

13374 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

TABLE A.7.3.—UGDP DATA: CARDIOVASCULAR DEATH RATES BY ASSIGNED TREATMENT, SEX, AND DOSE GIVEN¹

Dose given	Assigned treatment			
	Placebo	Tolbutamide	Standard dose insulin	Variable dose insulin ²
Females:				
As assigned	1.4/79.8=0.02	10.8/78.0=0.14	3.9/52.8=0.07	4.6/42.4=0.11
Dose modified	0/33.6=0	3/39.7=0.08	3.7/76.4=0.05	3.6/94.3=0.04
No drug	1.2/23.6=0.05	1.2/19.6=0.06	0.4/23.5=0.02	1.8/20.9=0.09
Males:				
As assigned	5/35.9=0.14	7.0/41.5=0.17	1/14.0=0.07	1/11.5=0.09
Dose modified	1/15.0=0.07	2.7/11.7=0.23	3.9/33.7=0.12	1/27.6=0.4
No drug	2/9.8=0.02	0.8/8.6=0.09	0.1/9.0=0.01	0/6.7=0

¹ Tables give ratio of cardiovascular deaths (relative allocation) to number of patients (relative allocation).² Combining both dose modification groups for IVAR results in the following: females $\theta = 8.2/136.7 = .06$; males $\theta = 2/39.1 = .05$.

TABLE A.7.4.—UGDP DATA: CARDIOVASCULAR DEATH RATES BY ADHERENCE AND DOSE MODIFICATION

Dose Modification	Treatment				Totals
	Placebo	Tolbutamide	Standard dose insulin	Variable dose insulin	
100 percent adherence: ¹					
No-----	4/64=0.06	16/77=0.21	4/51=0.08	4/27=0.15	28/219=0.13
Yes-----	1/12= .08	4/29= .14	3/50= .06	2/55= .04	10/146=0.07
<100 percent adherence:					
No-----	2.4/51.6= .05	1.9/42.5= .04	4.6/60.1= .08	1.6/26.9= .06	10.5/181.1= .06
Yes-----	1.8/36.6= .05	1.7/22.4= .08	0.9/15.7= .06	2.6/66.9= .04	7/141.6= .05
Totals-----	912/164.2= .06	23.6/170.9= .14	12.5/176.8= .07	10.2/175.8= .06	55.5/687.7= .08

¹ 100% adherence is defined as taking the initially assigned drug for every quarter of follow-up.

TABLE A.7.5.—UGDP DATA: CARDIOVASCULAR DEATH RATES BY ASSIGNED TREATMENT, SEX AND COMPLIANCE

Compliance ¹	Treatment			
	Placebo	Tolbutamide	Standard dose insulin	Variable dose insulin
Females:				
100 percent adherence—no dose modification	0/41=0	9/51=0.18	1/28=0.04	3/21=0.14
<100 percent adherence or dose modification	1.3/72.3=.02	4.8/66.6=.07	6.6/101.2=.07	5.2/115.8=.04
No drug	1.2/23.6=.05	1.2/19.6=.06	0.4/22.5=.02	1.8/20.9=.09
Males:				
100 percent adherence—no dose modification	4/23=.17	7/26=.27	2/22=.09	1/6=.17
<100 percent adherence or dose modification	2/27.8=.07	2.7/27.2=.10	2.9/25.7=.11	1/32.9=.03
No drug	0.2/9.8=.02	0.8/8.6=.09	0.1/9=.01	0/6.7=0

¹ Compliance is based on both adherence to the assigned treatment group and use of the prescribed dose.