Cephalosporins with Clavulinic Acid

The medicine market is flooded with combination of various antibiotics with Clavulanic Acid in suspension and dispersible form like Cefpodoxime with Clavulanate, Cefixime with Clavulanate etc. I want to know whether they have any pharmacological rationality?

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REPLY

Both cefpodoxime and cefixime (3rd generation oral cephalosporins) are not currently first line drugs for any pediatric illness. The only oral antibiotic combination with clavulinic acid that is listed in pediatric drug formularies is amoxiciilin with clavulinic acid. There are no RCT's available to date that compares cefpodoxime and cefixime given alone with their respective combinations with clavulinic acid. Therefore, organisms resistant to these drugs, which must be used only as second or third line drugs, must be treated with broad spectrum antibiotics and not with their combination with clavulinic acid.

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Intravenous Immunoglobulin in Rh Hemolytic Disease of Newborn

Girish, *et al*.(1) have reported that low dose intravenous immunoglobulin (IVIG) is as efficacious as high dose IVIG in reducing the duration of phototherapy in Rh hemolytic disease of the newborn.

The trial was designed as a superiority trial; however, the authors have presented the paper as though it was a non-inferiority equivalence trial. The results show that the duration of phototherapy was longer in the low dose group (77±57 hrs) compared to the high dose group (55±49 hrs). That this difference did not achieve statistical significance only means that superiority of the high dose could not be statistically demonstrated with the sample size available. It does not mean that the low dose IVIG is equivalent in efficacy to the high dose and that one can start using the low dose to reduce the cost of therapy.

Even when viewed through the prism of a superiority trial, the sample size was inadequate and the study was underpowered. This is because the actual standard deviation was wider (49 hr) than what the authors had assumed (24 hr). For a standard deviation of 49 hrs and effect size of 24 hrs the requisite sample size was approximately 150 (assuming equal variance), and not 38. There is a distinct possibility that an adequately powered study would show that the mean difference in phototherapy duration did achieve statistical significance or was close to achieving statistical significance–quite the opposite of the authors' conclusion.

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