行政院國家科學委員會專題研究計畫 成果報告

腹膜剝離術在胃癌併腹膜轉移治療上所扮演的角色(11)

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<u>計畫主持人</u>: 謝茂志 共同主持人: 吳秋文

計畫參與人員: Yutaka Yonemura

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腹膜剝離術在胃癌併腹膜轉移治療上所扮演的角色 - 第二年計畫

The role of peritonectomy in treatment of gastric cancer with peritoneal dissemination - the second year protocol

計畫類別: 個別型計畫 整合型計畫

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計畫主持人:謝茂志

共同主持人:吳秋文, Yutaka Yonemura

本成果報告包括以下應繳交之附件:

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執行單位:台北醫學大學醫學系

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腹膜剝離術在胃癌併腹膜轉移治療上所扮演的角色 - 第二年計畫

The role of peritonectomy in treatment of gastric cancer with peritoneal dissemination - the second year protocol

計畫編號:NSC92-2314-B038-0

執行期限:92年8月1日 至 93年7月31日 主持人:謝茂志,台北醫學大學醫學系 共同主持人:吳秋文,台北榮民總醫院

共同主持人: Yutaka Yonemura,

Shizuoka Cancer Center, Japan

一、中文摘要

本年度下半年獲衛生署通知本研究計畫不必經過人體試驗審核,因此實際計畫之執行只於下半年度開始,目前於台灣已包括四例病例,而於日本靜岡癌病中心醫院也已包括四例病例,相信未來會有更多之病例,而於下一年度將作期中檢討及分析。

二、英文摘要

We were informed that this study could be performed purely for surgical procedure clinical trial, so that the formal study was began in the later half year. There are four cases enrolled in this study in Taiwan, and there are also four cases enrolled in Shizuoka Cancer Center Hospital. We believe that there will be more cases enrolled in the next year and mid term analysis will be perform in the next year.

三、緣由

胃癌合併有腹腔內腹膜轉移, 一般視為末期狀況而不給予積極治 療,其五年存活率極低(<5%)。輔 助性切除的結果較不切除的結果為 佳。一般對於此類病患皆給予全身性 的化學療法,但效果不佳。腹腔內化 學治療的結果是一個可行的途徑,但 受限於各種因素,因此只能施行於手 術中的腹腔內化學治療。若於手術中 施行腹腔內的溫熱化學治療,前瞻性 的研究顯示結果亦較好。但是對於較 大的轉移病灶,若不以手術方式切 除,則腹腔內的溫熱化學治療結果亦 不好。腹膜剝離術便是針對此種狀況 而發展出來的,其在大腸癌的治療結 果雖然令人振奮,然而卻未有胃癌病 患的前瞻性的研究。

四、材料及方法

對於胃癌並有腹腔內轉移的病

患接受 D2 胃切除術後,隨機分配為兩組,一組接受腹膜剝離術及手術中施行腹腔內的溫熱化學治療(42-43

,90 分鐘,腹腔內加入 MMC 30 mg,cisplatin 150 mg,etoposide 100 mg,分三次給予),併術後早期腹腔內化學治療(Taxotere 20 mg/body/day,共三天),隨後每四週給予一次輔助性化學治療(腹腔內 5-FU 650 mg/m²/day,共五天; MMC 10 mg/m² – D1,etoposide 60 mg -- D3-5)共四個療程。另一組不施行腹膜切除,但仍接受腹腔內的溫熱化學治療、術後早期腹腔內化學治療,及隨後每四週給予一次輔助性化學治療,及隨後每四週給予一次輔助性化學治療共四個療程。

五、結果

此為三年性之研究計畫,目的在 觀察病患的存活期。預計三年內收集 至預定的病患數目,並於短期內可以 觀察出其結果。目前於台灣及日本國 立靜岡癌病中心醫院已經各有四例 病例進入本研究計畫之中,預計明年 將有更多之病例進入本項研究。我們 於下年度將舉行期中分析及檢討。預 估三年內可以完成此項研究,於五年 追蹤期滿後便有完整的結果。

六、討論

因為受到SARS之影響,我們未能 如期進行手術治療,但目前SARS情況 已趨穩定,本研究計畫也已經順利展 開,我們仍樂觀的期待未來於台灣及 日本國立靜岡癌病中心醫院會有足 夠的病患數目以供作為研究結果的 分析。

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[Schema]

Adenocarcinoma of the Stomach



Registration (Sign Informed Consent)



Laparotomy $\rightarrow \rightarrow \rightarrow$ not illegible $\rightarrow \rightarrow \rightarrow$ excluded and illegible



Randomization



D2 Gastrectomy

Subtotal Peritonectomy

HIIC

EPIC



Adjuvant Chemotherapy



Follow Up

D2 Gastrectomy

HIIC

EPIC



Adjuvant Chemotherapy



Follow Up