

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13375

TABLE A.7.6.—UGDP DATA: CARDIOVASCULAR MORTALITY RATES BY SEX, COMPLIANCE, AND MEDIAN AGE AT ENTRY

Compliance	Control ¹	Tolbutamide
Females:		
≤53 yr old:		
100 percent—no DM ²	0/45=0	0/22=0
<100 percent or DM.....	2.6/155.9=.02	1/33.4=.03
No drug.....	0.4/39=.01	0/11.7=0
>53 yr old:		
100 percent—no DM.....	4/45=.09	9/29=.31
<100 percent or DM.....	10.5/133.4=.08	3.8/33.2=.11
No drug.....	3/28=.11	1.2/6.9=.17
Males:		
≤53 yr old:		
100 percent—no DM.....	1/23=.04	3/10=.30
<100 percent or DM.....	1/35.6=.03	1.8/10.5=.17
No drug.....	0/16.7=0	0.2/4.9=.04
>53 yr old:		
100 percent—no DM.....	6/28=.21	4/16=.25
<100 percent or DM.....	4.9/51=.10	0.9/16.7=.05
No drug.....	0.3/8.8=.03	0.6/3.7=.16

¹ Control is made of of placebo and standard- and variable-dose insulin treatment groups.
² DM indicates dose modification.

TABLE A.7.7.—UGDP DATA: TREATMENT¹ VS PLACEBO ADJUSTED LOGARITHMS OF RATIOS OF FAILURE RATES BY SEX FOR CARDIOVASCULAR AND TOTAL DEATHS

	Tolb/Pibo	ISTD/Pibo	IVAR/Pibo	None/Pibo
Cardiovascular deaths:				
Female:				
Log ratio.....	2.64	1.79	1.75	1.69
SD ²	.99	1.05	1.03	1.21
P ³	.008	.09	.09	.16
Male:				
Log ratio.....	.094	-.35	-.29	-4.48
SD.....	.59	.69	.86	2.08
P.....	.87	.61	.73	.03
Total deaths:				
Female:				
Log ratio.....	1.12	.23	.64	-.51
SD.....	.55	.63	.56	.78
P.....	.04	.72	.26	.52
Male:				
Log ratio.....	-.30	.037	-1.49	-1.65
SD.....	.5	0	.86	1.18
P.....	.56	.94	.08	.16

¹ Tolb indicates tolbutamide; Pibo, placebo; ISTD, standard-dose insulin; and IVAR, variable-dose insulin.
² Refers to estimate of standard deviation of log of ratio of failure rates.
³ Refers to test of significance (two-tail) using normal theory.

TABLE A.8.1.—BEDFORD DATA: INFLUENCE OF BACKGROUND VARIABLES ON DEATH RATES

Factor	p [*]	λ̂(×10 ³)†
Hypertension:		
No.....	27/193=0.14	1.54
Yes.....	15/53=0.28	3.41
Blood glucose level:		
<139 mg/100 ml.....	17/124=0.14	1.55
>139 mg/100 ml.....	25/123=0.20	2.28
Arterial disease:		
No.....	30/218=0.14	1.54
Yes.....	12/30=0.40	5.02
Sex:		
Male.....	20/129=0.15	1.76
Female.....	22/119=0.18	2.08
Age:		
<45 yr.....	0/54=0	
>45 yr.....	42/194=0.22	2.52

*p is the number of deaths/total.

†λ is the number of deaths/total time followed up (6-mo periods).