

The Efficacy of Trimethoprim/Sulphamethoxazole as an Oral
Treatment of *Neisseria gonorrhoeae* Infection of Females

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OBJECTIVE: To determine the efficacy of trimethoprim/sulphamethoxazole (co-trimoxazole) as an oral medication for gonorrhoea in females.

BACKGROUND: An oral medication for the treatment of gonorrhoea is desirable for several reasons: 1) the large amounts of penicillin required to effectively treat gonorrhoea in South East Asia is often associated with a great deal of pain, 2) some individuals report a sensitivity to penicillin, and 3) as an alternative for treatment of penicillin resistant *Neisseria gonorrhoeae*. A real problem in this area of the world with oral medications is that the full regimen is often not completed by the patient. This may be due to an apparent abeyance of symptoms or the desire to share the medication with a friend or partner. We have therefore designed an efficacy protocol to evaluate the use of trimethoprim/sulphamethoxazole (co-trimoxazole) in increased quantities capable of being administered in the clinic.

DESCRIPTION: Promiscuous Thai females reporting to a VD control clinic for routine examination were selected for this study. Those girls with positive (intracellular, gram negative diplococci) cervical smears were selected and assigned a two digit random number. Those with numbers totaling an even number were assigned to one protocol, those with odd sums, the other protocol.

One protocol (Y) called for immediate culture of the urethra, cervix, rectum, and vagina, acquisition of history and explanation of the study, and IM treatment with 4.0 mega units of penicillin G. Patients in group Y were requested to return to the clinic at 24 and 72 hours. At these visits, cultures were made of the same four sites to determine treatment cure or failure.

Protocol X called for cultures as above, history acquisition with specific questions regarding pregnancy, known blood dyscrasias, or any known sensitivity to drugs. Those patients with affirmative responses to the above three questions were eliminated from the study. After the history, the patients in group X were given 4 tablets, each containing 80 mg trimethoprim and 400 mg sulphamethoxazole. These tablets were administered with at least 300 ml of water. The patients were observed for any side effects for 2 hours and then blood was obtained from the patients in group X to be used to monitor haemoglobin, erythrocyte count, leukocyte count, hematocrit, and cell morphology. At this time an additional 4 tablets of co-trimoxazole were again carefully administered. These patients were told to return to the clinic in 24 hours. The next day cultures were made from the 4 sites indicated above, blood for CBC was obtained, and another 4 tablets of co-trimoxazole were administered. The patients were requested to return the next day (72 hours after initial treatment) for final cultures. At each visit, the patient was examined and asked questions regarding side effects.

RESULTS: To date, we have placed 106 females in this study. 72 have returned for the second and third visit with 3 of these excluded because their initial cultures were negative for *N. gonorrhoeae*. One of these had a positive culture on the third visit but was still excluded because we considered that culture the possible result of a new exposure.

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With a positive culture from any one of the four culture sites on the third visit as our definition of treatment failure, we found that co-trimoxazole had a cure rate of 52.7% while 4.0 mega units of penicillin G had a cure rate of 66.6%. Table 1 presents this data. Chi square test reveals that with this population, the difference in cure rate is not significant. We have not observed any blood dyscrasias due to either of these two drug regimens. Four patients receiving co-trimoxazole complained of headache, 2 of headache and nausea, and another 2 complained of vomiting within 1-2 hours after taking the second series of tablets. Three patients being treated with 4.0 mega units of penicillin G had complaints, with 2 fainting after receiving medication.

It is evident from our data that the efficacy of co-trimoxazole cannot be evaluated with this sample size. We are continuing with this study and will increase the sample size.

Table 1.
Results of Cultures of *Neisseria gonorrhoeae* in Co-trimoxazole
Treated Patients and Patients Receiving 4.0 mega units
of Penicillin G

Treatment Regimen (No. of Patients)	Initial visit	Second visit	Third visit
X (13)	+	-	-
Y (23)	+	-	-
X (6)	+	+	-
Y (1)	+	+	-
X (14)	+	+	+
Y (4)	+	+	+
X (3)	+	-	+
Y (5)	+	-	+

X = 12 tabs of co-trimoxazole in 24 hours

Y = 4.0 mega units penicillin G