まえがき

ウレイド型合成広域 penicillin, Piperacillin の追跡調査

-----発売 10 年後における臨床検討成績

Piperacillin (PIPC)はわが国の富山化学工業綜合研究所で開発した広域ペニシリン系注射用剤であり、優れた β -ラクタム系抗生剤の一つとして、広く世界各国から評価されている。

PIPC の諸検討成績は1976年日本化学療法学会新薬シンポジウムで報告して以来ほぼ 10 年が経過するが、今回の検討成績はその間の感染症の変貌、それをとりまく諸状況の変遷を踏えて、現時点での本剤の細菌学的評価および臨床領域における成績を広く全国研究機関の協力をえて追試検討を 行いまとめたものである。検討項目はつぎの通りである。

(1) 細菌学的検討

PIPC の各種起炎菌に対する現況での抗菌力並びにその変遷の実態について、各領域から収集した臨床分離菌の集計成績を開発時における成績と比較検討した(出口)。

(2) 臨床領域における検討

- ① Compromised host における感染症治療薬としてのPIPCの検討:造血器腫瘍,固形癌に合併した各種感染症を対象に、PIPC の単独療法および他抗菌薬との併用療法での臨床成果と安全性について検討した(島田ら)。
- ② 熱傷に続発する難治感染症に対しての検討:本感染症に対する PIPC の臨床成果を検討した(大 塚ら)。
- ③ 術後感染症の予防的効果についての検討:外科手術後の予防的化学療法について, 前立腺肥大症 術後感染症を例にとり, その術後の予防効果を PIPC と他の注射用セフェム剤との比較で検討し た (河田ら)。
- ④ 難治呼吸器感染症についての検討:難治呼吸器感染症について, PIPC の単独使用とアミノ配糖 体剤との併用療法を比較検討した(副島ら)。
- ⑤ 外科系感染症についての検討:急性化膿性腹膜炎を対象にして PIPC の単独療法とアミノ配糖体 剤との併用療法との比較検討した(由良ら)。

本特集号は PIPC を中心にして今日の抗菌剤化学療法における諸問題の幾つかについて、わが国の多くの研究機関の協力をえて検討した成績である。すぐれた抗菌剤の開発直後の成績の検討は多数にあるが、使用承認以降 10 年を超えた時点での広い規模での抗菌剤の再評価は今日まで全く試みられていない。変貌する感染症、多彩化する化学療法に対して、いかなる薬剤を選択してゆくかの問題は重要で、意義ある研究と考える。今回のこの研究の成果は多くの示唆を与えるものであり、これからの抗菌剤化学療法学の在るべき方向の一端を示すものと考える。

おわりに、膨大な成績をまとめられた世話役の先生がたおよび本研究班に参加、研究に協力いただいた各研究機関の先生がたに心より感謝の意を表する。 さらに本研究のとりまとめその他に協力いただいた富山化学工業、三共両社の関係者に謝意を表わすものである。

1988 年 8 月

PREFACE

A follow-up survey of Piperacillin,

an ureido type broad spectrum synthetic penicillin

Result in recent clinical studies 10 years after its launch.

Piperacillin (PIPC) is one of the broad-spectrum penicillins for injection developed by the Research Laboratory of Toyama Chemical Co., Ltd., Japan and it has been widely accepted as an excellent β -lactam hitherto introduced all over the world.

More than ten years have elapsed since The New Drug Symposium of The Japanese Society of Chemotherapy was held in 1976 in which the basic and clinical studies on PIPC were first evaluated and discussed by investigators of many institutes and laboratories.

The contributions compiled in this issue on a nation-wide scale describe accumulated data of the drug in the field of bacteriology as well as clincal medicine for the purpose of reappraisal and current evaluations on the background of changing status of infectious diseases and their surroundings having taken place in the past decade.

Topics of the current issue are to be summarized as following:

(1) Bacteriological studies

Antimicrobial activities of PIPC against various causative organisms at present and the changing status from the time of drug developement were studied on isolated organisms collected from clinical materials of various fields of medicine and compared with those of initial phase of developement. (Deguchi K.)

- (2) Clinical investigations
- 1) Evaluations of PIPC as a therapeutic agent for infectious diseases of the immunocompromised host:

In various infections complicated with hematological neoplasms and solid tumors, clinical efficacy and safty of PIPC were studied by either PIPC alone or combined with other antimicrobial agents. (Shimada K. et al.)

2) Evaluations of PIPC against refractory infections following burns:

A clinical study was performed with a particular reference to the infections concerned. (Otsuka T. et al.)

3) A study on the prophylactic effects of the drug for postoperative infections:

To evaluate the prophylactic effects of the drug on postoperative infections, infections following operations for prostate hypertrophy were chosen for materials and the therapeutic results with PIPC alone and those combined with other injectable cephems were compared. (Kawada Y. et al.)

4) Studies on refractory infections of respiratory organs:

Evaluations were carried out on refractory infections of respiratory organs and therapeutic results with PIPC alone and those combined with aminoglycosides were compared. (Soejima R. et al.)

5) Evaluations of the drug in surgical infections:

The therapeutic results of PIPC alone and those combined with aminoglycosides were compared in cases with acute purulent peritonitis. (Yura J. et al.)

In this special issue, the results of current antimicrobial chemotherapy with a special reference to PIPC and its problems involved are presented in collaboration with many institutes and laboratories in Japan.

Numerous data have been accumulated in the literature on the effective antimicrobial agents soon after each drug developement, but no drug reappraisal study on such a large scale so

late as 10 years after the drug approval has ever been attempted.

It seems to be very important and meaningful to determine what are the choices of drugs to cope with changing status of infectious diseases and with a trend of increasing variability of chemotherapy. The results of contributions compiled in this issue concerning this drug will provide a bulk of suggestions and some directions for the ideal method of the antimicrobial therapy.

Finally I would like to express my sincere appreciation to those of organizing committee who contributed to summarize voluminous data and to those who have participated in this study from many institutes and laboratories. I am also indebted to those concerned with this study in Toyama Chemical Co., Ltd., and Sankyo Company, Ltd., for collecting and compilating data of this study.

August 1988 Yasushi Ueda