



藥訊

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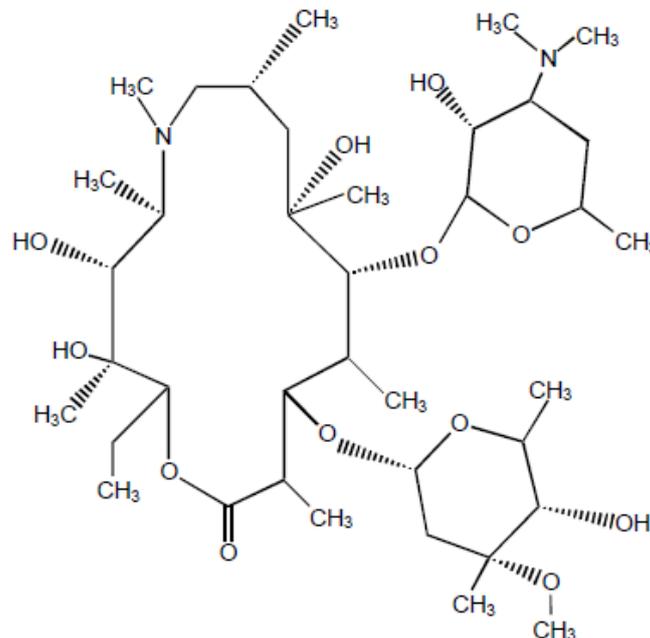
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Azithromycin 藥物安全公告

壹、前言

Azithromycin 是化學結構設計上屬於 azalides 類的抗生素(屬於 macrolides 類藥物的亞群)中可供口服使用的抗生素。Azithromycin 的化學學名為 9-deoxy-9a-aza-9amethyl-9a-homoerythromycin A，其內酯環之 9A 位置具有一個含甲基取代基的氮原子。Azithromycin 是經由與具感受性病原菌的 50S 核糖體次單元結合，而干擾該微生物的蛋白質合成。Azithromycin 不會影響核酸的合成。

結構式為：



貳、臨床使用

Azithromycin 用於革蘭氏陽性、陰性及厭氧菌引起之下呼吸道感染（支氣管炎及肺炎）、皮膚及軟組織感染、中耳炎、上呼吸道感染和性傳染病。

1. Atypical pneumonia
2. Chlamydia trachomatis urethritis 、 cervicitis
3. Chancroid(致病菌為 Haemophilus ducreyi)
4. Mycobacterium avium intracellulare(MAI)

參、常用劑量

A. 成人

1. 治療 atypical pneumonia : 1.5gm; 有 2 種給藥方法
 - a. 3 天的給藥方法 : 500 mg PO q24h×3 天
 - b. 5 天的給藥方法
 - 第 1 天 : 500mg PO
 - 第 2-5 天 : 250mg PO q24h×4 天
2. 治療 Legionnaires' disease : 500mg PO q24h×7 天
3. 治療 C. Trachomatis urethritis 、 cervicitis : 1gm PO 單一劑量
4. 治療 chancroid : 1gm PO 單一劑量

B. 兒童

1. 3 天的給藥方法 : 10mg/kg PO q24h×3 天

2. 5 天的給藥方法

a. 第一天：10mg/kg PO

b. 第 2-5 天：5mg/kg PO q24h×4 天

C. 肝腎功能不全的病患：不必調整劑量

肆、安全公告

2013 年 3 月 12 日，美國食品和藥物管理局(FDA)公告 Azithromycin 可能會導致潛在致命性的心臟節律不規則的電位活動變化。在使用 Azithromycin 下包括常見與已知的危險因素，例如 QT 間期延長，血中鉀與鎂之濃度偏低，心跳速率緩慢，或使某些藥物用於治療心律不整異常及心律不整。這個訊息是由醫學研究人員的一項研究報告，評估潛在的 Azithromycin 所導致的心臟電位活動異常變化。

美國食品和藥物管理局 (FDA) 在 New England Journal of Medicine，2012 年 5 月 17 日發表的 Azithromycin and the Risk of Cardiovascular Death，該研究報告指出 Azithromycin 有小幅增加心血管疾病死亡的風險。

參考資料

1. *The new england journal of medicine* Azithromycin and the Risk of Cardiovascular Death Wayne A. Ray, Ph.D., Katherine T. Murray, M.D., Kathi Hall, B.S., Patrick G. Arbogast, Ph.D., and C. Michael Stein, M.B., Ch.B
2. FDA Statement regarding azithromycin (Zithromax) and the risk of cardiovascular death
3. FDA Drug Safety Communication: Azithromycin (Zithromax or Zmax) and the risk of potentially fatal heart rhythms

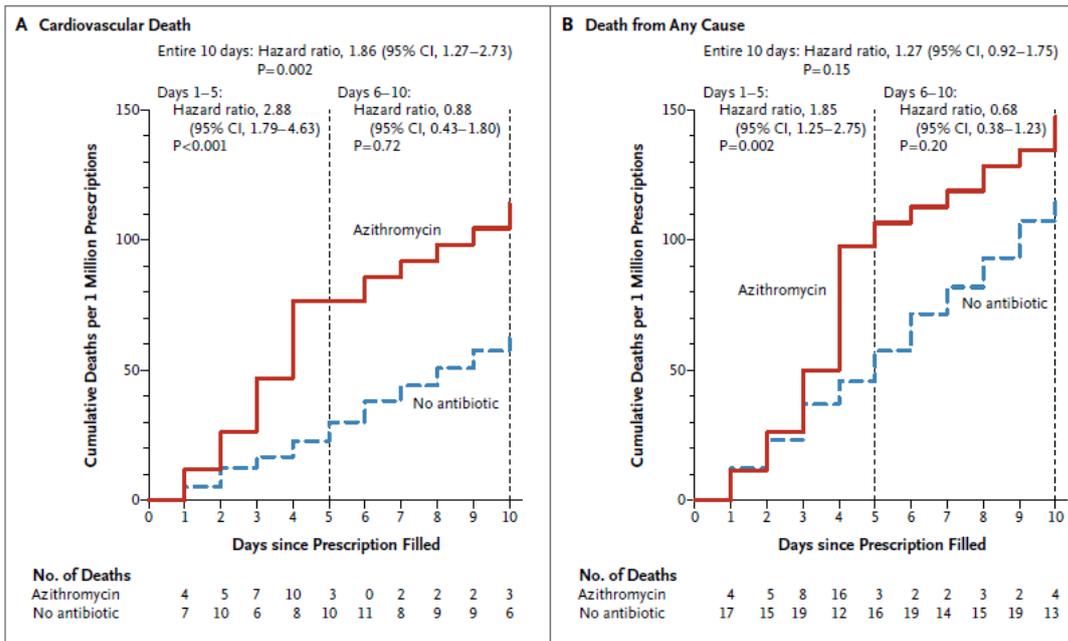


Figure 1. Cumulative Incidence of Cardiovascular Death and Death from Any Cause among Patients Who Took Azithromycin and Persons Who Did Not Take Study Antibiotics during a 10-Day Period.

The 10-day period began with the date on which the prescription was filled for patients who took azithromycin, with a matched period for persons who did not take study antibiotics (the reference group). The cumulative incidence in the reference group was not adjusted; the cumulative incidence in the group of patients who took azithromycin was adjusted for demographic factors and propensity score by multiplying the unadjusted incidence by the ratio of the adjusted to the unadjusted hazard ratio for the 10-day period.

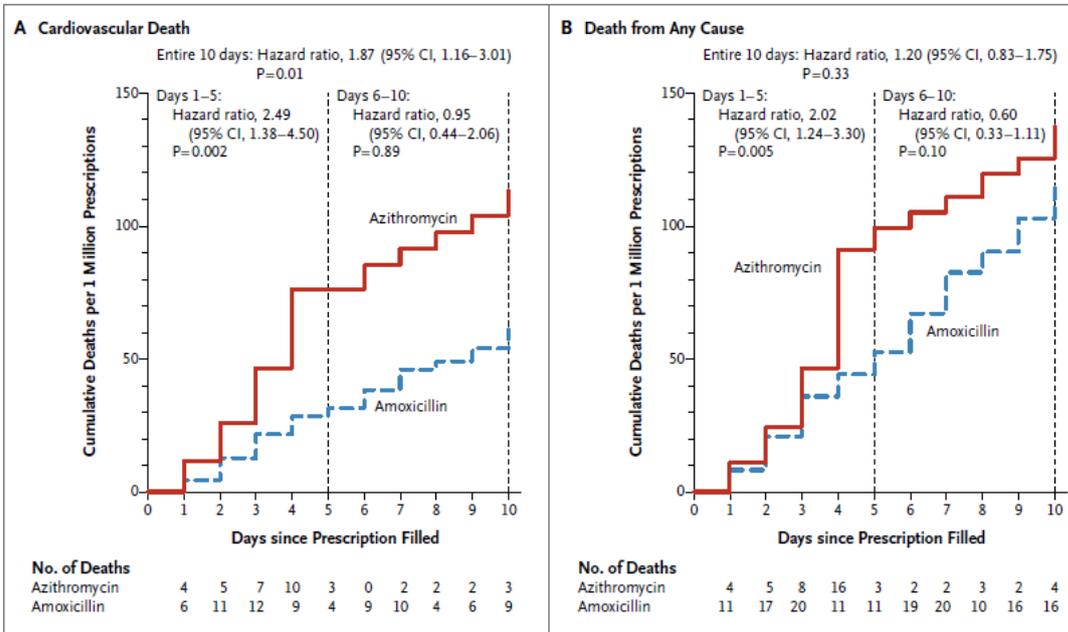


Figure 2. Cumulative Incidence of Cardiovascular Death and Death from Any Cause for Patients Who Took Azithromycin or Amoxicillin during a 10-Day Period.

The 10-day period began with the date on which the prescription was filled. The cumulative incidence for patients who took amoxicillin (the reference group) was not adjusted; the cumulative incidence for patients who took azithromycin was adjusted for demographic factors and propensity score by multiplying the unadjusted incidence by the ratio of adjusted to unadjusted hazard ratios for the 10-day period.