it indicates piperacillin/tazobactem has better than action than clindamycin for the stabilization of infection in foot ulcer.

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CONCLUSION:

The prospective study comparing piperaciilin/tazobactem injection with clindamycin reveals that piperacillin/tazobactem is more effective for the treatment of diabetic foot ulcer.

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