

A study undertaken by members of the Milnerton branch of The South African Academy of Family Practice/Primary Care to evaluate the efficacy and tolerability of Augmentin demonstrated that Augmentin was bacteriologically statistically superior to amoxicillin in treating urinary tract infections, skin and soft tissue infections and all infections caused by amoxicillin resistant organisms.

In a discussion of the trial, Dr J H Levenstein of Pinelands, Cape Town, notes that the trial has a special significance for general practitioners in that it shows a high incidence of penicillin-resistant organisms (51 per cent). "This observation, as yet limited to one area in South Africa, has wide implications for the general practitioners' management of infections".

According to Dr Levenstein different strategies have been utilised to meet the problem of penicillin-resistant organisms, including the development of further semisynthetic penicillins and cephalosporins. "The addition of clavulanic acid to a known broad spectrum semi-synthetic penicillin amoxicillin (Augmentin) represents a novel approach to meet the problem".

An article by researchers Reading and Cole which was published in *Antimicrobial Agents Chemotherapy* (1977: 11,852-857), which refers to clavulanic acid as an irreversible inhibitor of many of the B-lactamase enzymes produced by strains of the penicillin/ampicillin/amoxicillin resistant organisms, is cited by Dr Levenstein. "With the clavulanic acid binding the penicillin destructive enzymes, the amoxicillin is free to exhibit its antibacterial activity," says Dr Levenstein.

Ten general practitioners of the Milnerton Group of the South African Academy of Family Practice/Primary Care participated in this study. The 164 patients who participated in the trial, were treated with either Augmentin 375 mg tablets or amoxicillin 250 mg capsules, three times daily, for seven days at the start of a meal. Ten patients whose treatment with amoxicillin failed, were retreated with Augmentin.

In the initial stages of the trial 102 patients were randomly located to either Augmentin or amoxicillin treatment. Eighty-nine of the patients were clinically assessable. Bacterio-

GP trial demonstrates efficacy and tolerability of Augmentin



Dr Joseph Levenstein

logically 63 were assessable. Of these 32 received amoxicillin and 31 Augmentin treatment. Subsequently a further 62 patients received Augmentin treatment. Of these 50 were clinically assessable and 40 were bacteriologically assessable.

Bacteriological assessment was thus done in 71 patients treated with Augmentin and 32 treated with amoxicillin, as well as a further six patients who after having failed amoxicillin treatment, received Augmentin.

Evaluating the overall results, Dr Levenstein states: "Overall, the clinical success rate following Augmentin in 68 skin and soft tissue infections was 64 (94,1 per cent). Seven of these had previously received amoxicillin. Bacteriological success was obtained in 35 of the 47 patients (74,5 per cent), four of which had previously received amoxicillin."

Referring to the 39 patients with urinary tract infections who were treated with Augmentin in the trial, including two patients who had had a previous unsuccessful amoxicillin therapy, Dr Levenstein states that the

clinical success rate in this case was 97,4 per cent (38 patients).

"Of the 30 patients of which two had previously received amoxicillin who were bacteriologically assessable, success was achieved in 23 (76,7 per cent). Twenty seven of the patients with skin and soft tissue infections were treated with amoxicillin and clinical success was achieved in 21 (77,8 per cent)".

The success rate in the 21 patients who were bacteriologically assessable while treated with amoxicillin was 57,1 per cent. Clinical success was achieved in 71,4 per cent of the patients with urinary tract infections treated with amoxicillin. "Eleven patients were bacteriologically assessable and amoxicillin was successful in four (36,5 per cent)," according to the Study Group.

An evaluation of the overall bacteriological success of Augmentin and amoxicillin in treating ampicillin/amoxicillin sensitive and resistant organisms show that both drugs are equally successful at treating amoxicillin organisms (82,7 per cent in the case of Augmentin and 71,4 per cent of amoxicillin). Amoxicillin is however statistically far less successful than Augmentin in the treatment of amoxicillin resistant organisms (17,8 per cent success in the case of Augmentin, 33,3 per cent success for amoxicillin).

Bacteriological findings in this study demonstrated that *Staphylococcus aureus* was the commonest pathogen implicated in skin and soft tissue infection, occurring in 49 cases of which 36 (73,5 per cent) were Augmentin/amoxicillin resistant. The commonest pathogen implicated in urinary tract infections were coliform organisms.

Dr Levenstein states in conclusion: "Augmentin performed satisfactorily in the General Practice situation. Amoxicillin appeared successful too in the clinical assessment where amoxicillin sensitive organisms were cultured. However, Augmentin was statistically superior to amoxicillin both clinically and bacteriologically where amoxicillin resistant organisms were cultured.

"While bacterial pathogens in Primary Care may still differ to those in the hospital it is evident from our and other data that the problem of penicillin resistant staphylococci and *Escherichia coli* is no longer confined to the hospital environment, but is widespread in General Practice." □