Supplementary materials for Application of Bayesian predictive probability for interim futility analysis in single-arm early phase II trial

(Additional report)

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Supplementary Table 1 (S1): Evaluation of the effect of η and the cutoff of the predictive probability (γ) on probability of early termination, type I error, and power.

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## Probability of early termination
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	η	response.rate	γ=0.01	γ=0.05	γ=0.1	γ=0.15	γ=0.2
0.02	0.9	0.02	0.7386	0.7386	0.9647	0.9647	0.9647
0.07	0.9	0.07	0.3367	0.3367	0.7168	0.7168	0.7168
0.12	0.9	0.12	0.147	0.147	0.4476	0.4476	0.4476
0.17	0.9	0.17	0.0611	0.0611	0.2489	0.2489	0.2489
0.22	0.9	0.22	0.0241	0.0241	0.1259	0.1259	0.1259
0.27	0.9	0.27	0.0089	0.0089	0.0583	0.0583	0.0583
0.32	0.9	0.32	0.0031	0.0031	0.0248	0.0248	0.0248
0.37	0.9	0.37	0.001	0.001	0.0096	0.0096	0.0096
0.42	0.9	0.42	3e-04	3e-04	0.0034	0.0034	0.0034
0.021	0.95	0.02	0.7386	0.9647	0.9647	0.9647	0.997
0.071	0.95	0.07	0.3367	0.7168	0.7168	0.7168	0.9171
0.121	0.95	0.12	0.147	0.4476	0.4476	0.4476	0.7346
0.171	0.95	0.17	0.0611	0.2489	0.2489	0.2489	0.5181
0.221	0.95	0.22	0.0241	0.1259	0.1259	0.1259	0.3269
0.271	0.95	0.27	0.0089	0.0583	0.0583	0.0583	0.1863
0.321	0.95	0.32	0.0031	0.0248	0.0248	0.0248	0.0962
0.371	0.95	0.37	0.001	0.0096	0.0096	0.0096	0.045
0.421	0.95	0.42	3e-04	0.0034	0.0034	0.0034	0.0189
0.022	0.99	0.02	0.7386	0.9647	0.997	0.997	0.997
0.072	0.99	0.07	0.3367	0.7168	0.9171	0.9171	0.9171
0.122	0.99	0.12	0.147	0.4476	0.7346	0.7346	0.7346
0.172	0.99	0.17	0.0611	0.2489	0.5181	0.5181	0.5181
0.222	0.99	0.22	0.0241	0.1259	0.3269	0.3269	0.3269
0.272	0.99	0.27	0.0089	0.0583	0.1863	0.1863	0.1863
0.322	0.99	0.32	0.0031	0.0248	0.0962	0.0962	0.0962
0.372	0.99	0.37	0.001	0.0096	0.045	0.045	0.045
0.422	0.99	0.42	3e-04	0.0034	0.0189	0.0189	0.0189

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## Power and type I error
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	η	response.rate	γ=0.01	γ=0.05	γ=0.1	γ=0.15	γ=0.2
0.02	0.9	0.02	0.0000	0.0000	0.0000	0.0000	0.0000
0.07	0.9	0.07	0.0161	0.0161	0.0151	0.0151	0.0151
0.12	0.9	0.12	0.1422	0.1422	0.1343	0.1343	0.1343
0.17	0.9	0.17	0.4010	0.4010	0.3829	0.3829	0.3829
0.22	0.9	0.22	0.6717	0.6717	0.6494	0.6494	0.6494
0.27	0.9	0.27	0.8573	0.8573	0.8384	0.8384	0.8384
0.32	0.9	0.32	0.9501	0.9501	0.9382	0.9382	0.9382
0.37	0.9	0.37	0.9859	0.9859	0.9799	0.9799	0.9799
0.42	0.9	0.42	0.9968	0.9968	0.9943	0.9943	0.9943
0.021	0.95	0.02	0.0000	0.0000	0.0000	0.0000	0.0000
0.071	0.95	0.07	0.0040	0.0039	0.0039	0.0039	0.0033
0.121	0.95	0.12	0.0605	0.0588	0.0588	0.0588	0.0512
0.171	0.95	0.17	0.2386	0.2330	0.2330	0.2330	0.2071

	η	response.rate	γ=0.01	γ=0.05	γ=0.1	γ=0.15	γ=0.2
0.221	0.95	0.22	0.5000	0.4908	0.4908	0.4908	0.4467
0.271	0.95	0.27	0.7376	0.7279	0.7279	0.7279	0.6792
0.321	0.95	0.32	0.8897	0.8824	0.8824	0.8824	0.8429
0.371	0.95	0.37	0.9628	0.9585	0.9585	0.9585	0.9335
0.421	0.95	0.42	0.9900	0.9880	0.9880	0.9880	0.9751
0.022	0.99	0.02	0.0000	0.0000	0.0000	0.0000	0.0000
0.072	0.99	0.07	0.0008	0.0008	0.0008	0.0008	0.0008
0.122	0.99	0.12	0.0220	0.0217	0.0201	0.0201	0.0201
0.172	0.99	0.17	0.1240	0.1226	0.1145	0.1145	0.1145
0.222	0.99	0.22	0.3331	0.3301	0.3119	0.3119	0.3119
0.272	0.99	0.27	0.5851	0.5811	0.5560	0.5560	0.5560
0.322	0.99	0.32	0.7918	0.7880	0.7638	0.7638	0.7638
0.372	0.99	0.37	0.9161	0.9135	0.8958	0.8958	0.8958
0.422	0.99	0.42	0.9731	0.9717	0.9615	0.9615	0.9615

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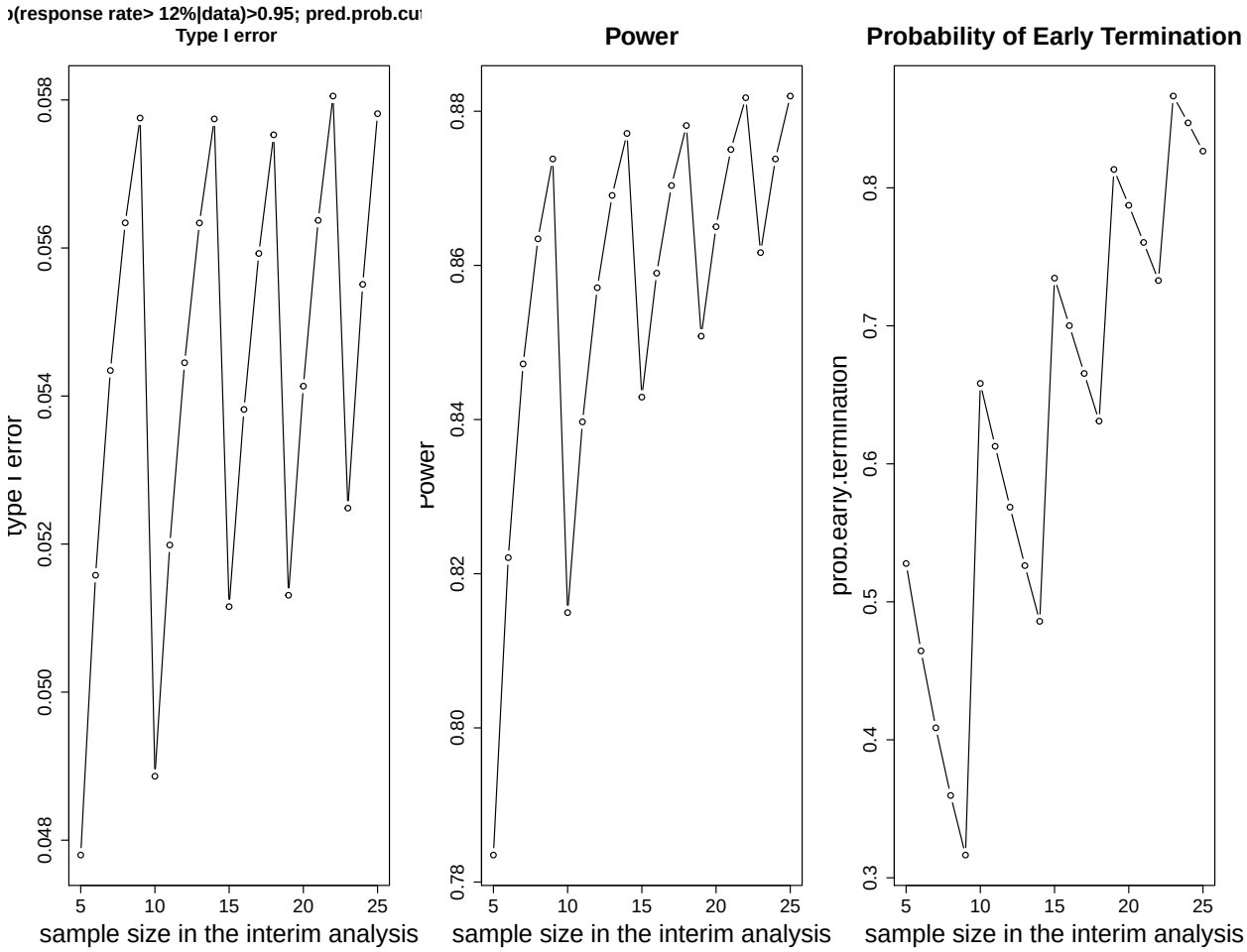
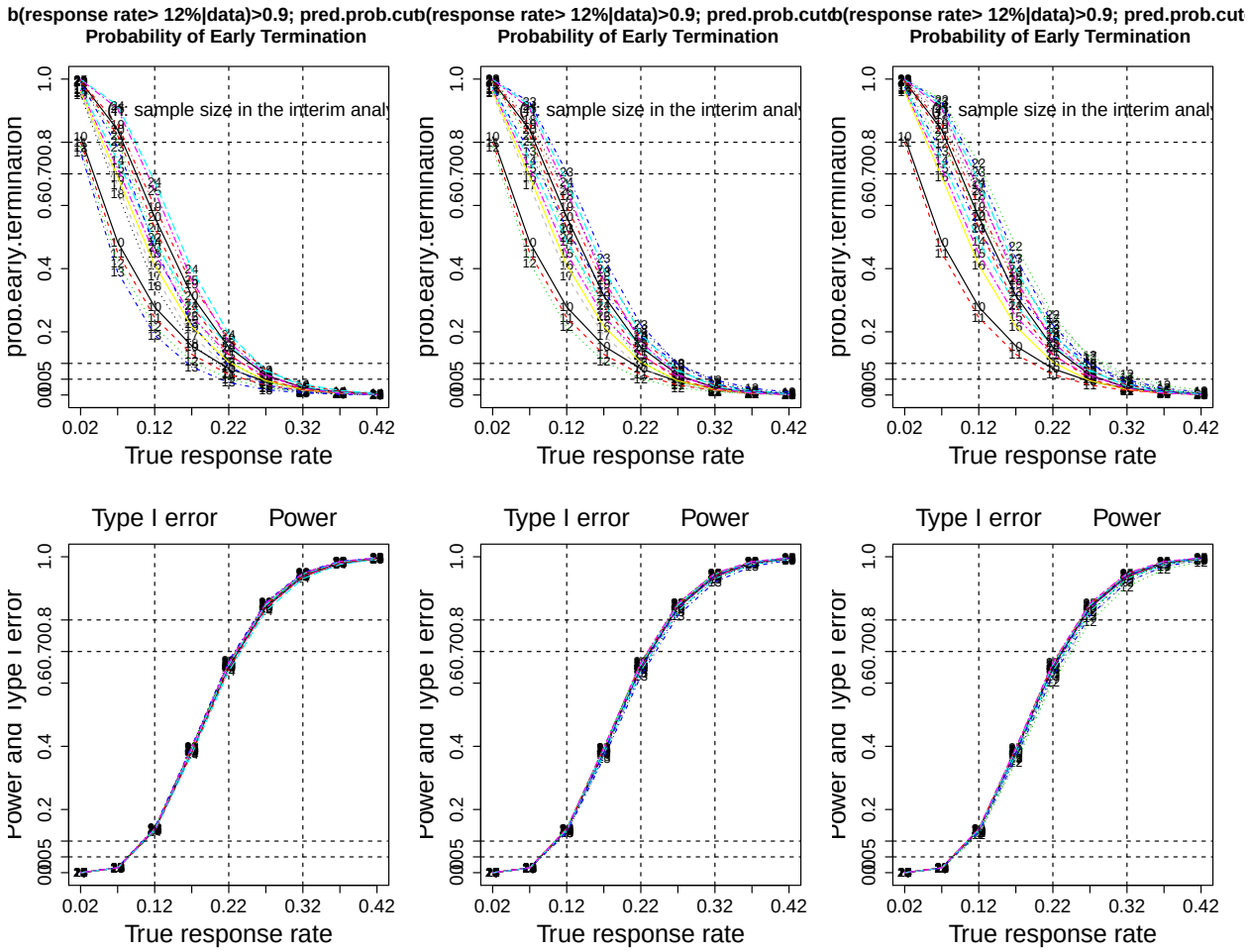
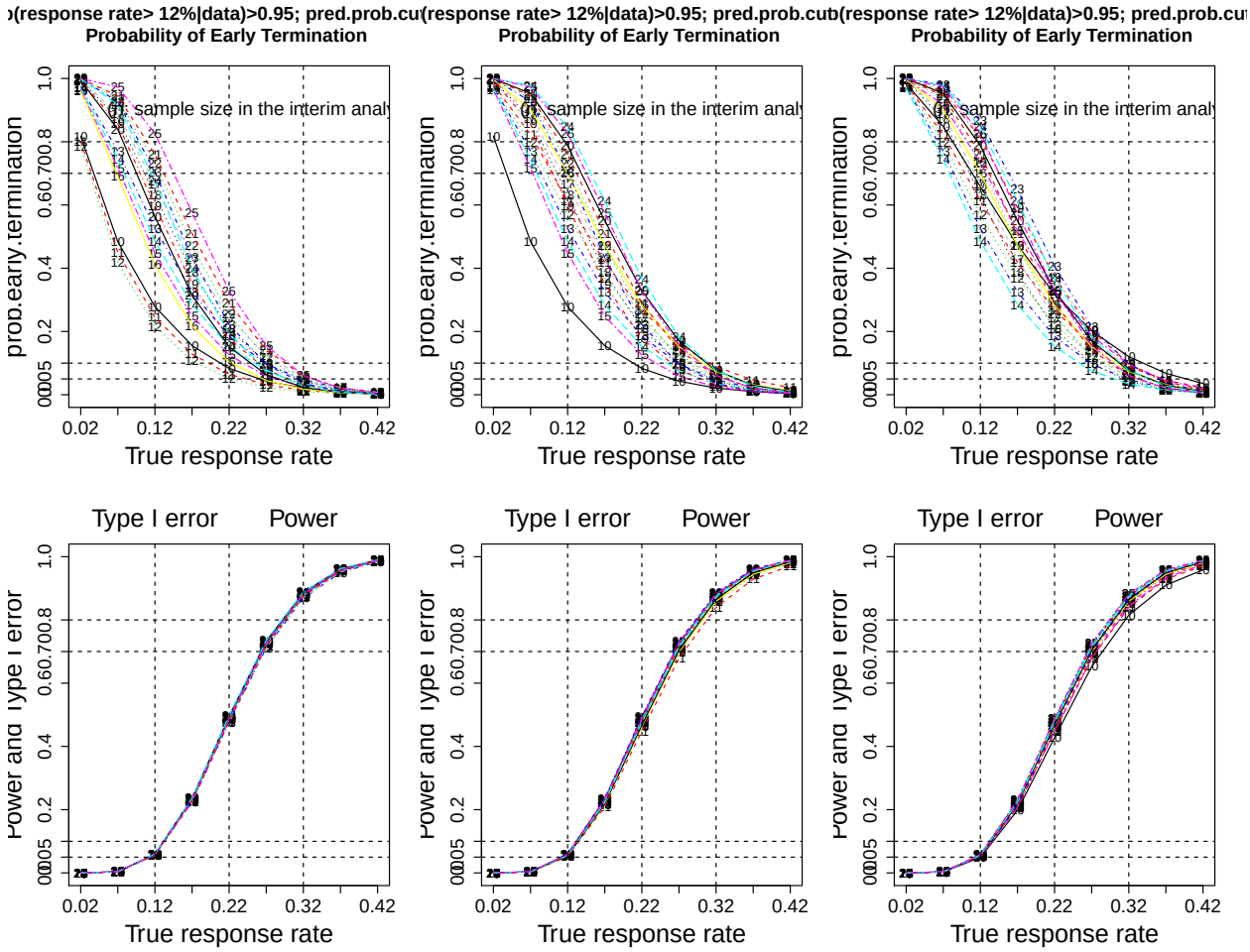
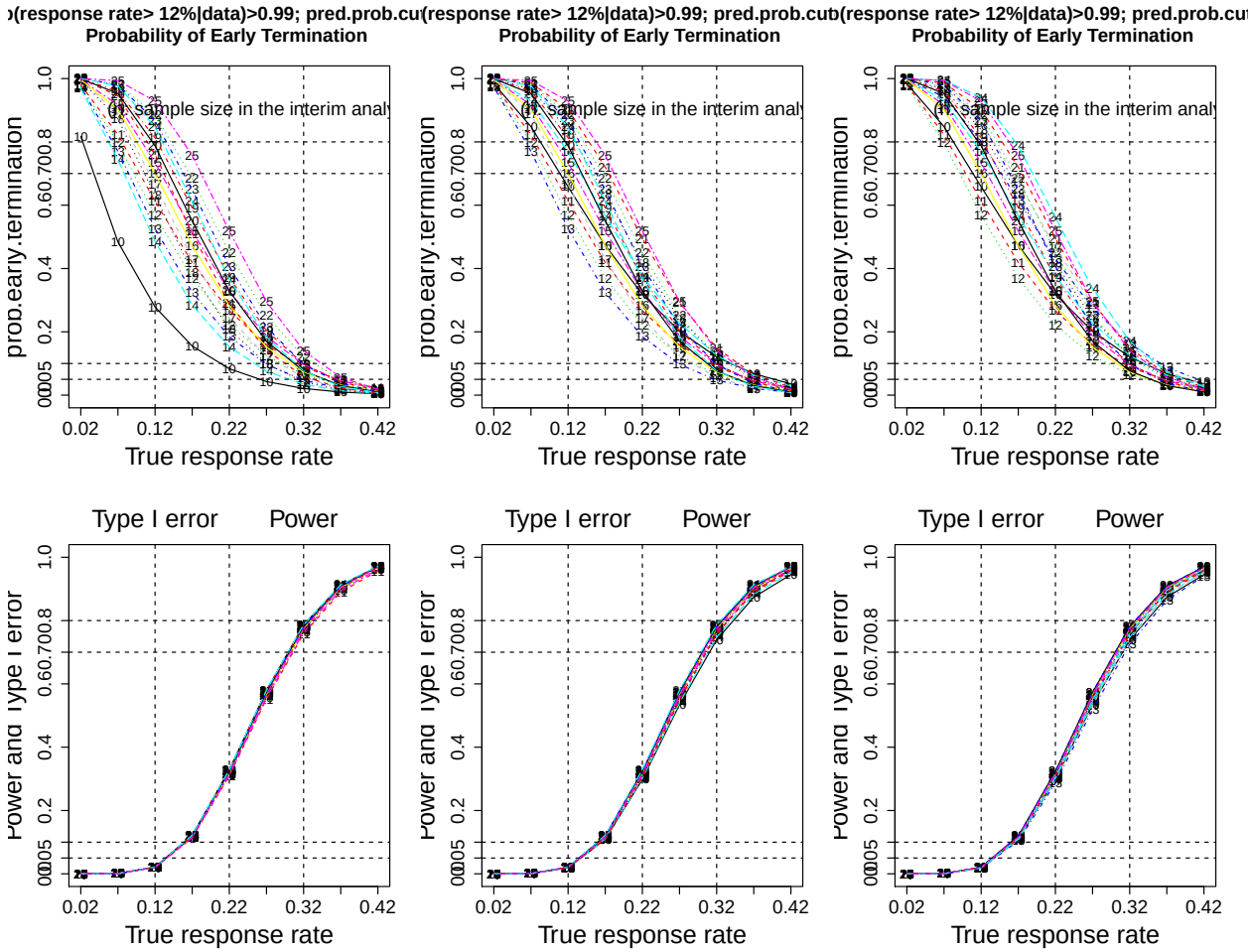
Supplementary Figure 1 (Fig.S1): Evaluation of sample size allocation for interim analysis



Supplementary Figure 2 (Fig.S2): Evaluation of sample size allocation for interim analysis for various cutoffs of predictive probability and η




(response rate> 12%|data)>0.95; pred.prob.cu
Probability of Early Termination
sample size in the interim anal
prob.early.termination
True response rate
Type I error
Power
Power and Type I error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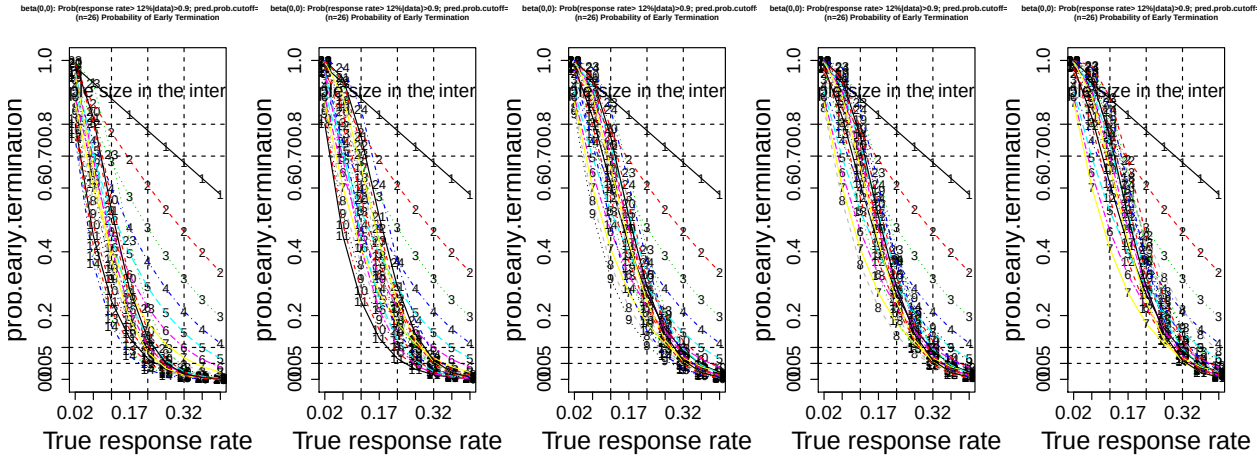
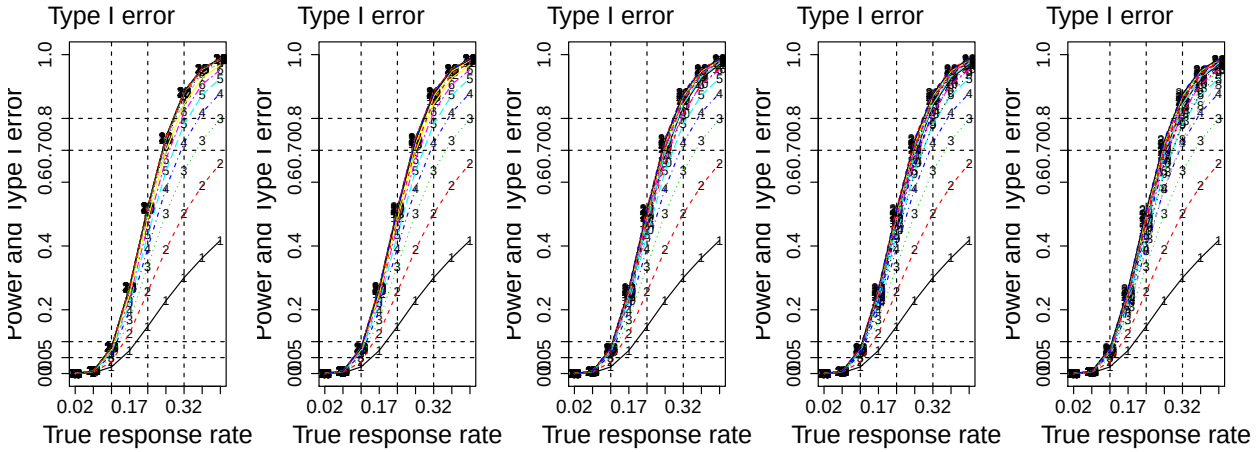
Probability of Early Termination
(response rate> 12%|data)>0.99; pred.prob.cut
Probability of Early Termination
(response rate> 12%|data)>0.99; pred.prob.cu
Probability of Early Termination
(n: sample size in the interim analy
prob.early.termination
True response rate
Type I error
Power
Power and Type I error
True response rate

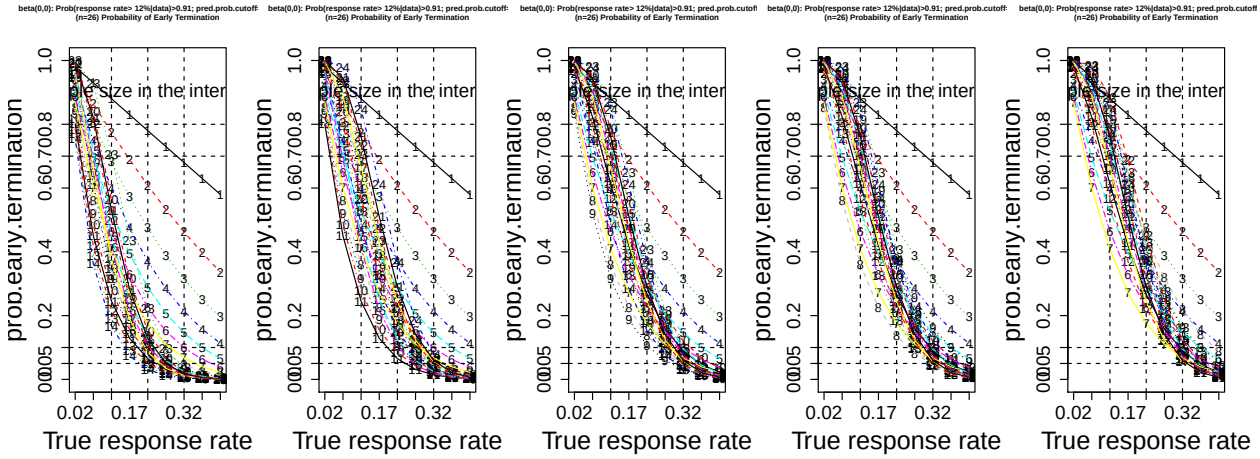
Supplementary Figure 3 (Fig.S3): Evaluation of differential priors

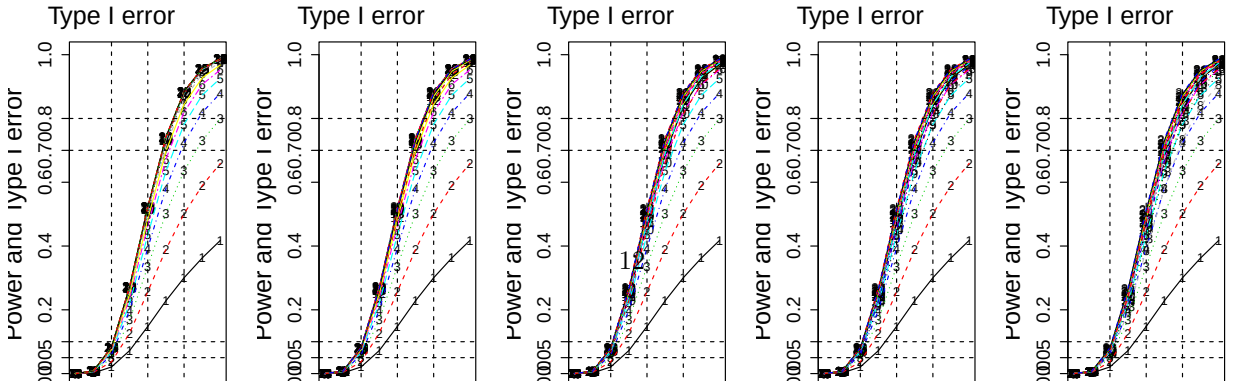
Results of prior distribution of response rate: The example in the main text uses a non-informative beta prior, beta(1,1), for the response rate to evaluate the performance. Here we further explore a series of beta prior distributions: (i) two non-informative priors, with beta(c,c): c=0 (Haldane prior) and 1 (Bayes prior); (ii) an unfavorable prior (more drug-resistant) with beta(0,1), equivalent to one-sided Fisher exact test; (iii) a favorable prior (more drug-sensitive) with beta(1,0); and (iv) a prior based on the null-hypothesis's response rate with standard deviation of 0.1 (i.e., beta(1.15, 8.41) for the 12% response rate). Results in the figures below show the smallest total sample size is 27 subjects in order to reach power above 80% and type I error below 5% by all the priors depending on γ and δ. Specifically, this condition (i.e., power>80% and type I error<5% at n=27) holds for γ=0.01 to 0.2 in most priors. For δ, to retain the same condition, all non-informative priors, the unfavorable prior, and the null-hypothesis's prior require δ in a range of 0.90-0.97 while the favorable prior needs δ to be 0.97-0.98. Regarding the interim analysis sample size, n_1, high PET occurs only when the interim analysis is performed at a late stage, such as n1=17 (17/27=63%) for a targeted PET>60%. On the other hand, for a moderate targeted PET, 45%-50%, all the priors give the smallest n1 of 14 (14/27=52%) for the interim analysis. When the interest is to have PET at least 70% with n_1 less than 50% of the total sample size, the smallest total sample size will increase to 29 subjects with the smallest n_1=14 (14/29=48%) in all priors except the favorable prior.

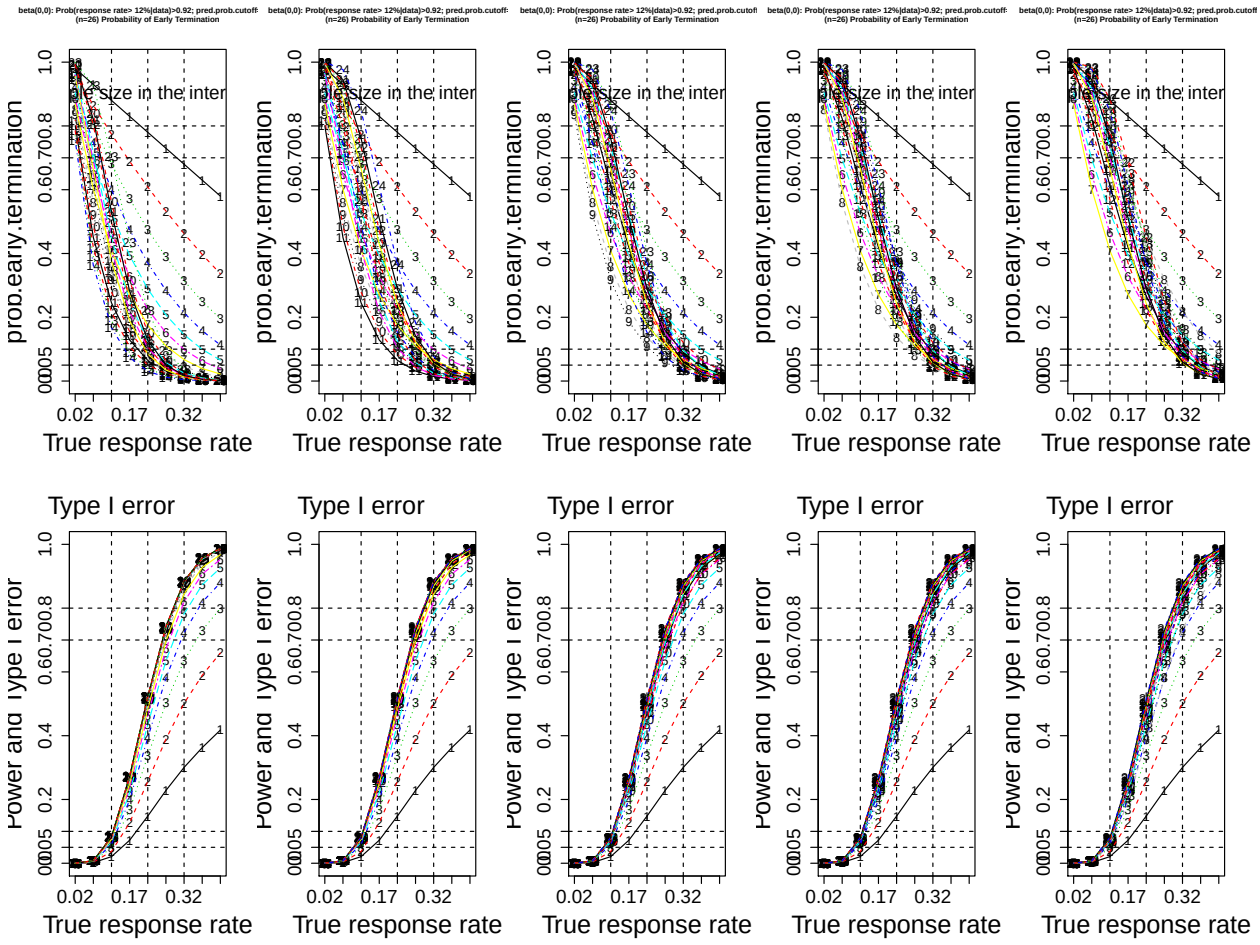
Prior Distribution: beta(0,0)







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Type I error
Power and Type I error
True response rate
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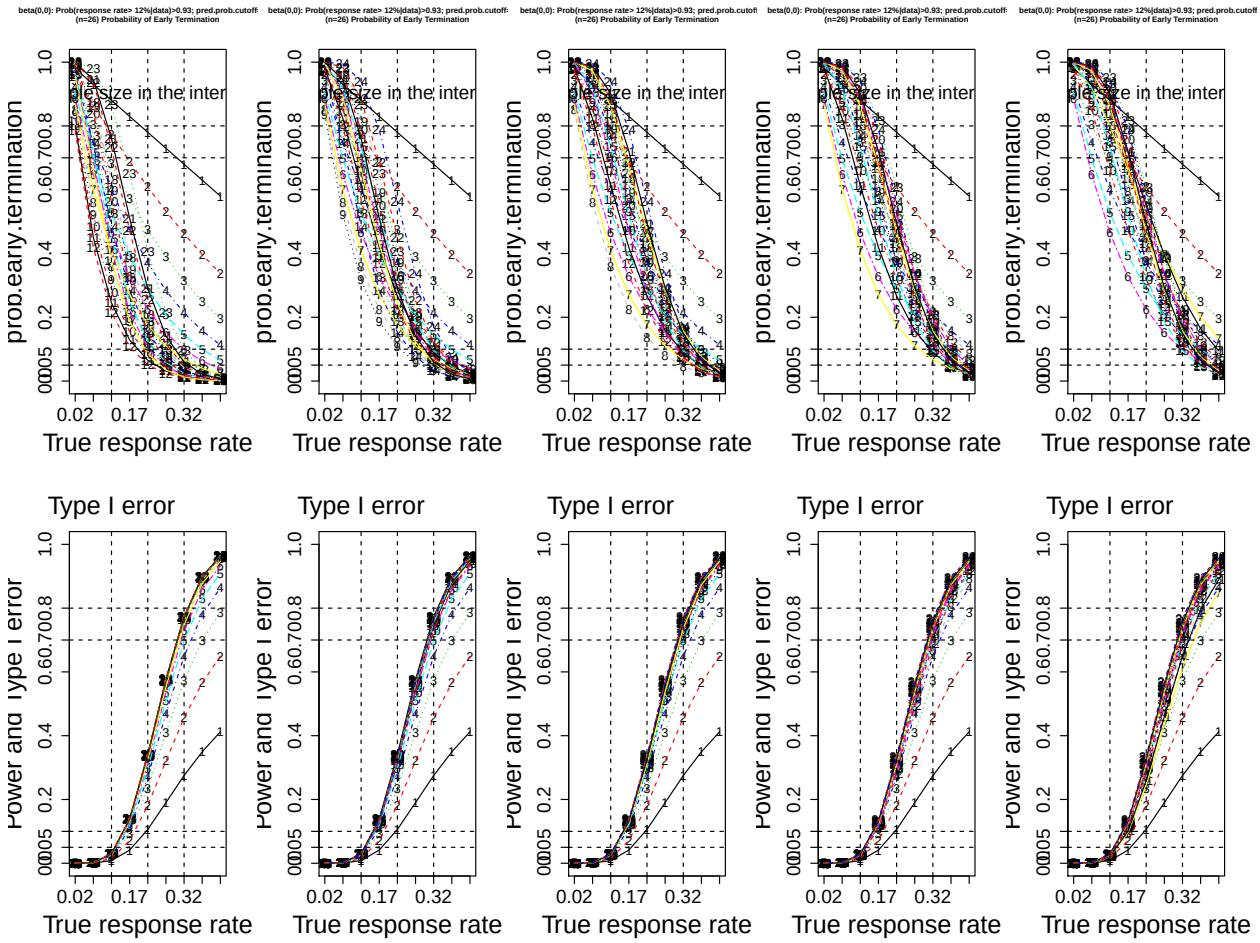
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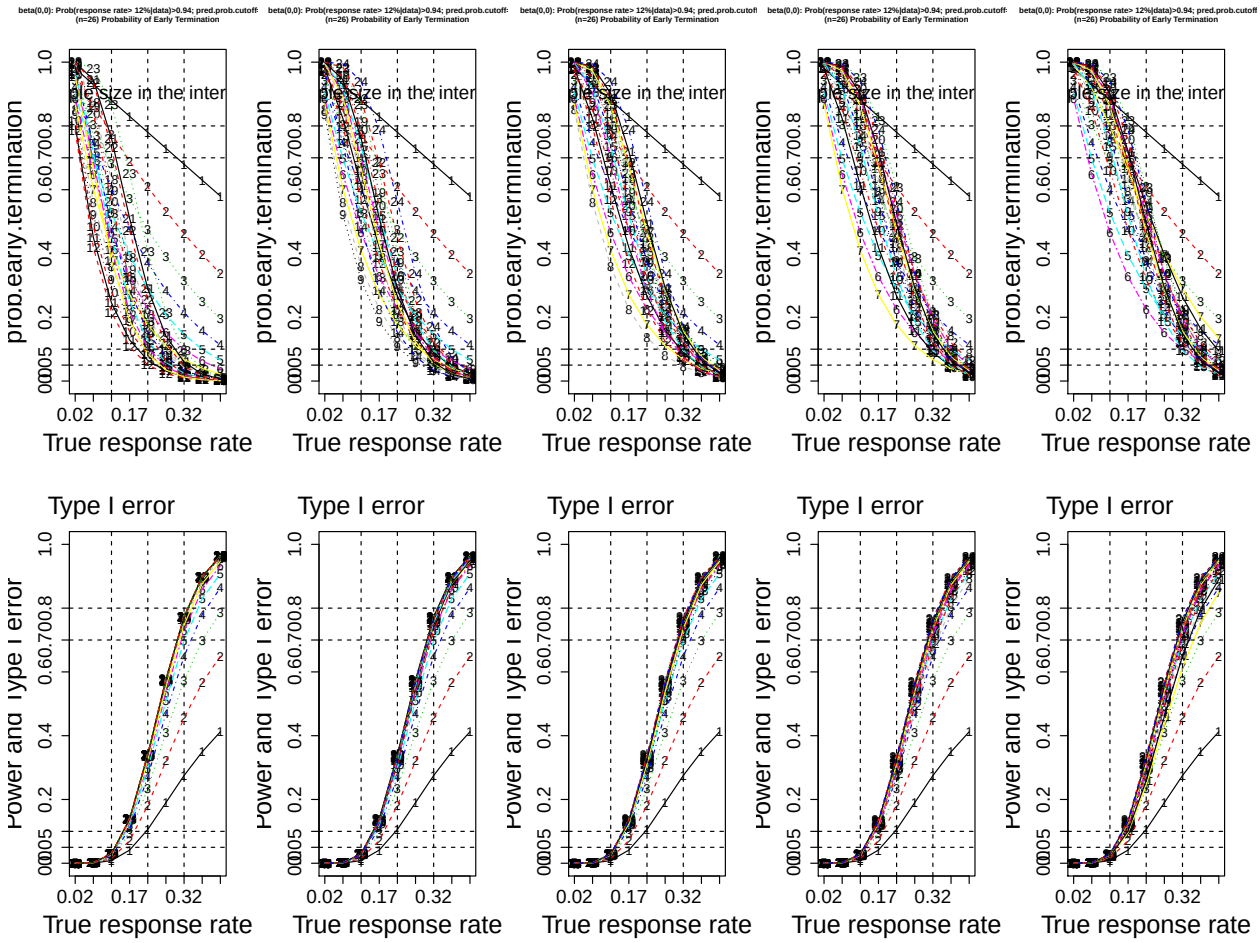
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(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
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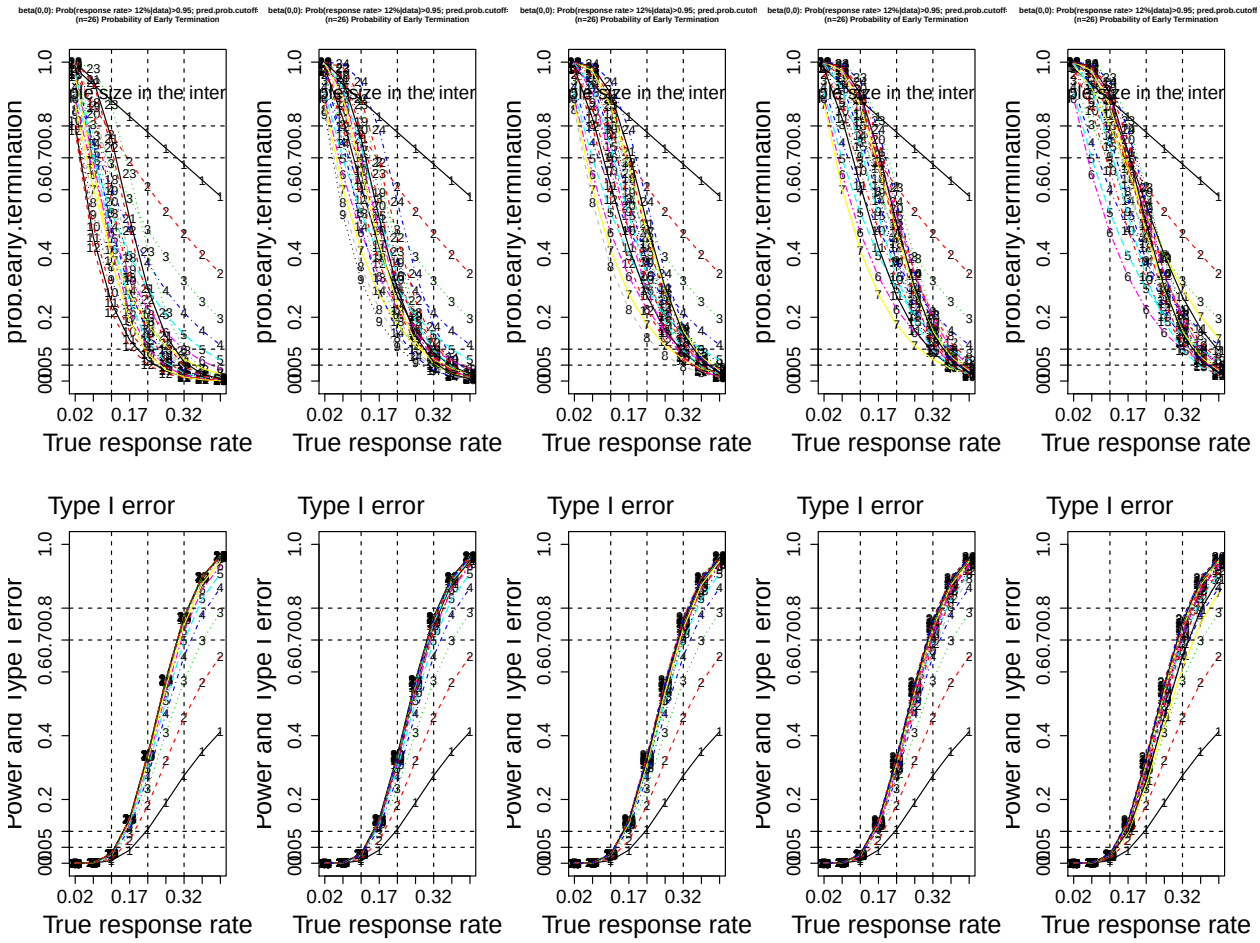
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Power and Type I error
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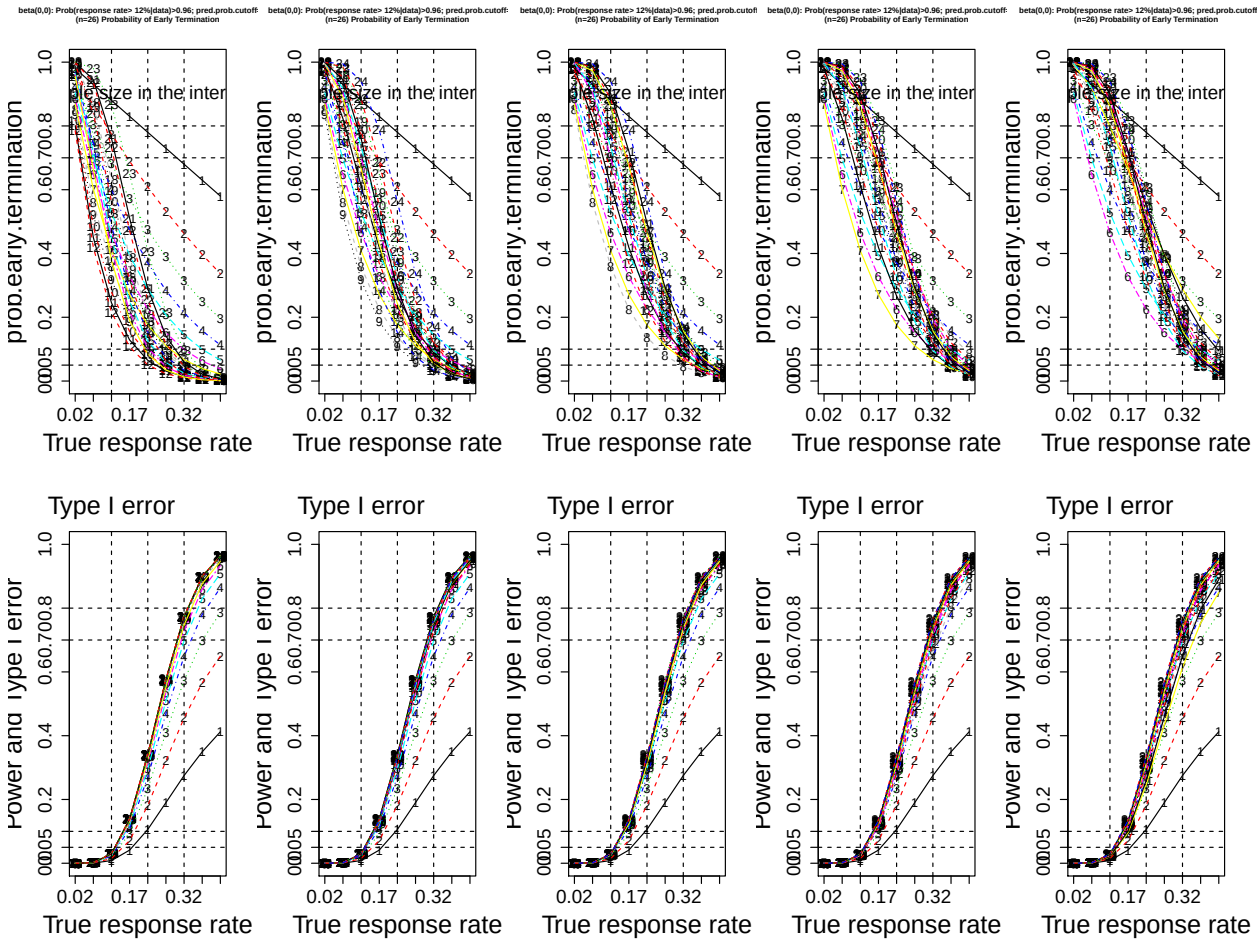
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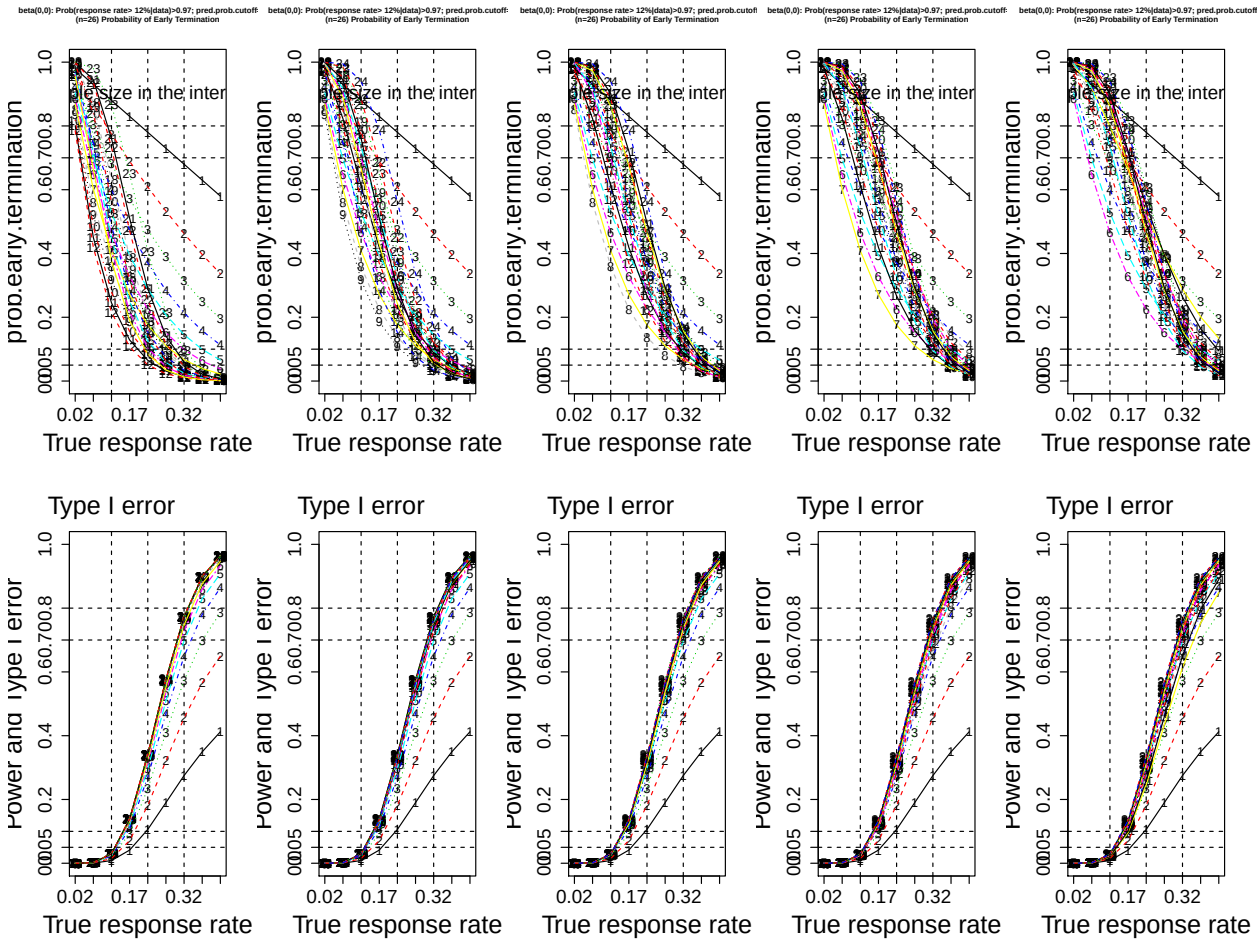
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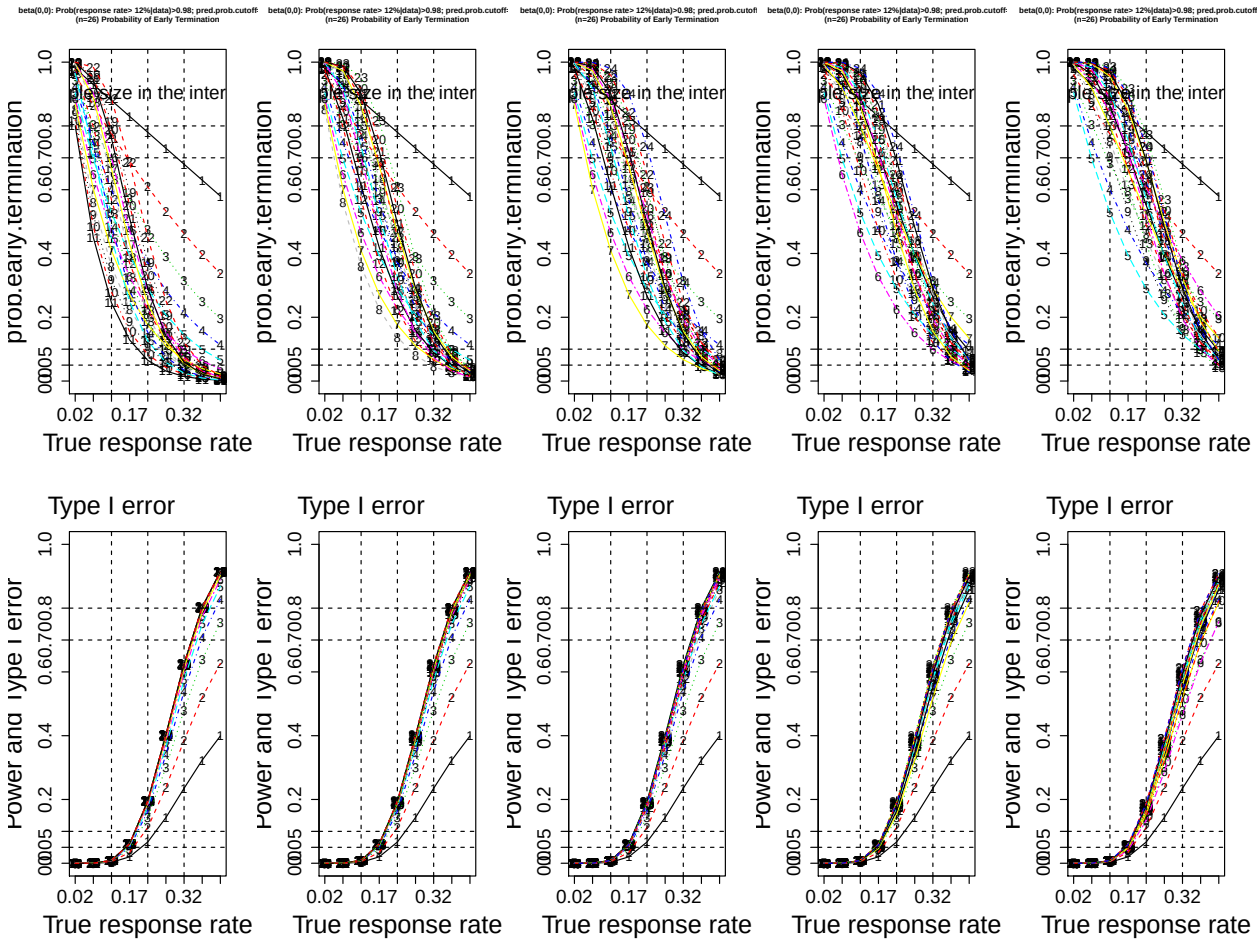
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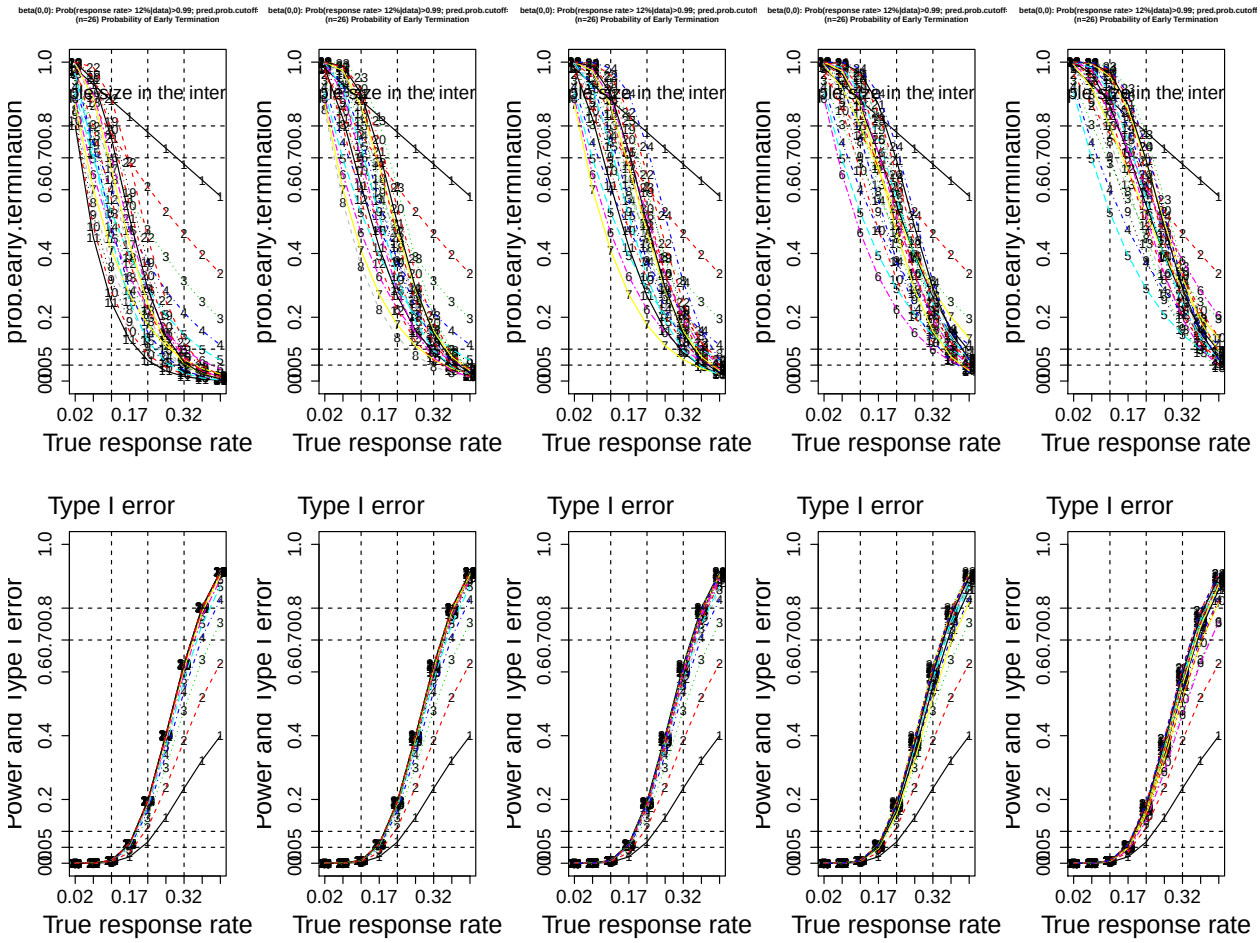
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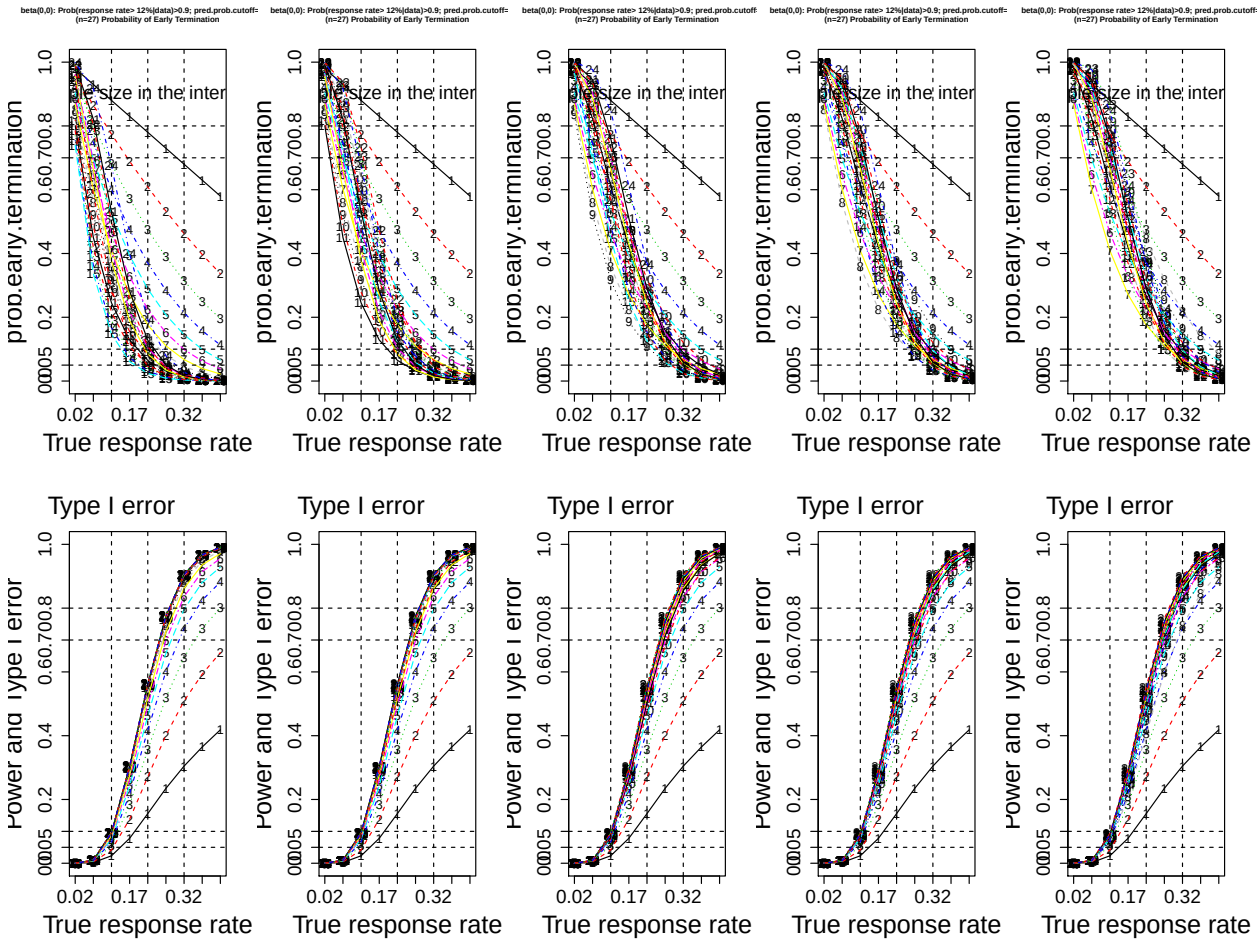
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(n=27) Probability of Early Termination
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Power and Type I error
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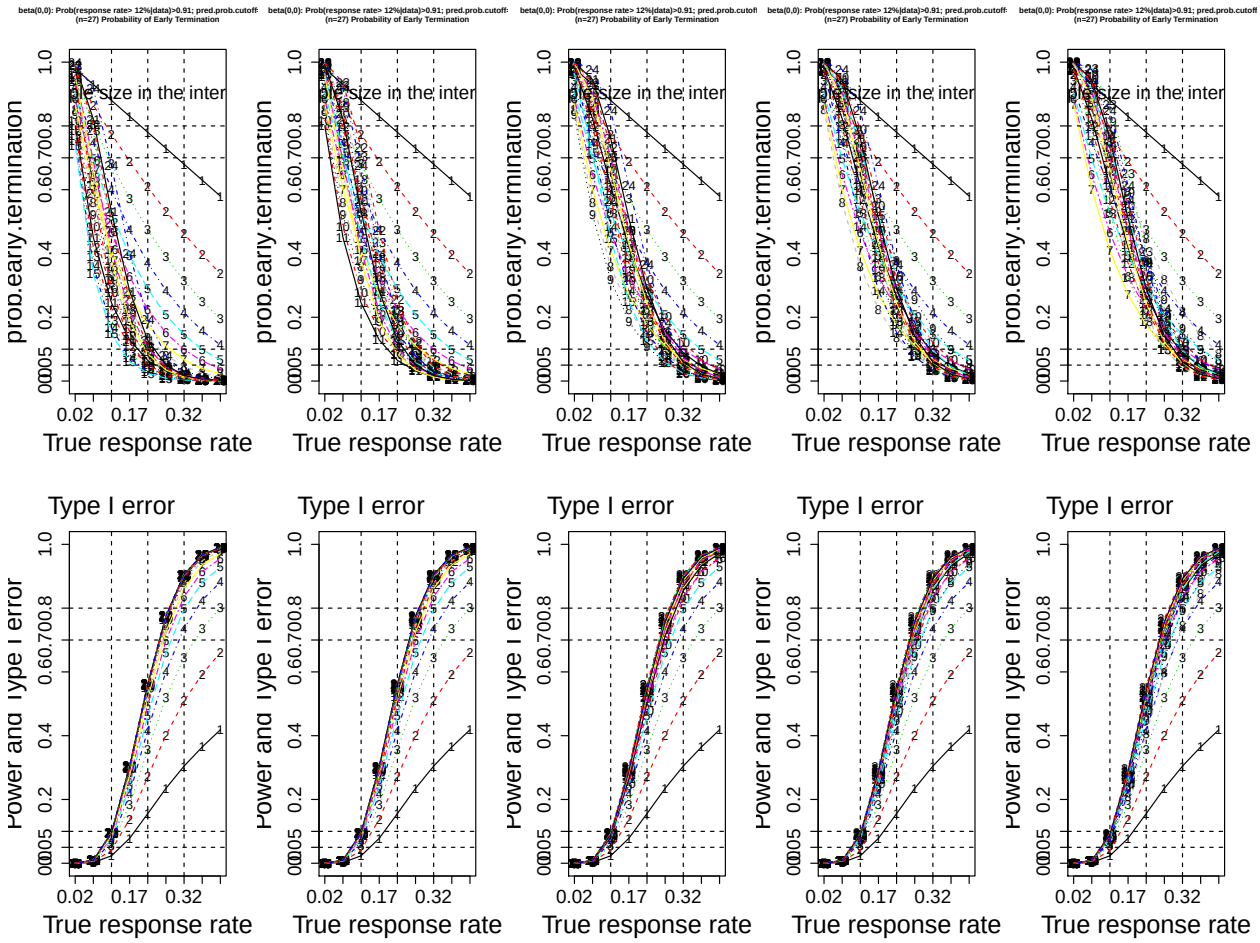
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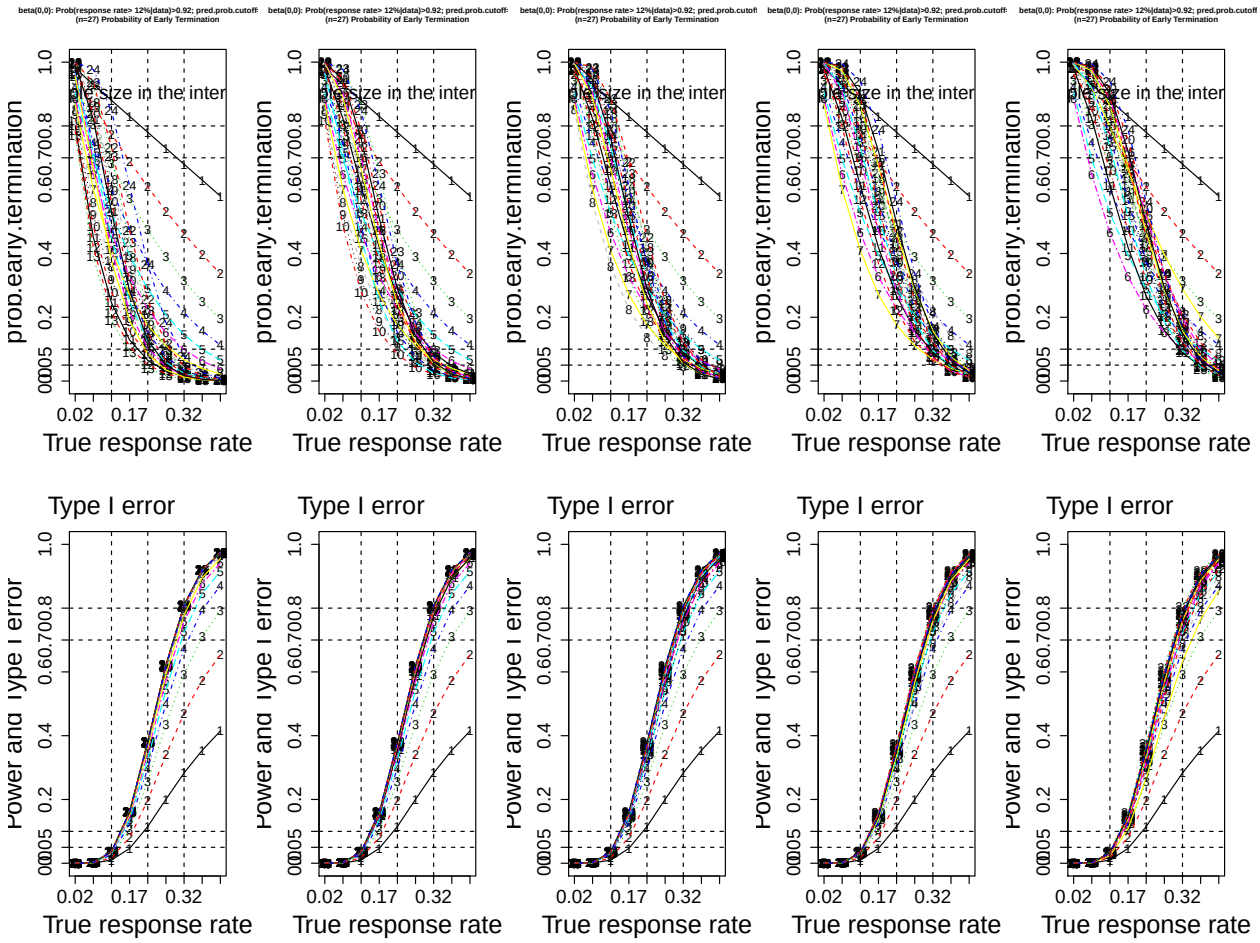
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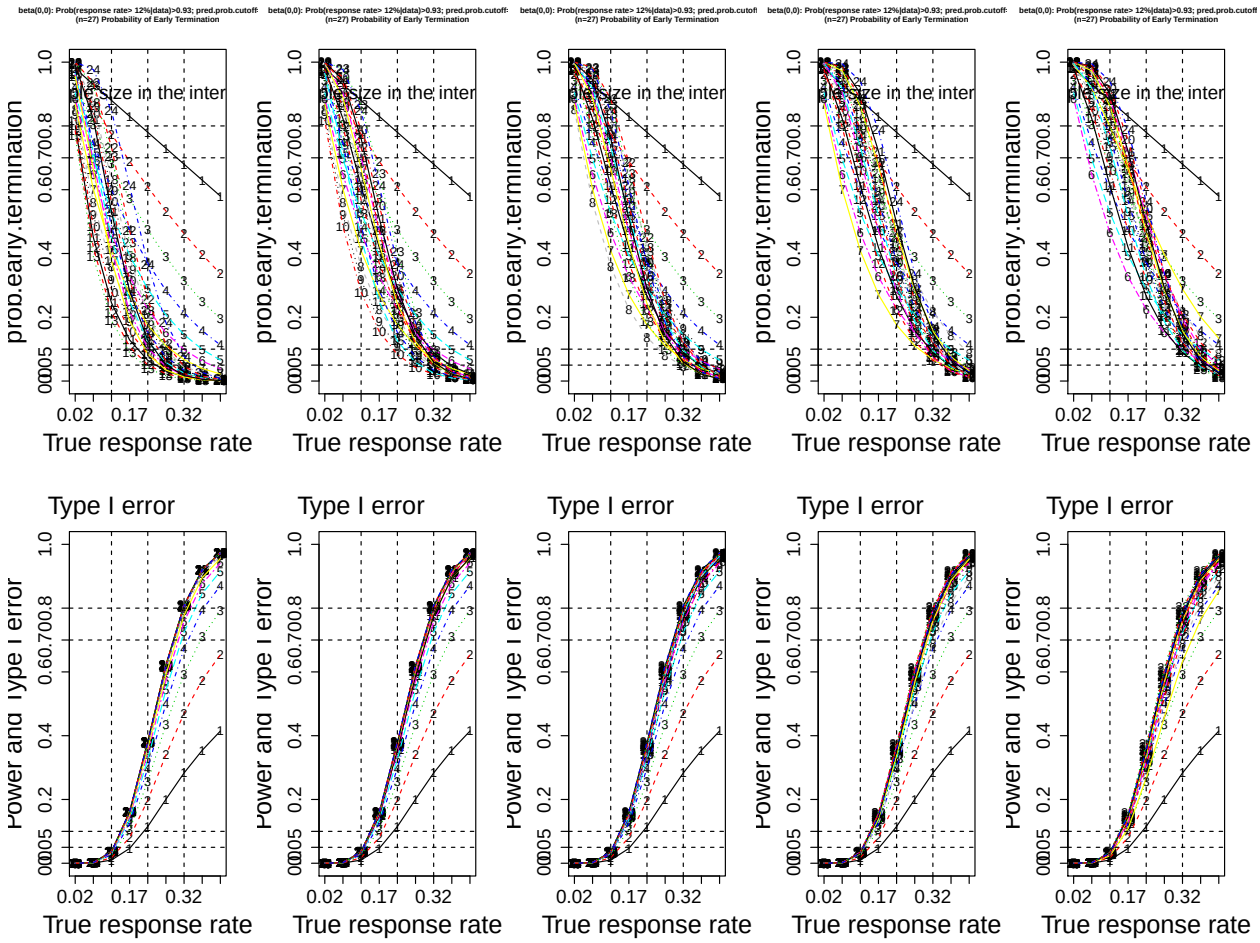
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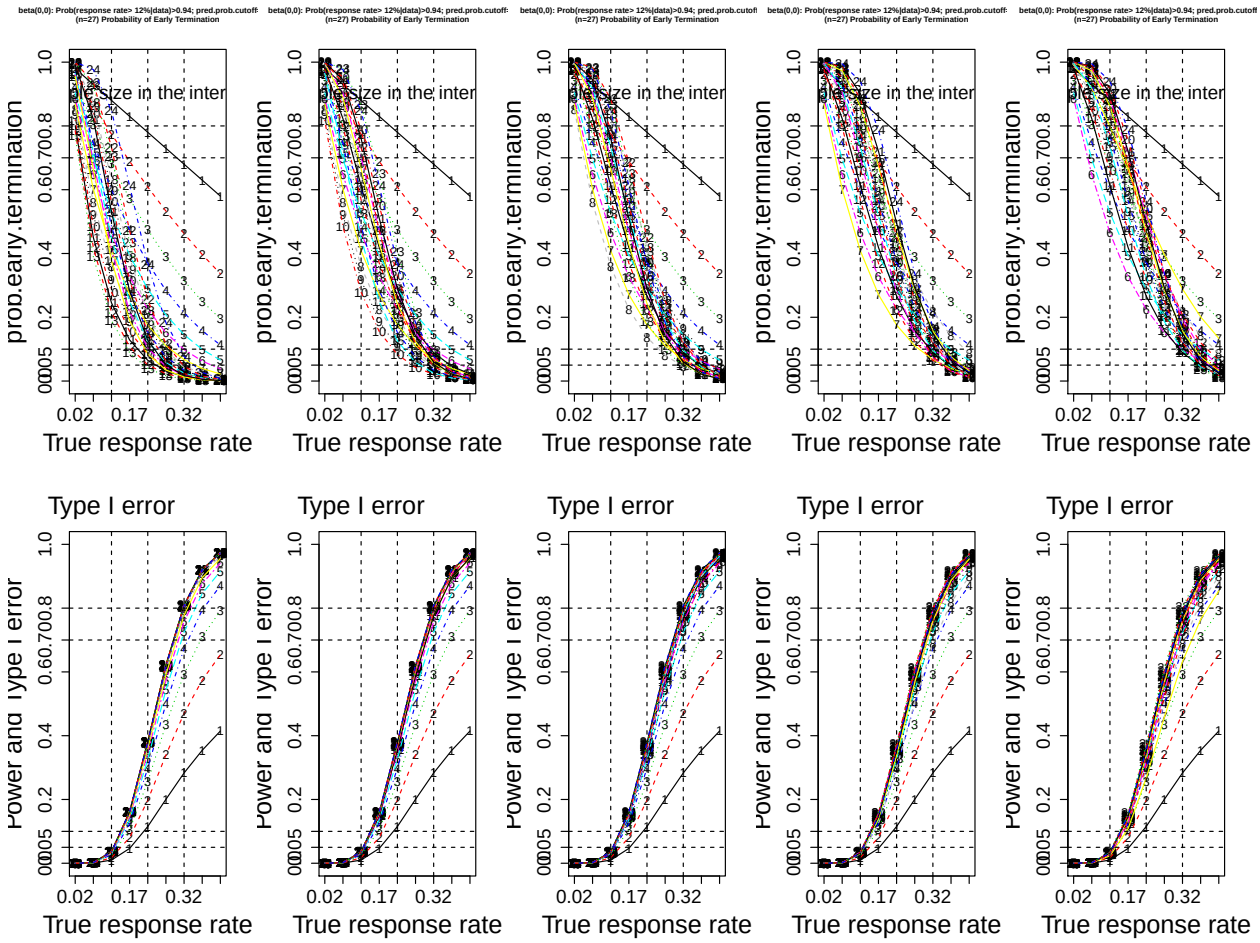
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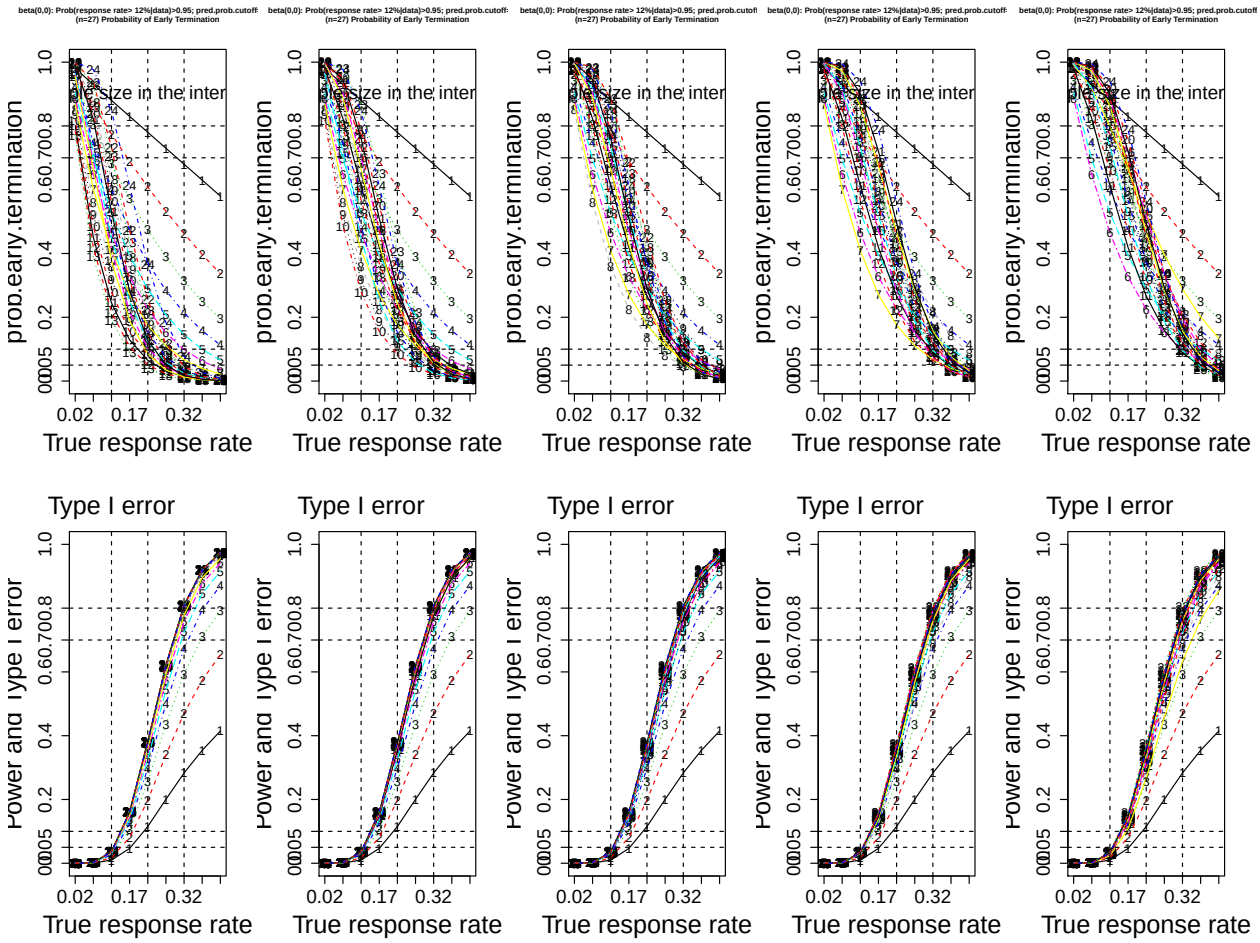
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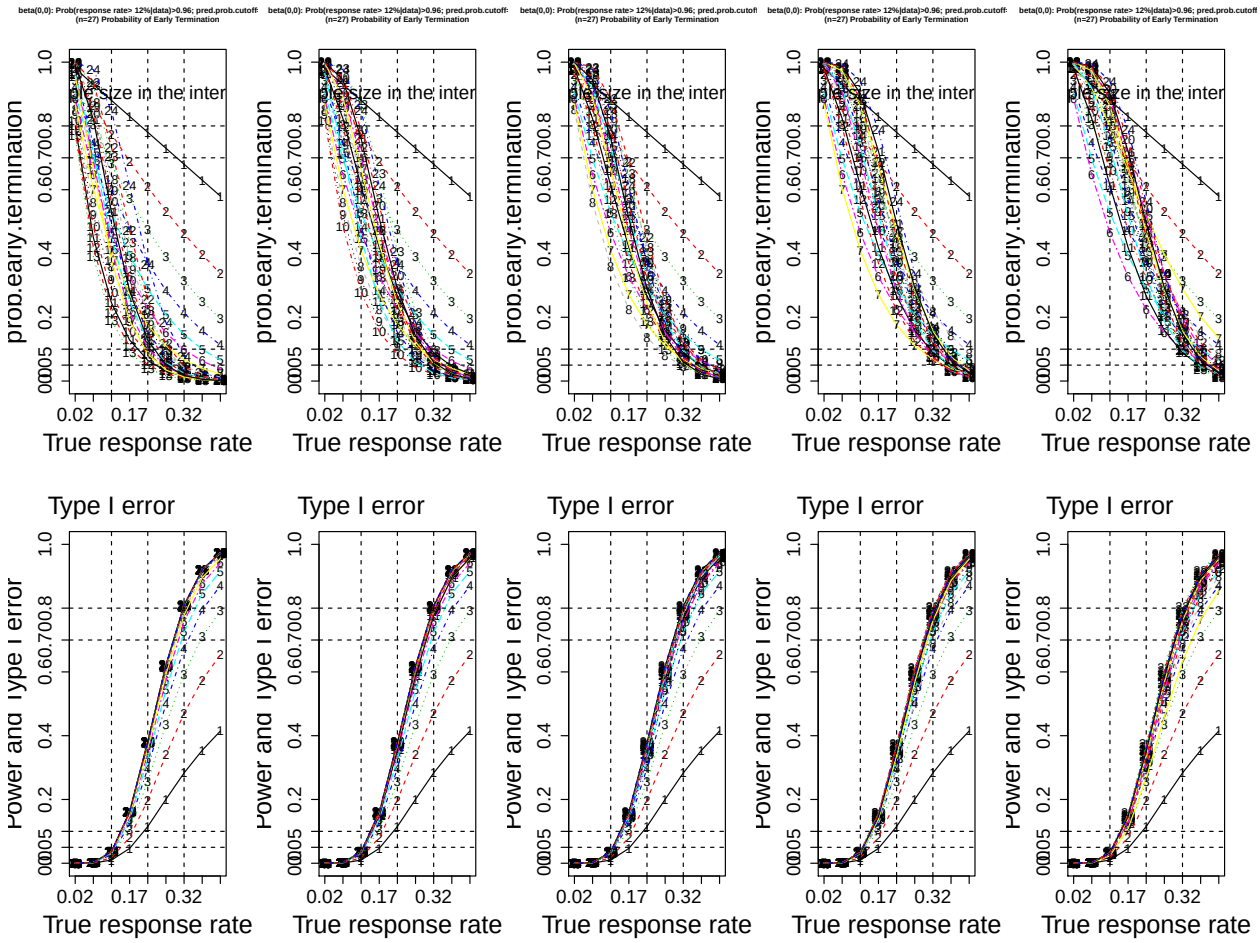
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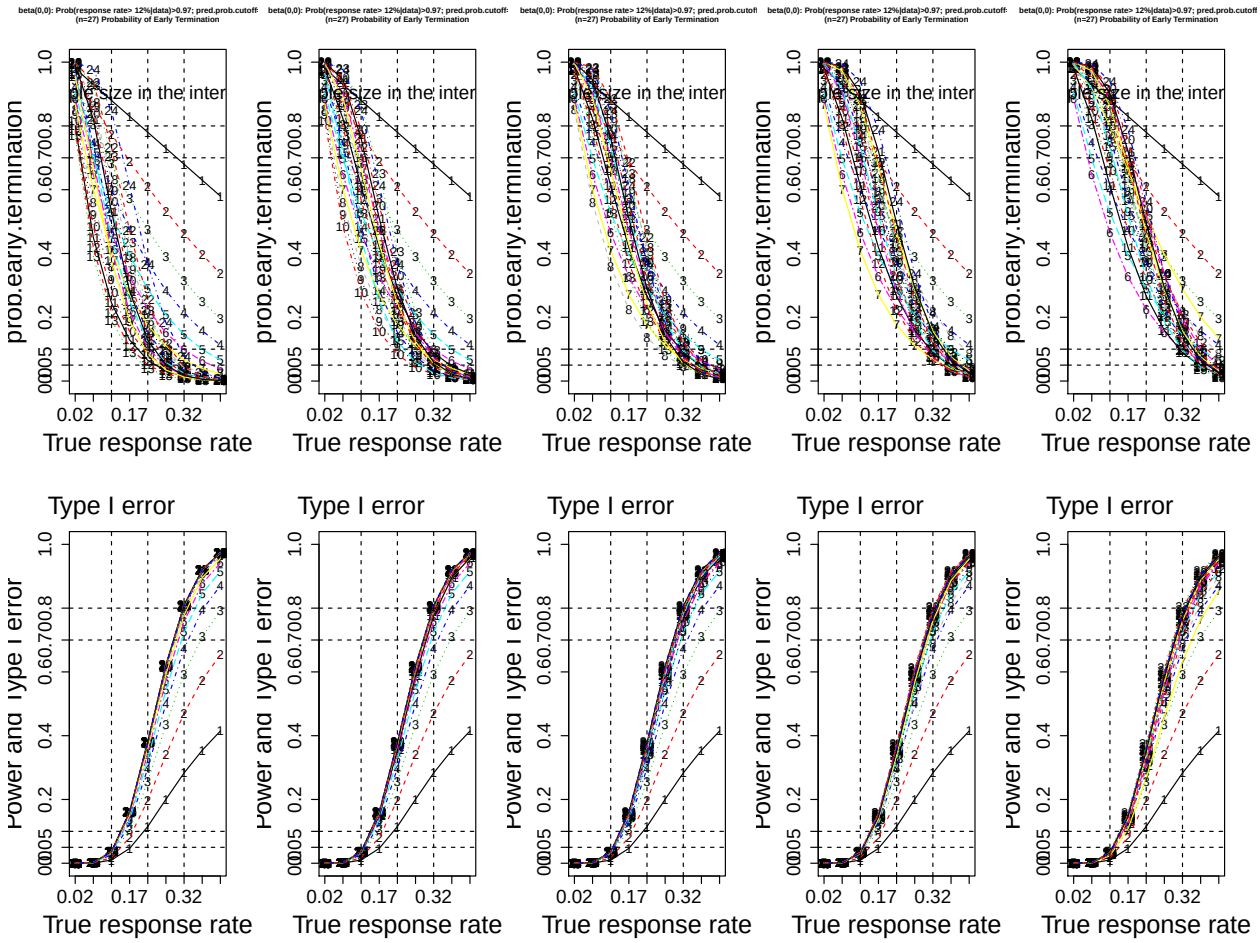
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prob.early.termination
Type I error
Power and Type I error
True response rate
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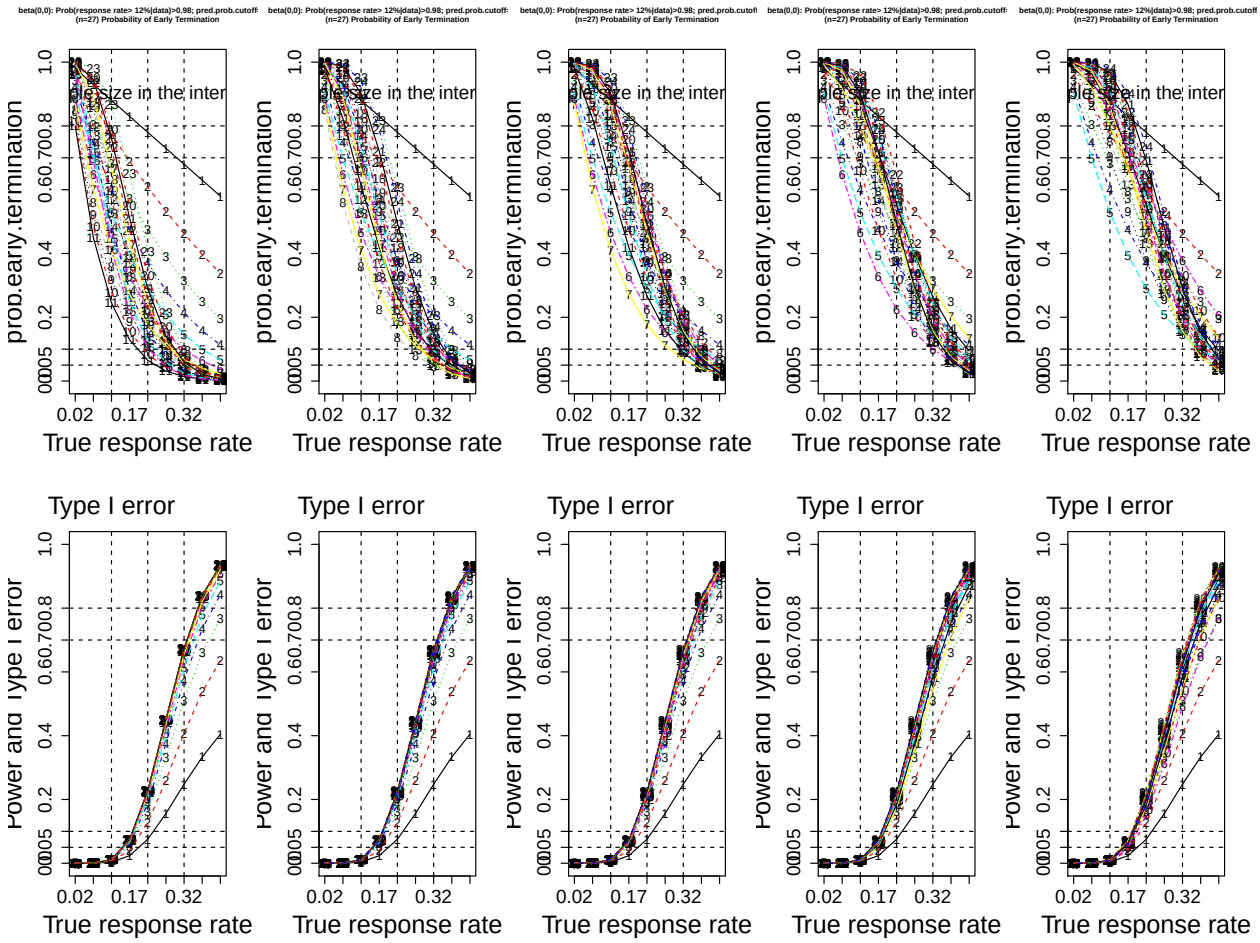
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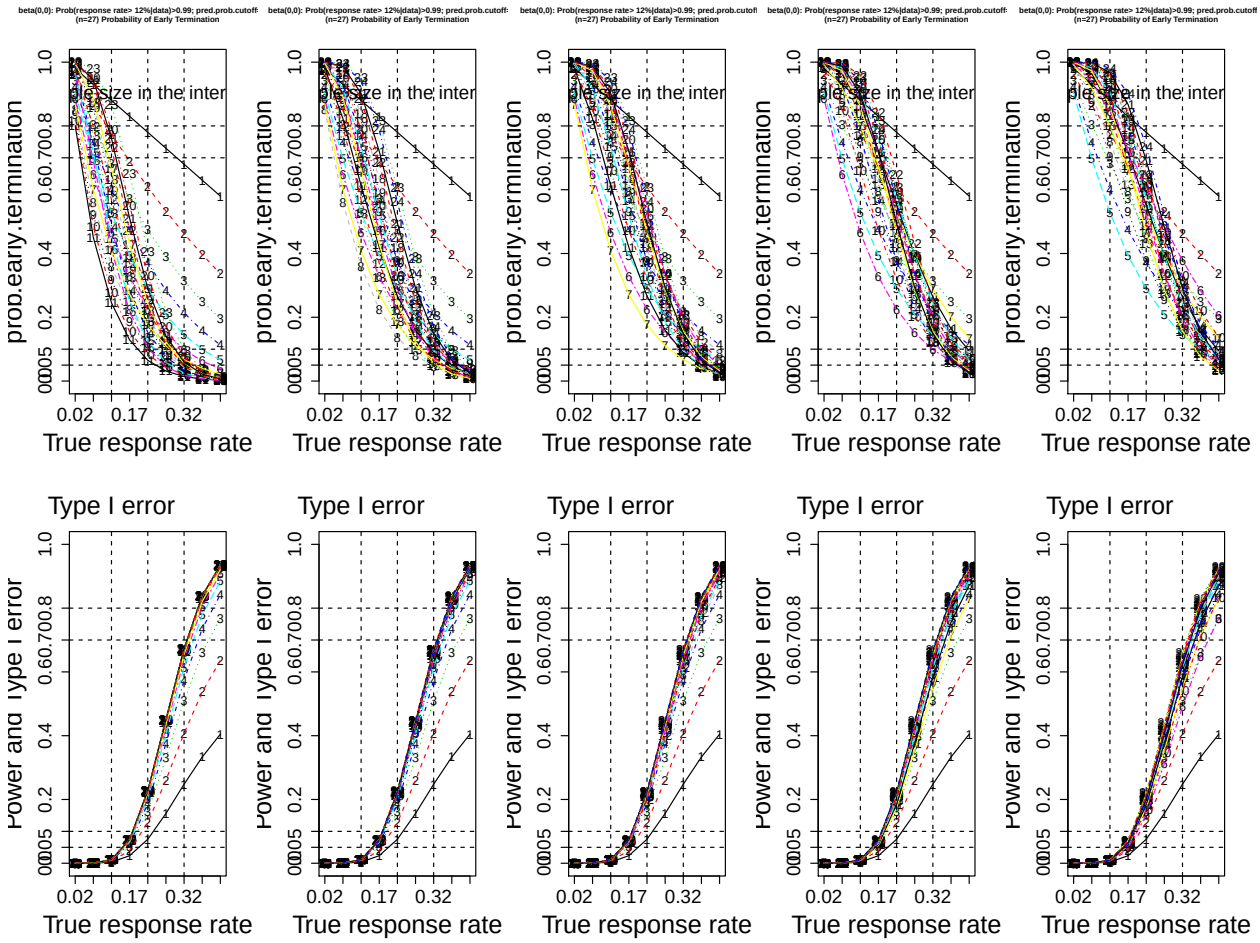
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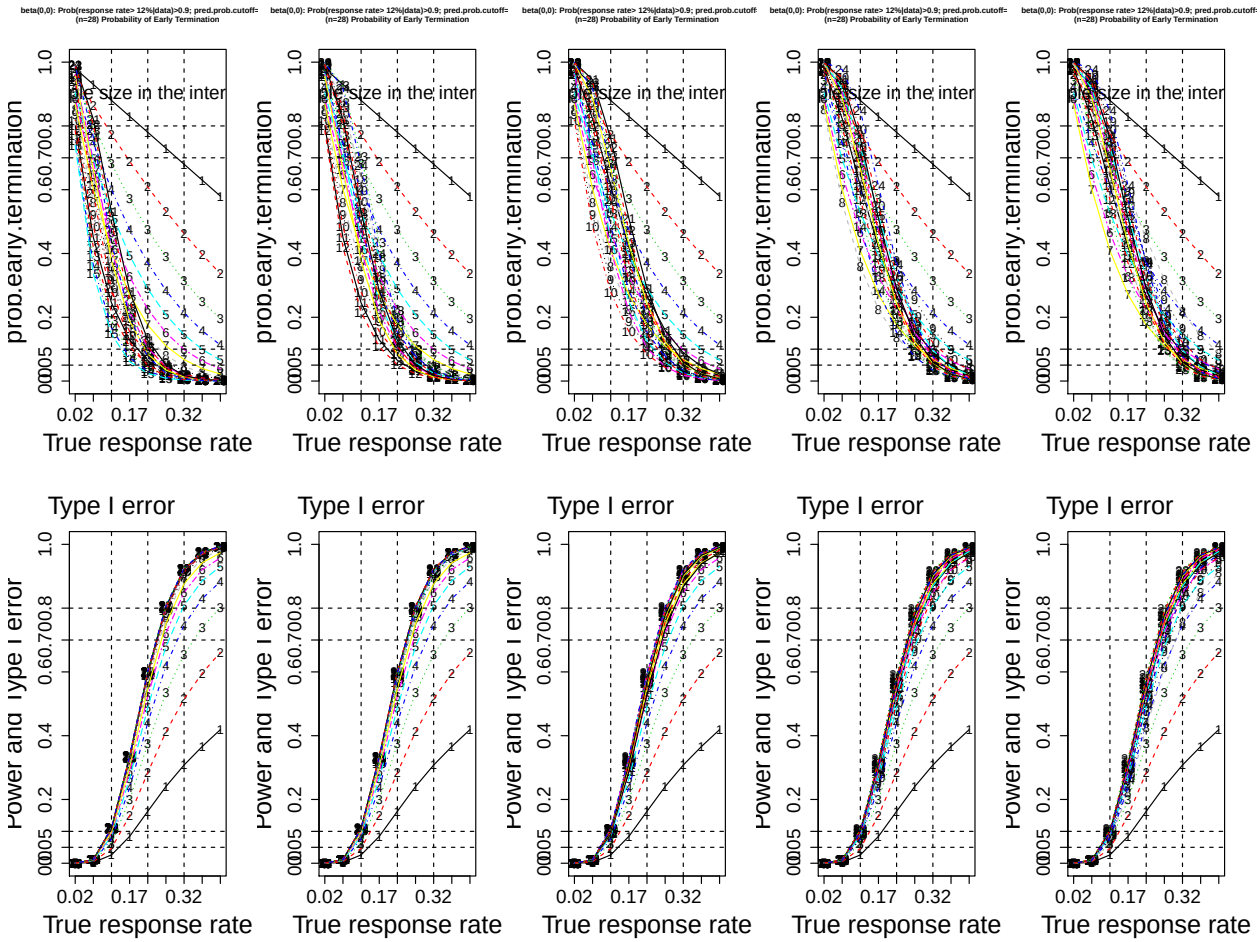
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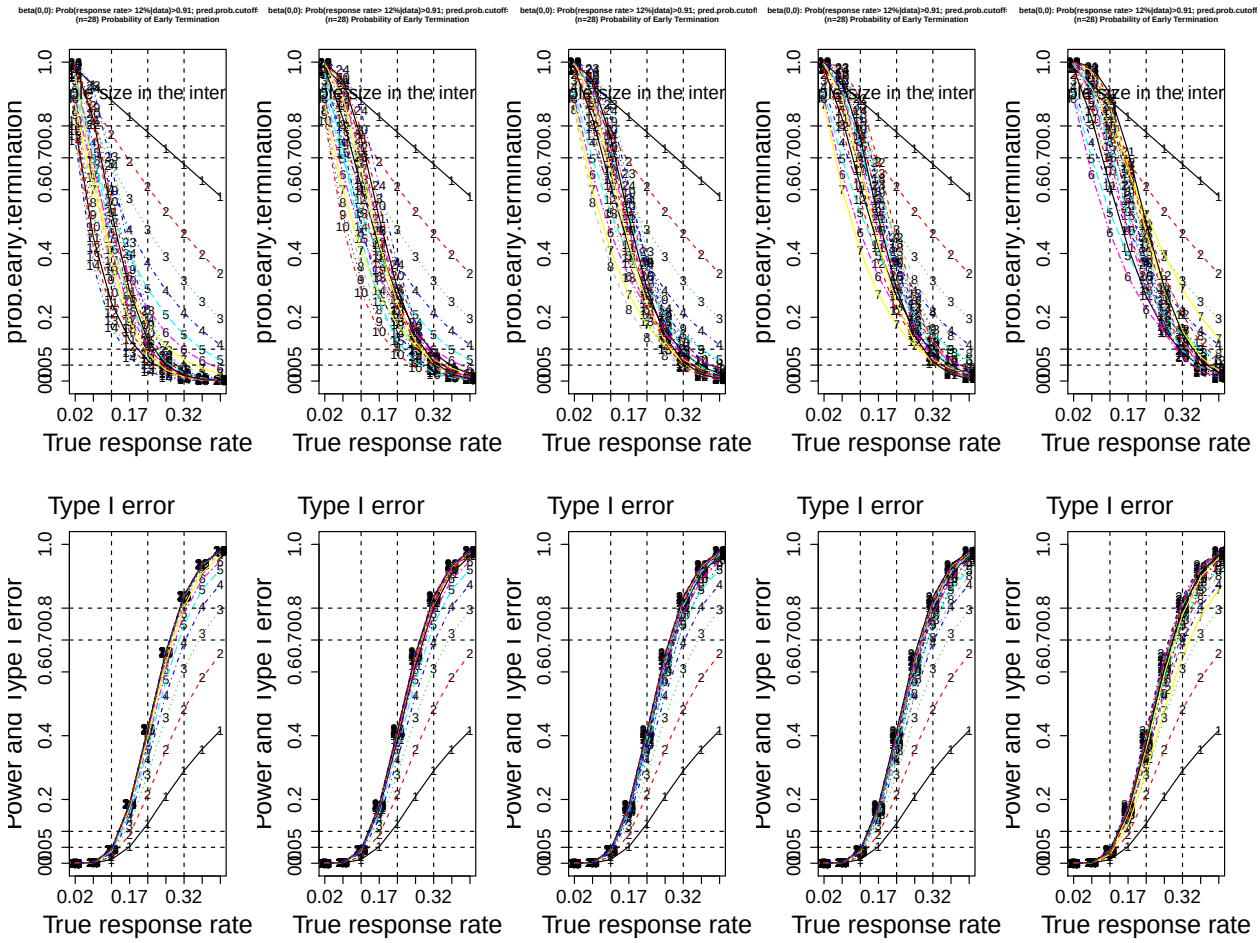
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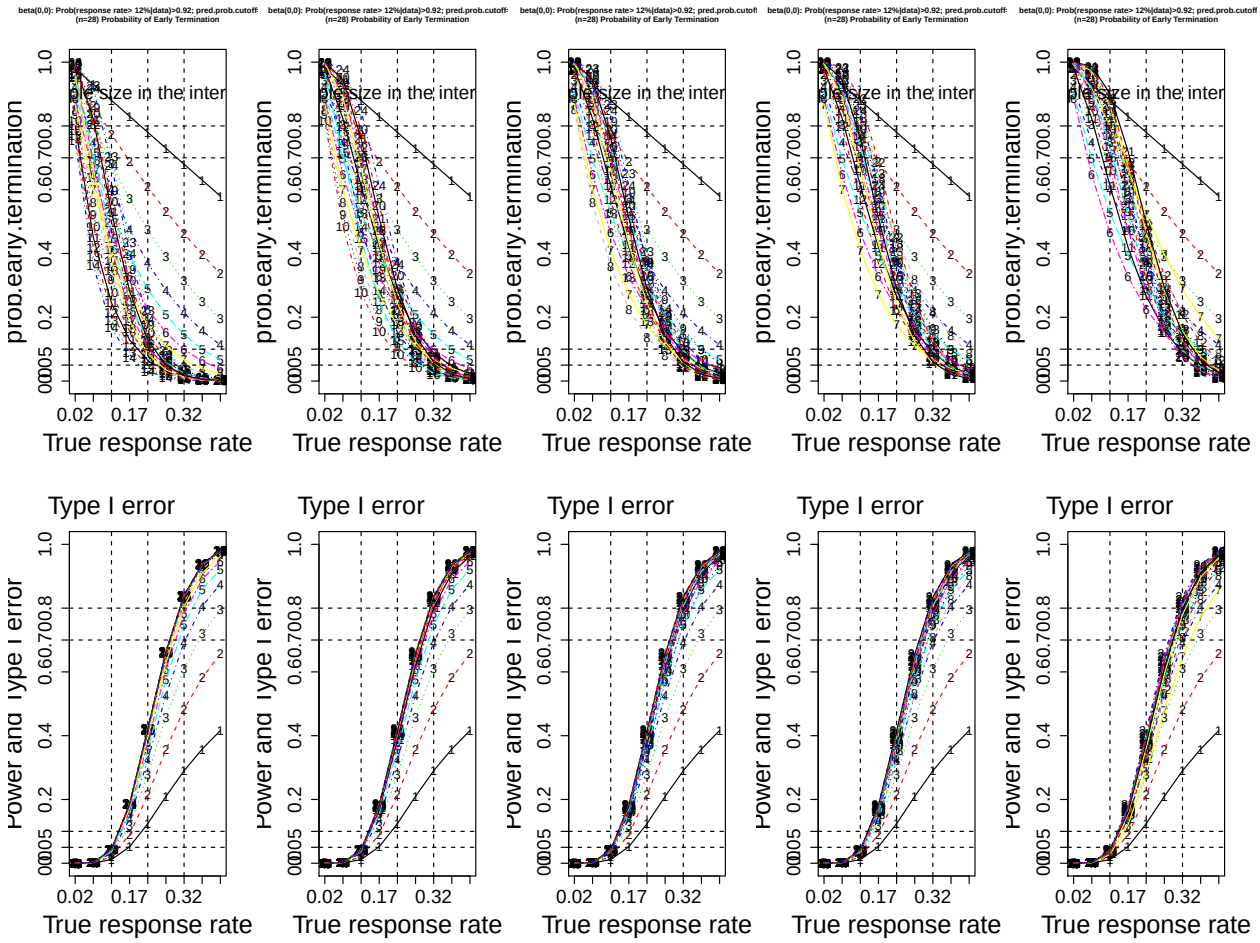
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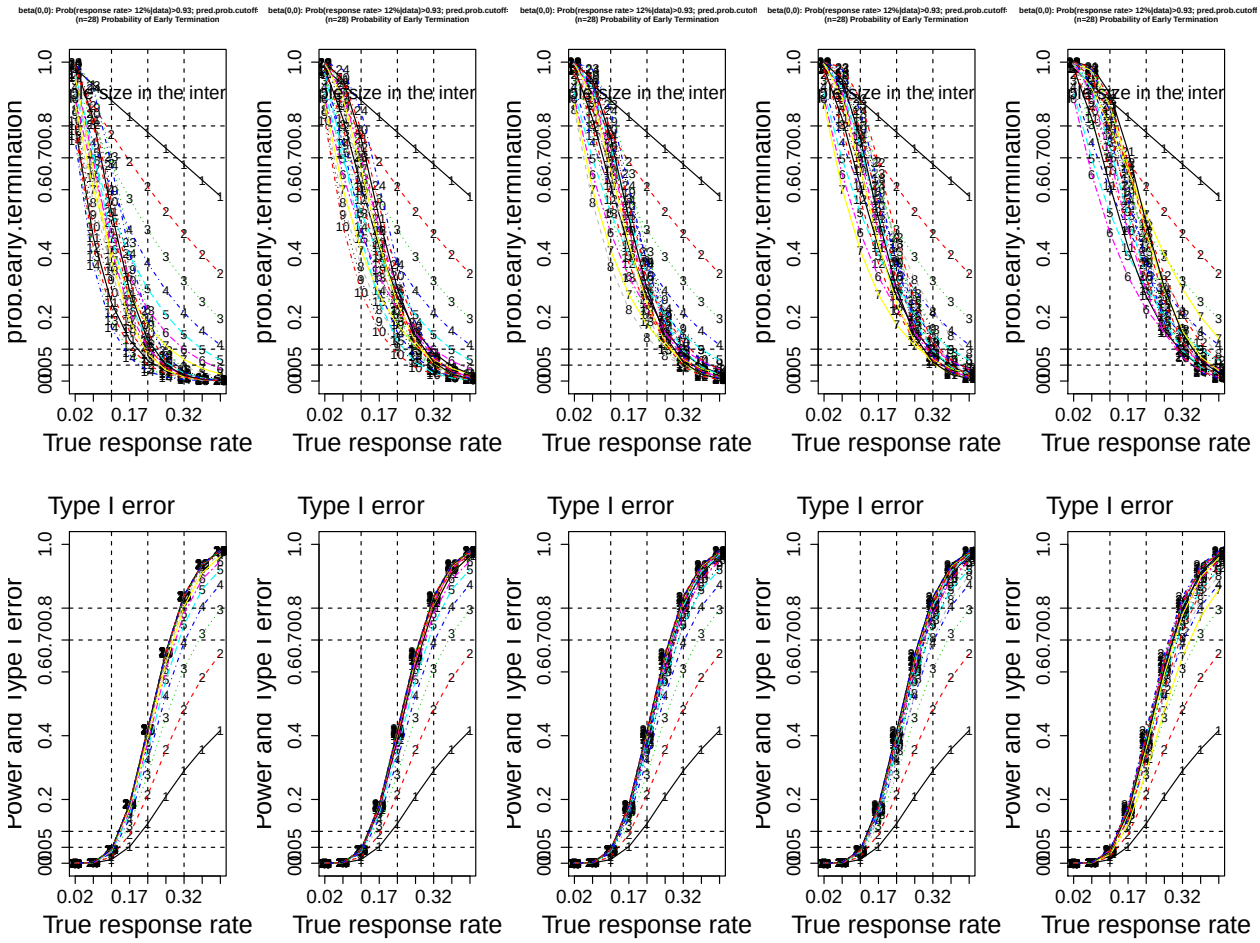
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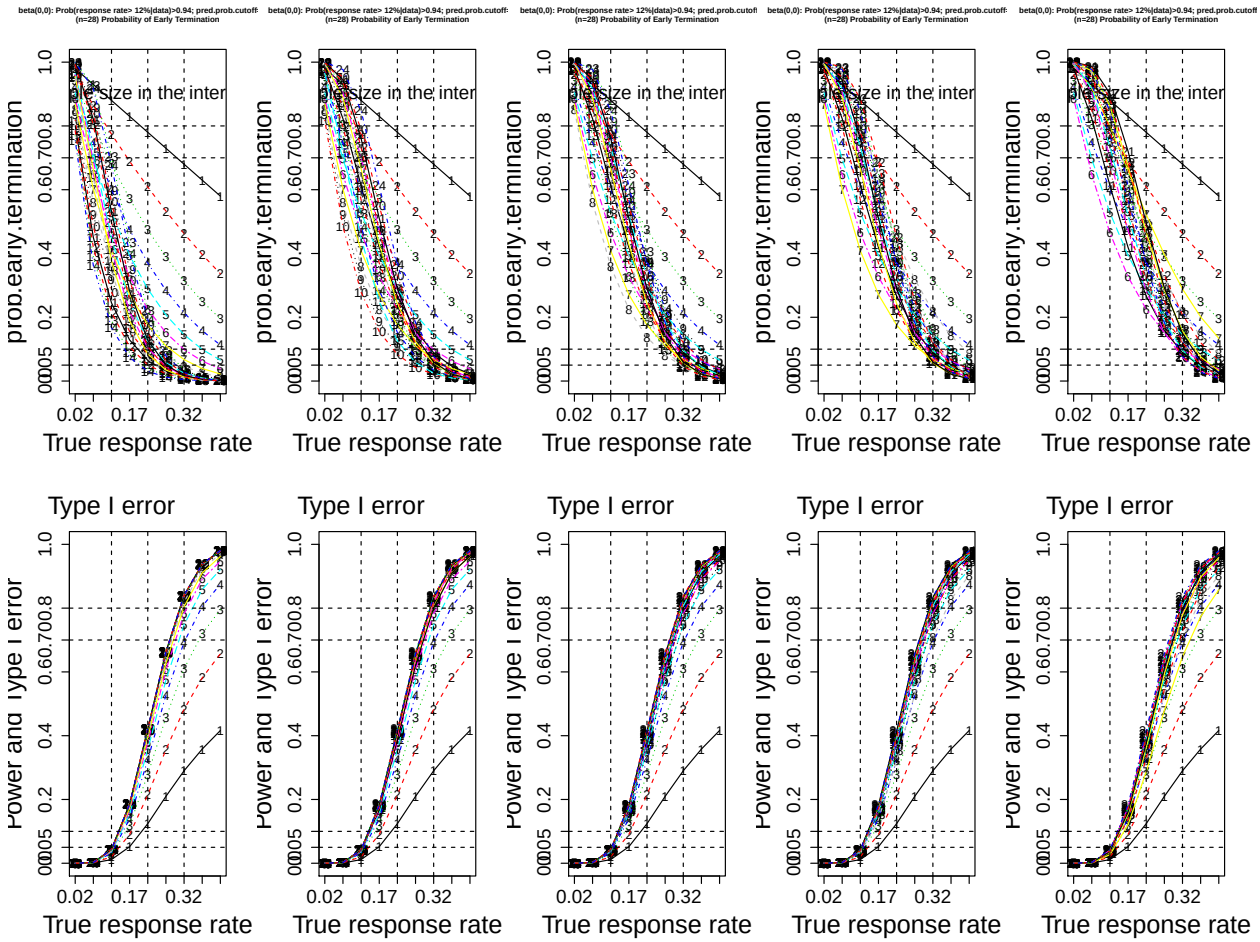
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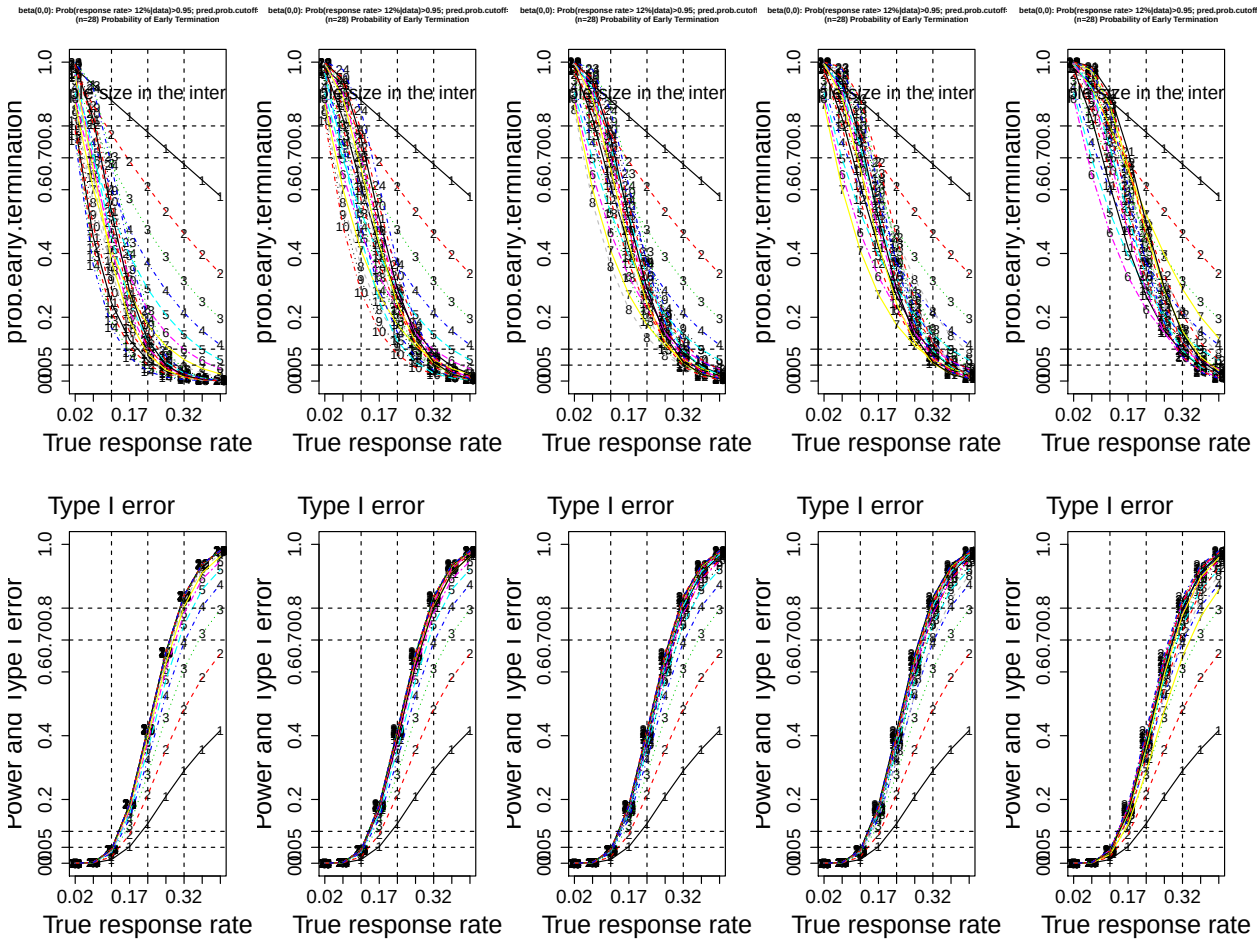
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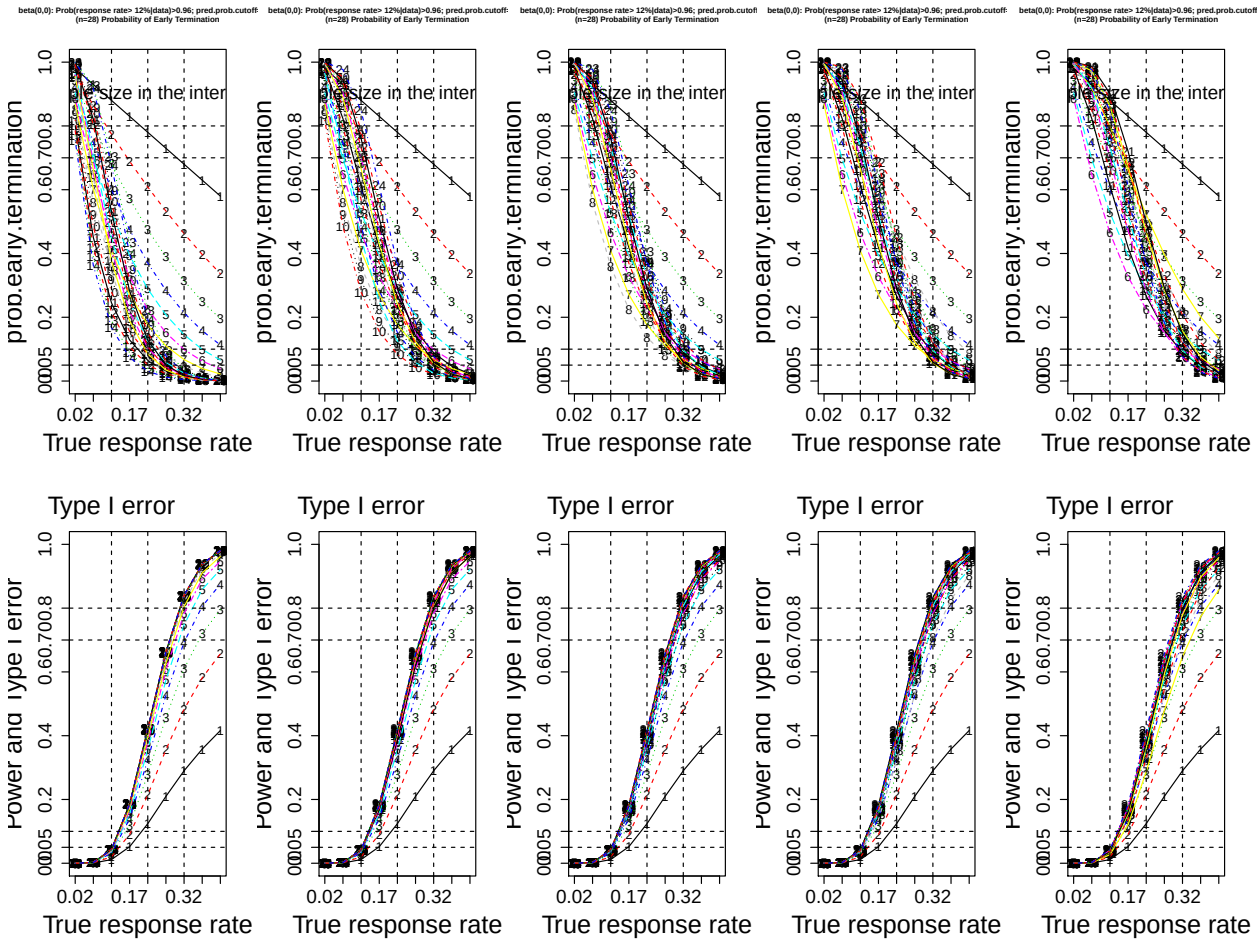
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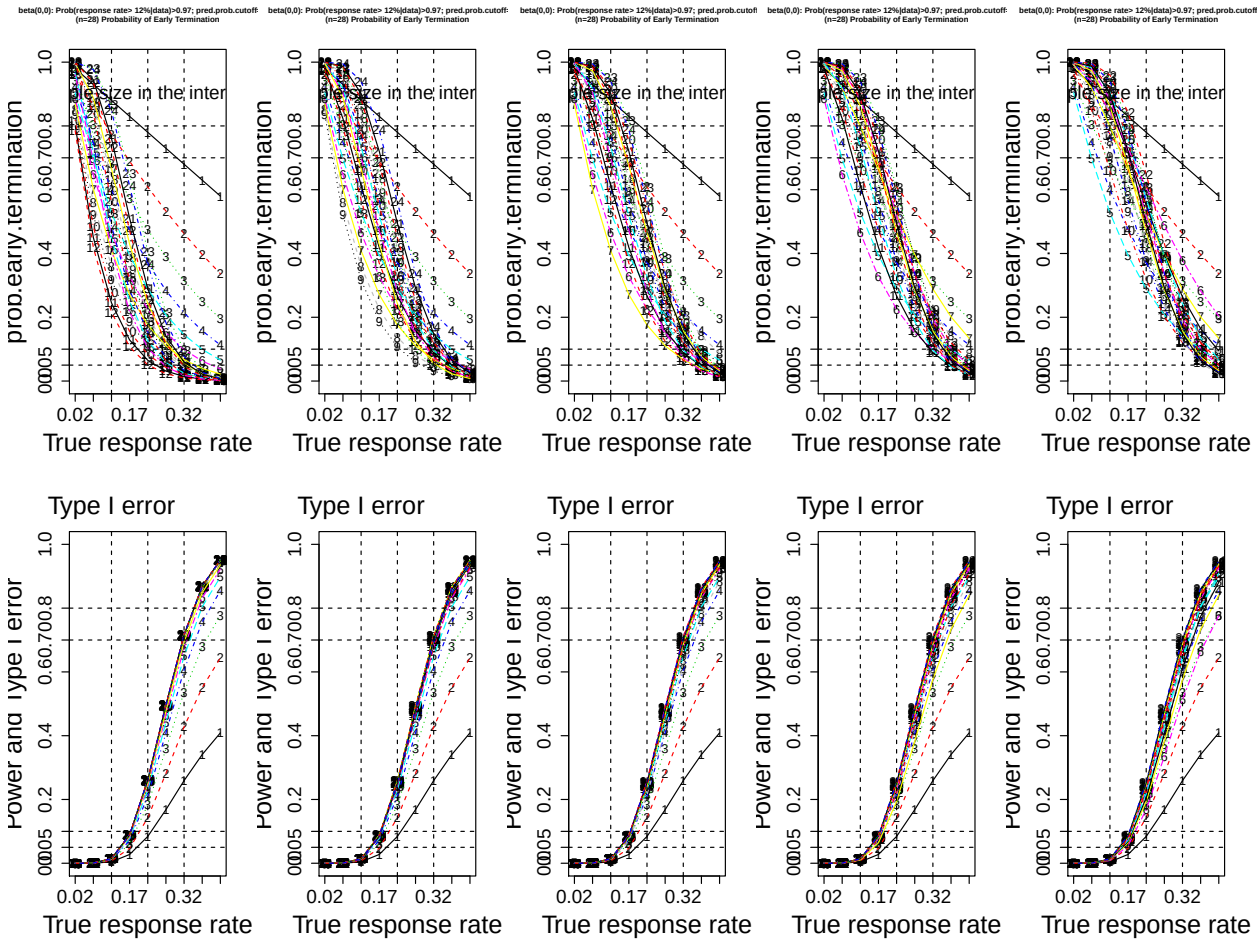
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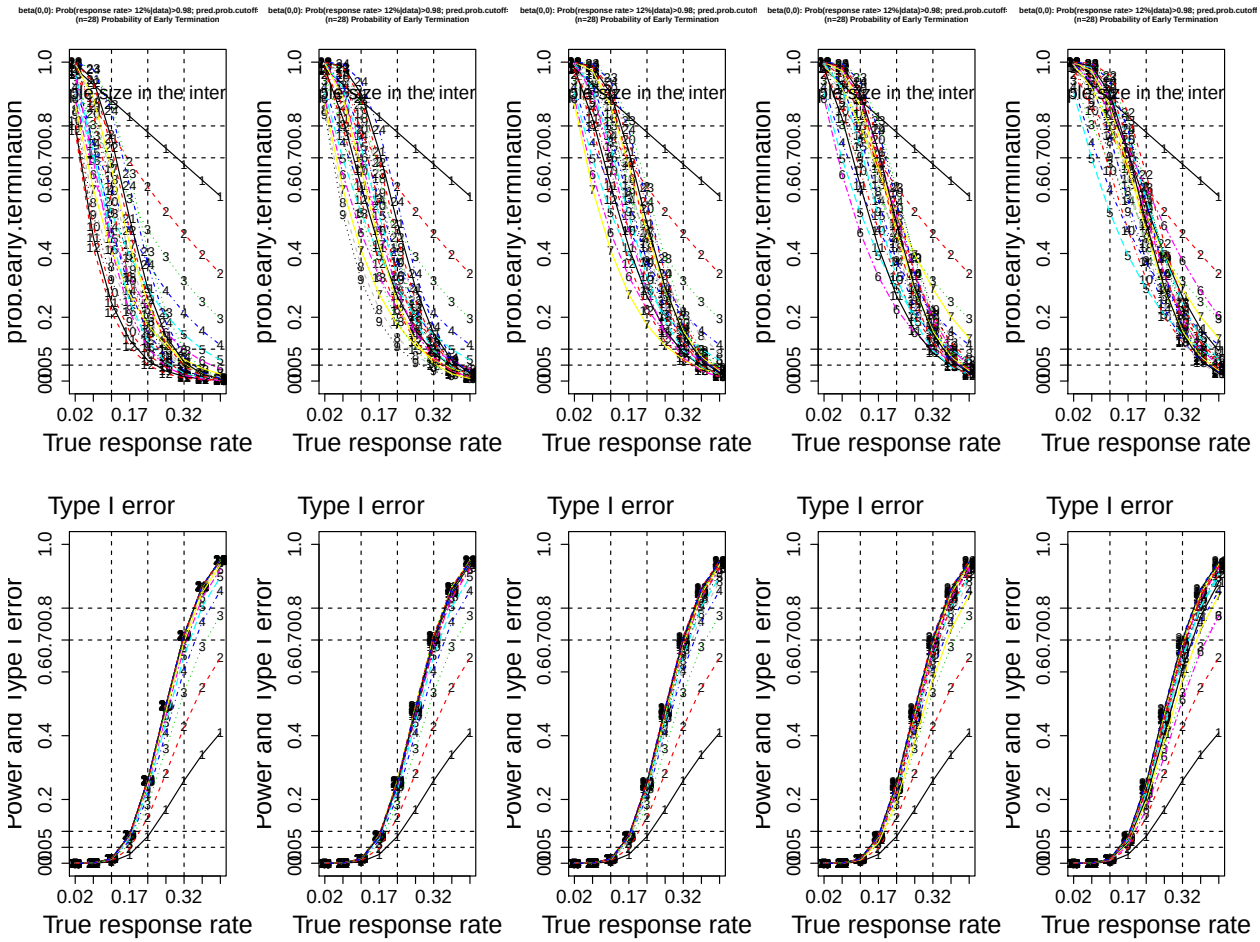
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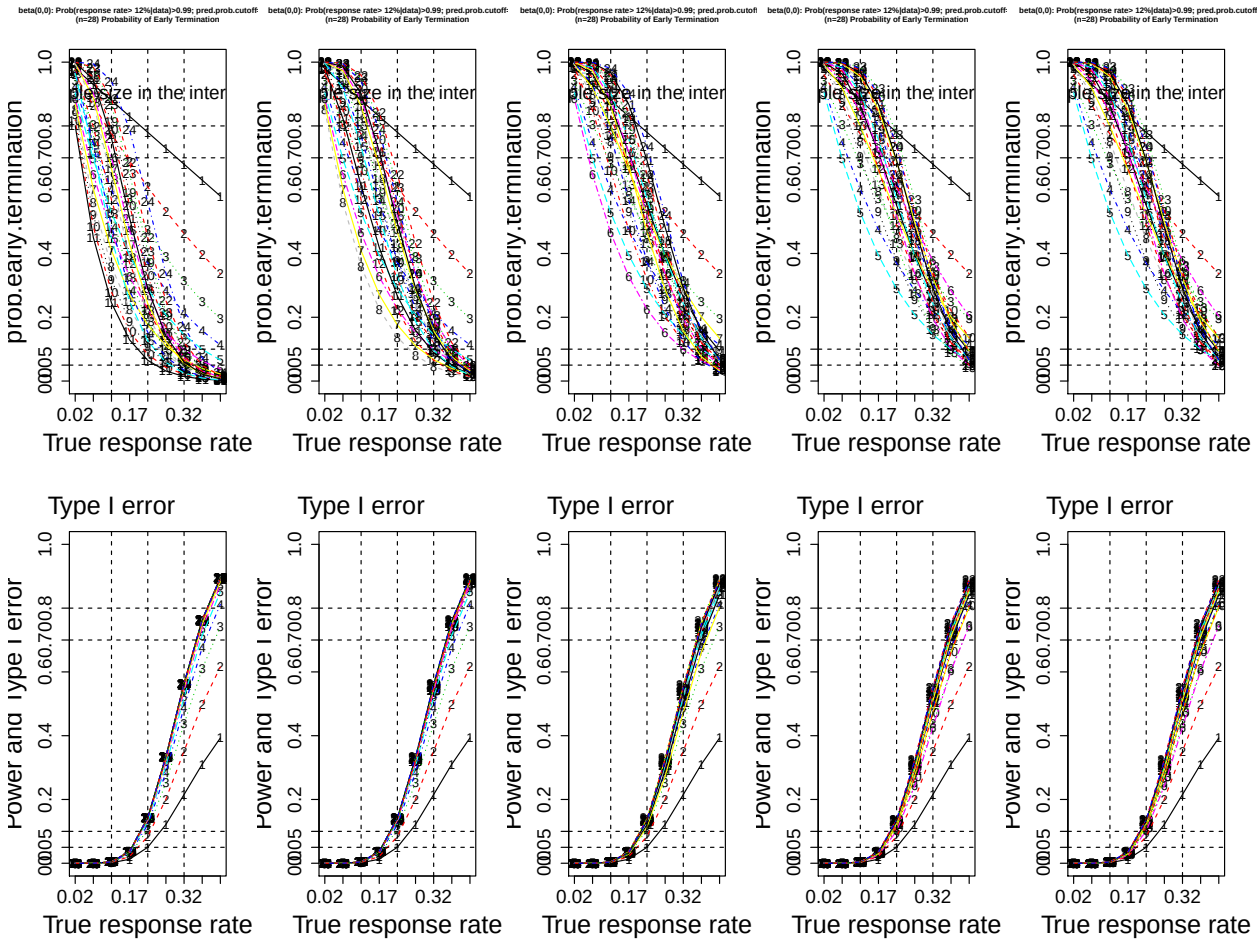
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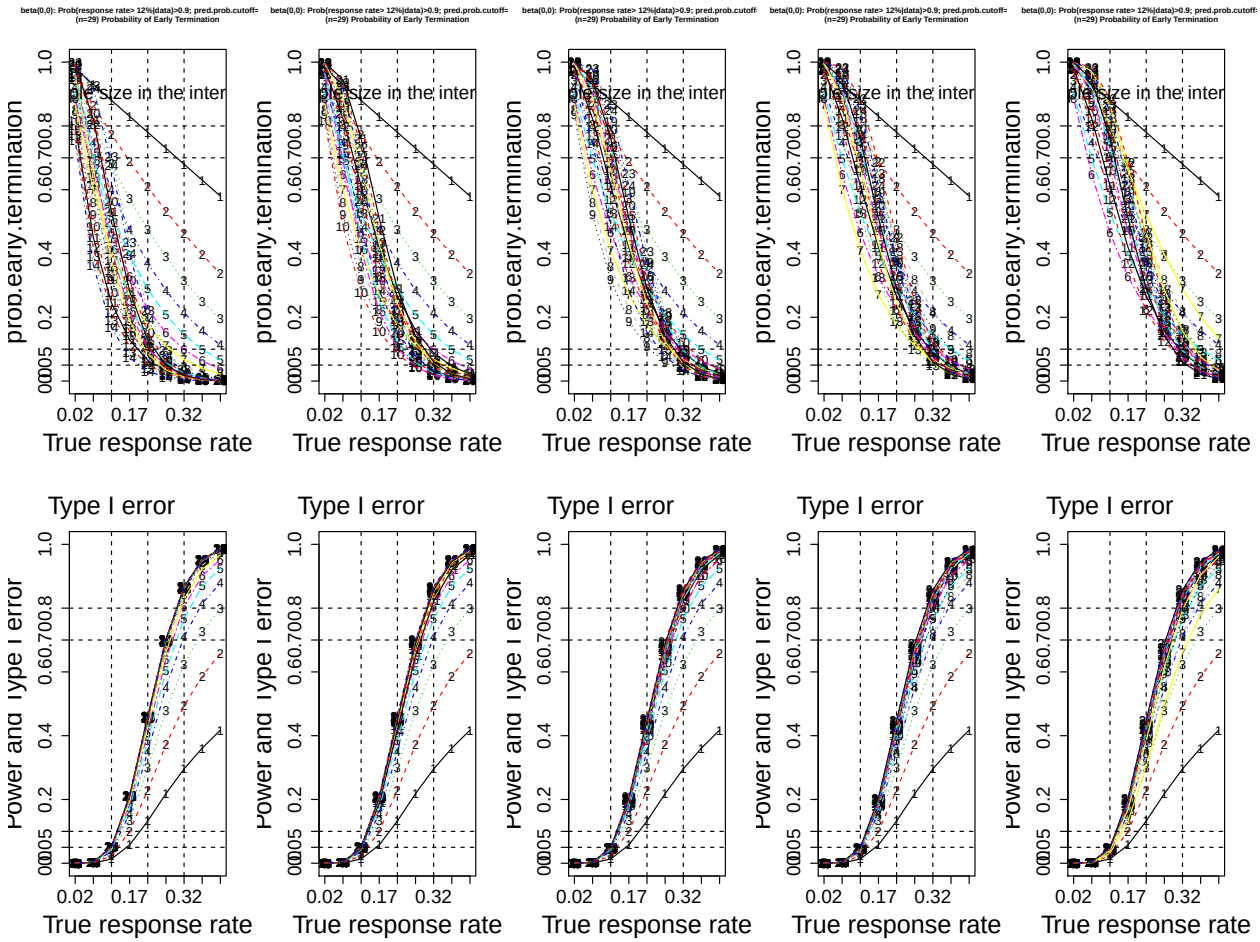
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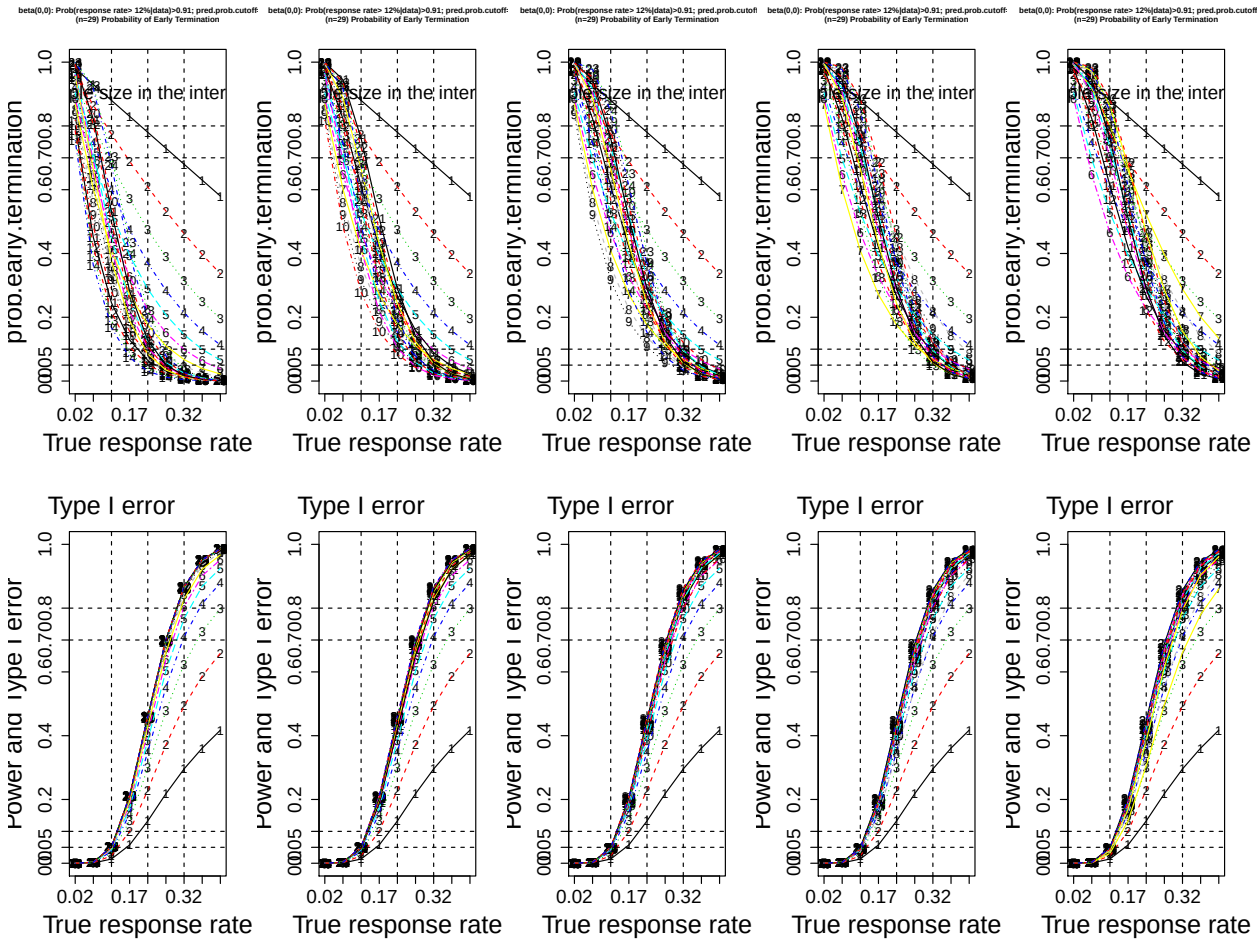
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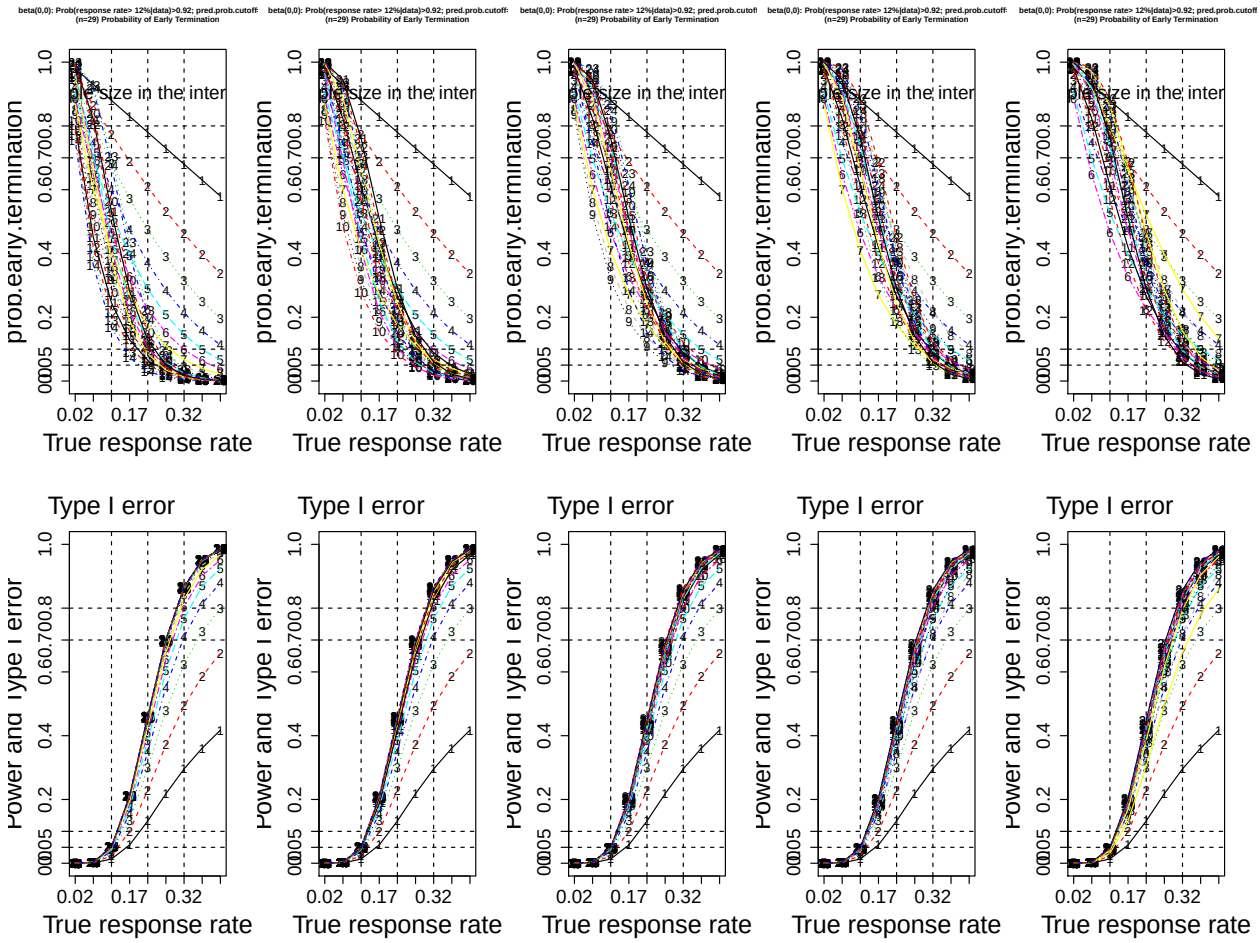
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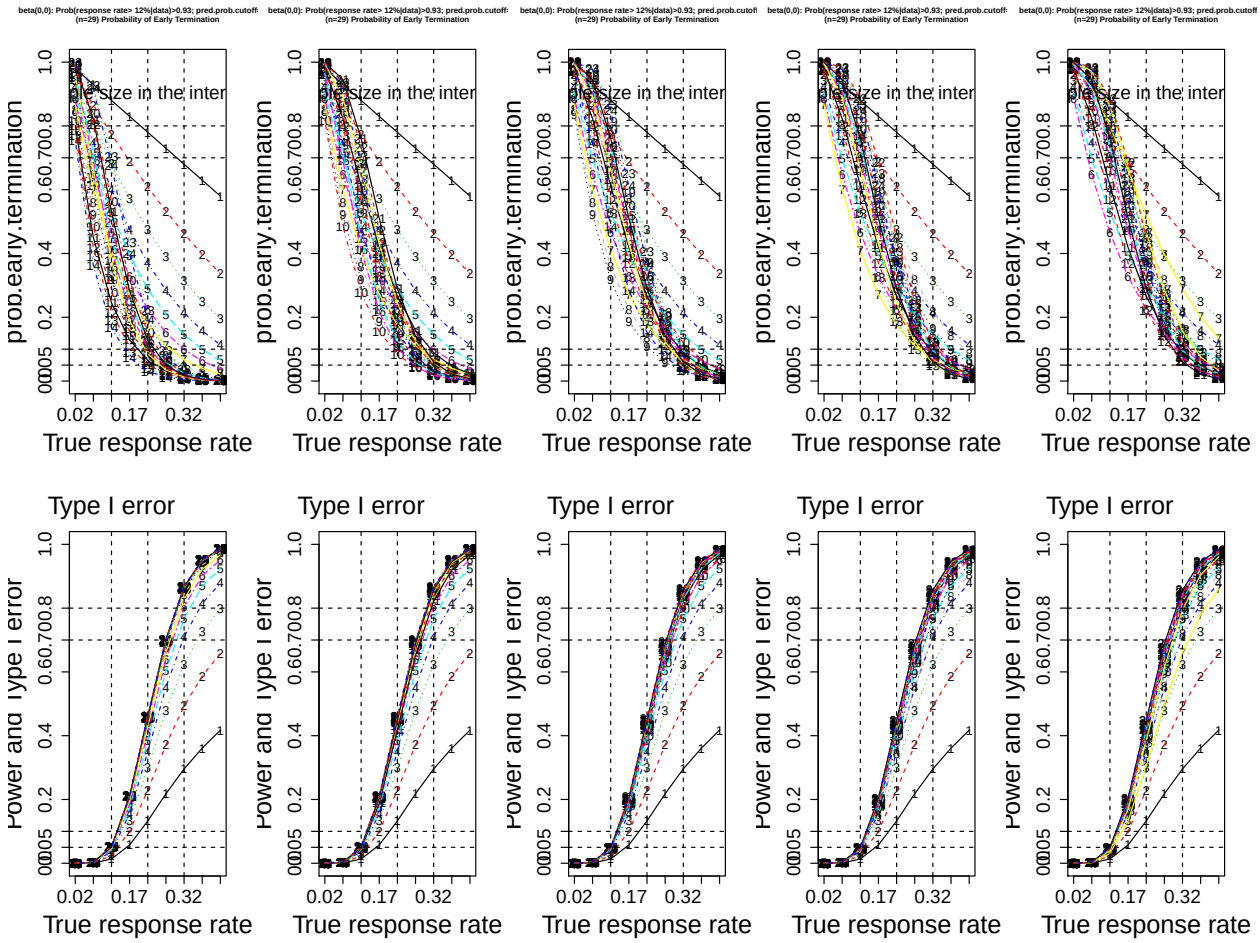
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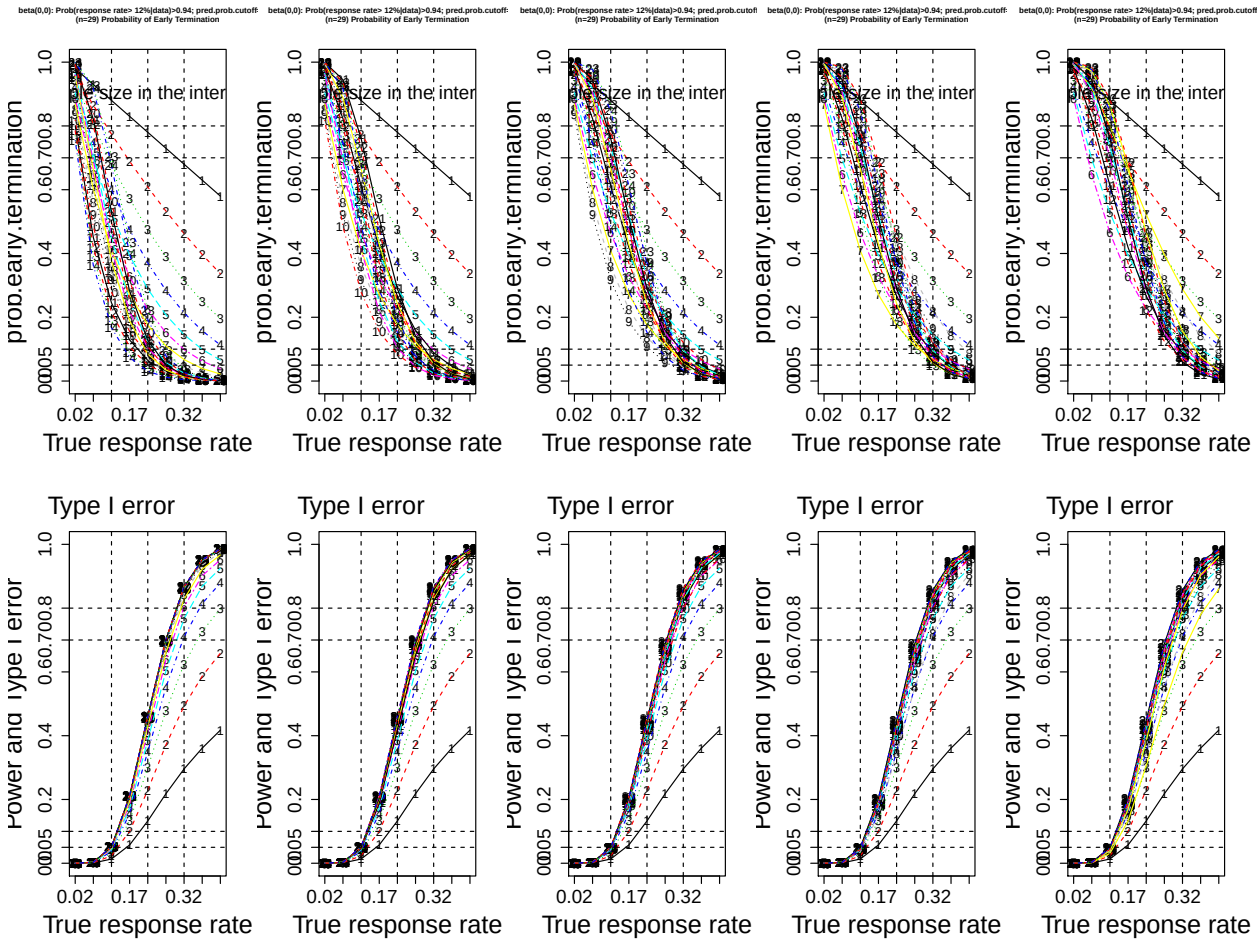
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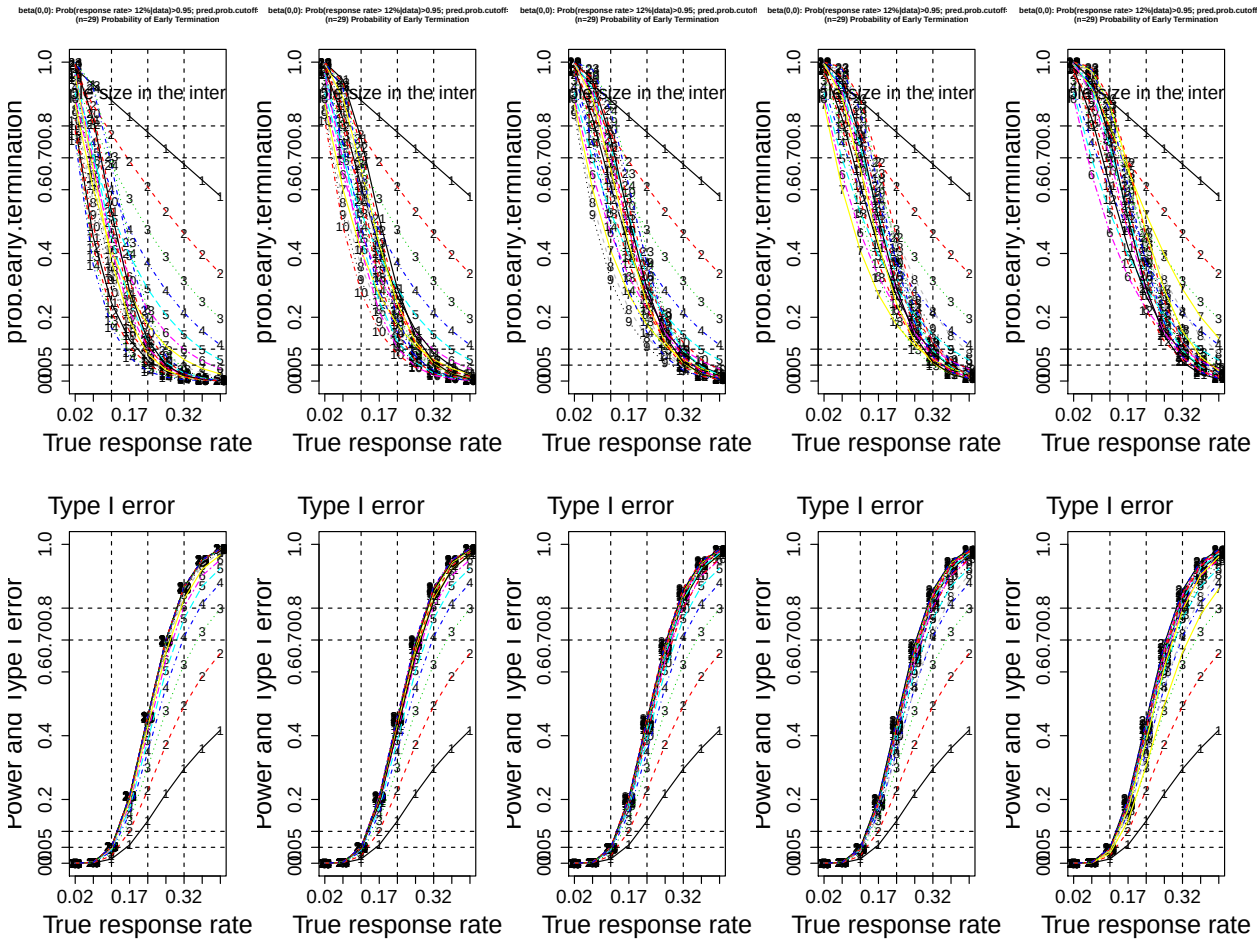
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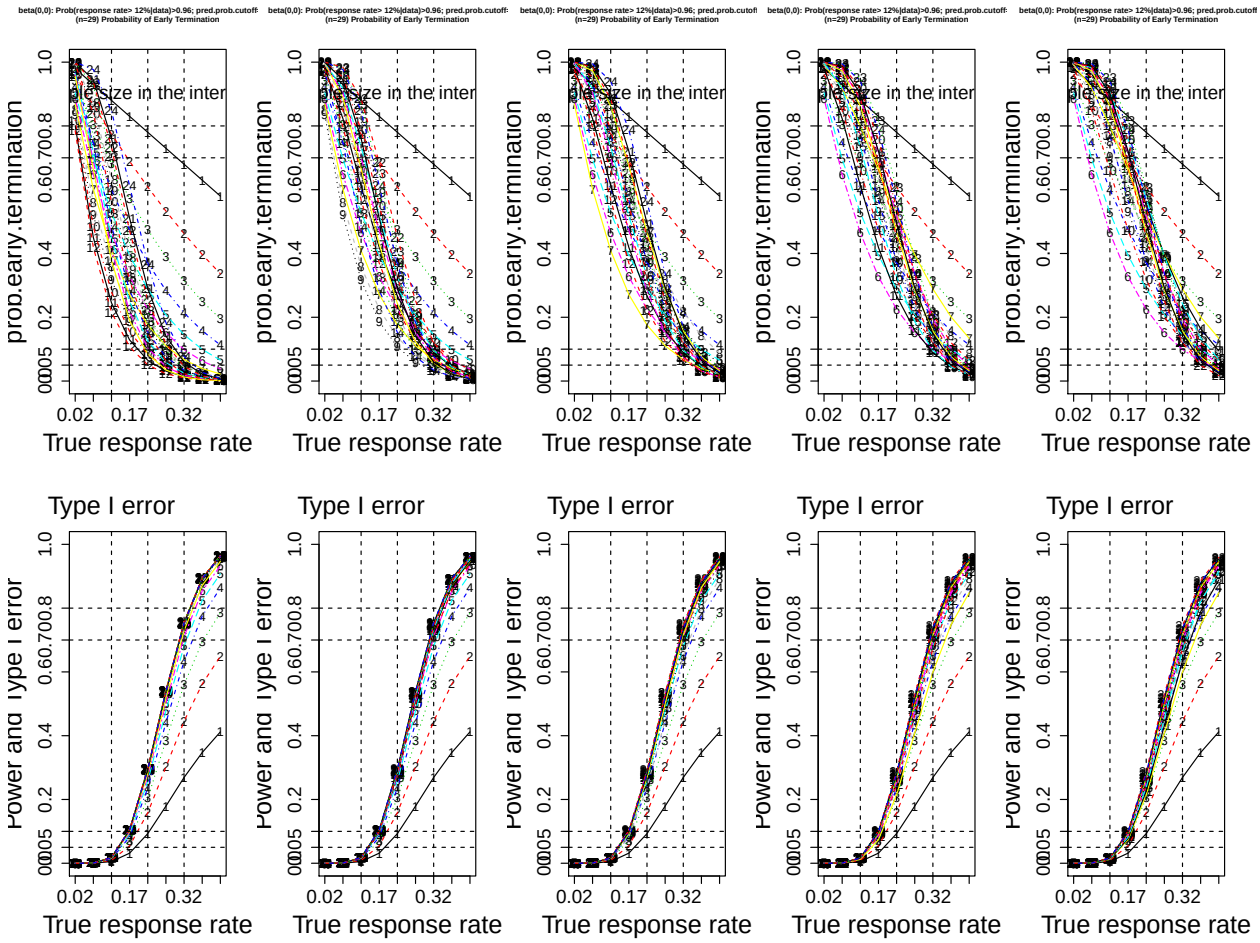
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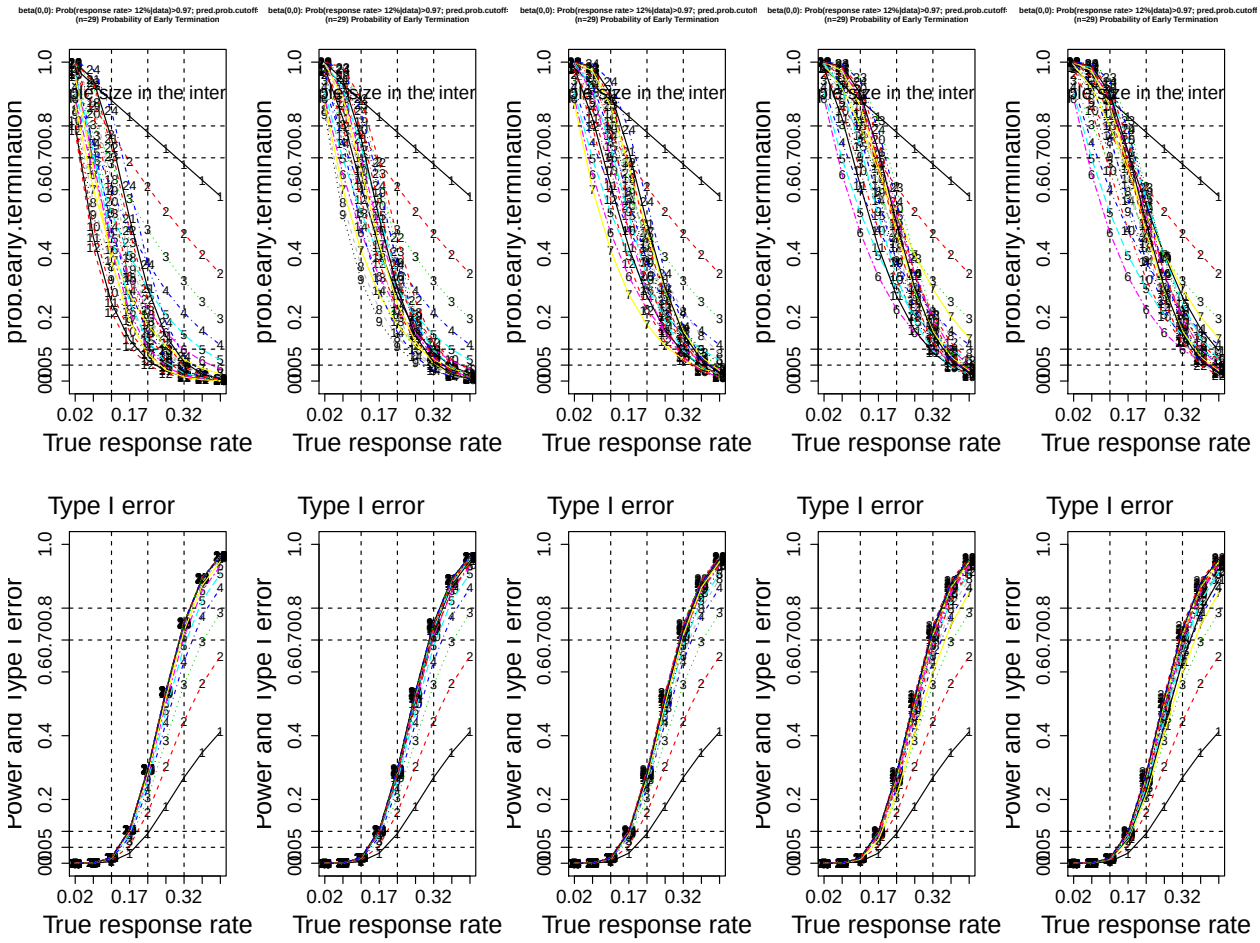
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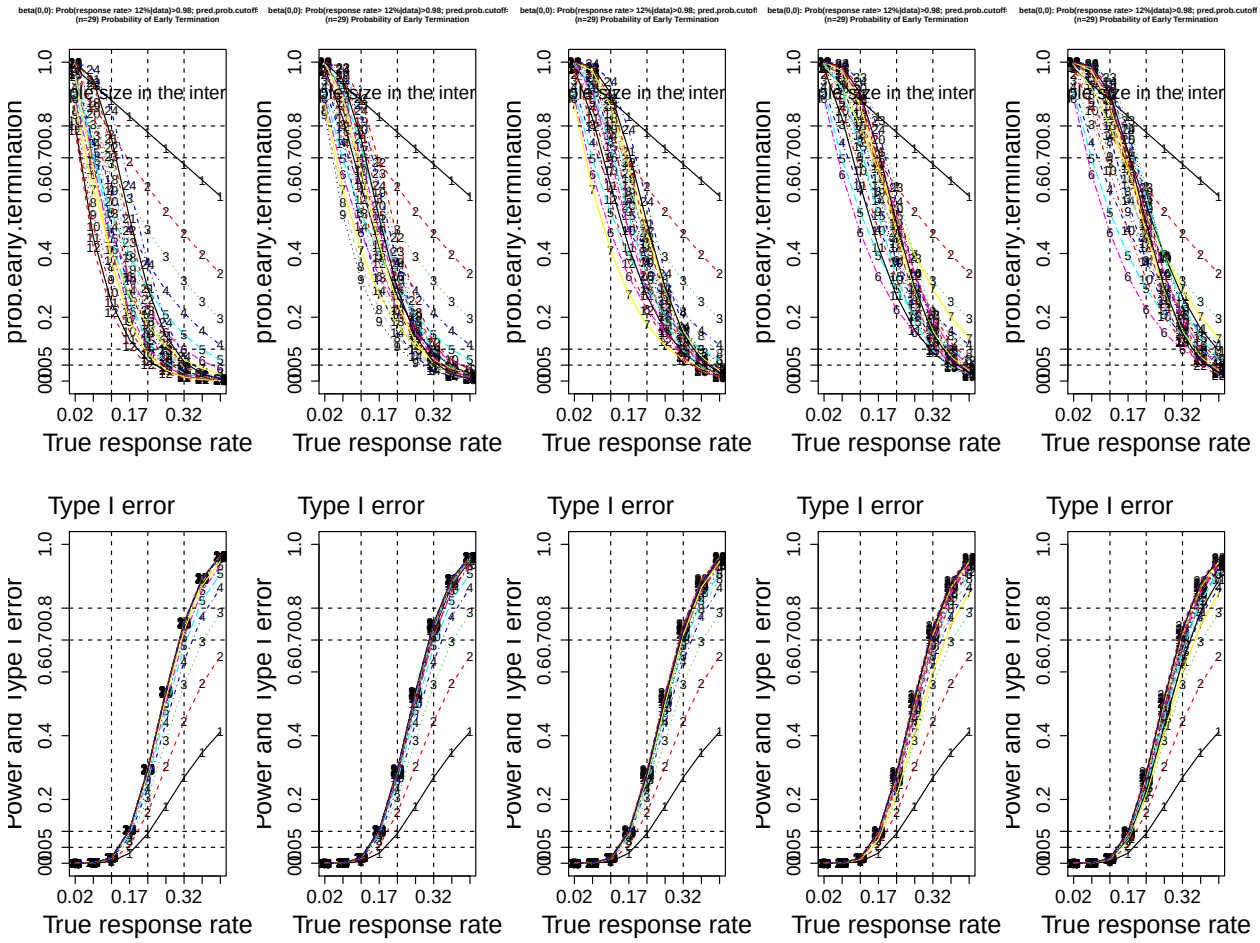
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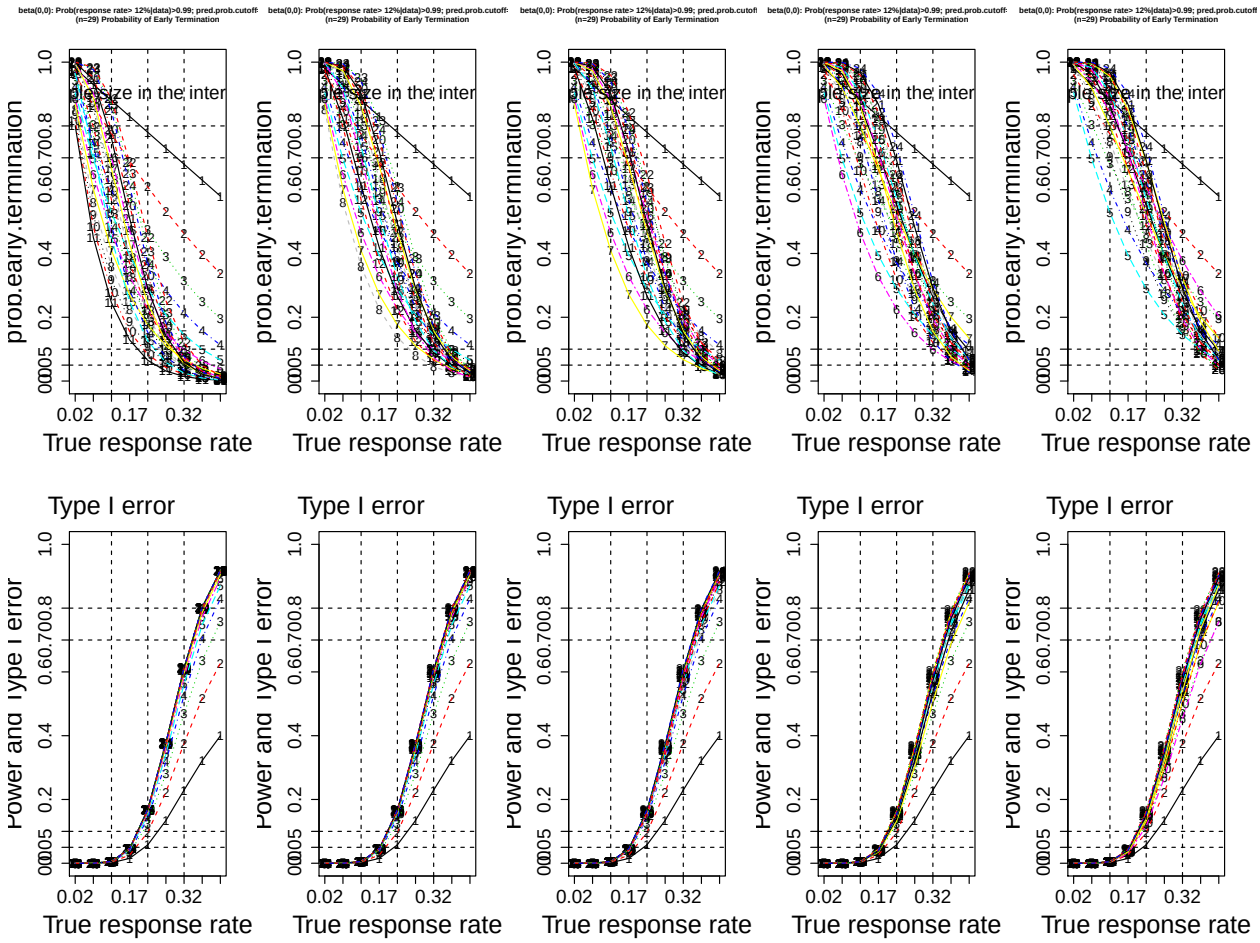
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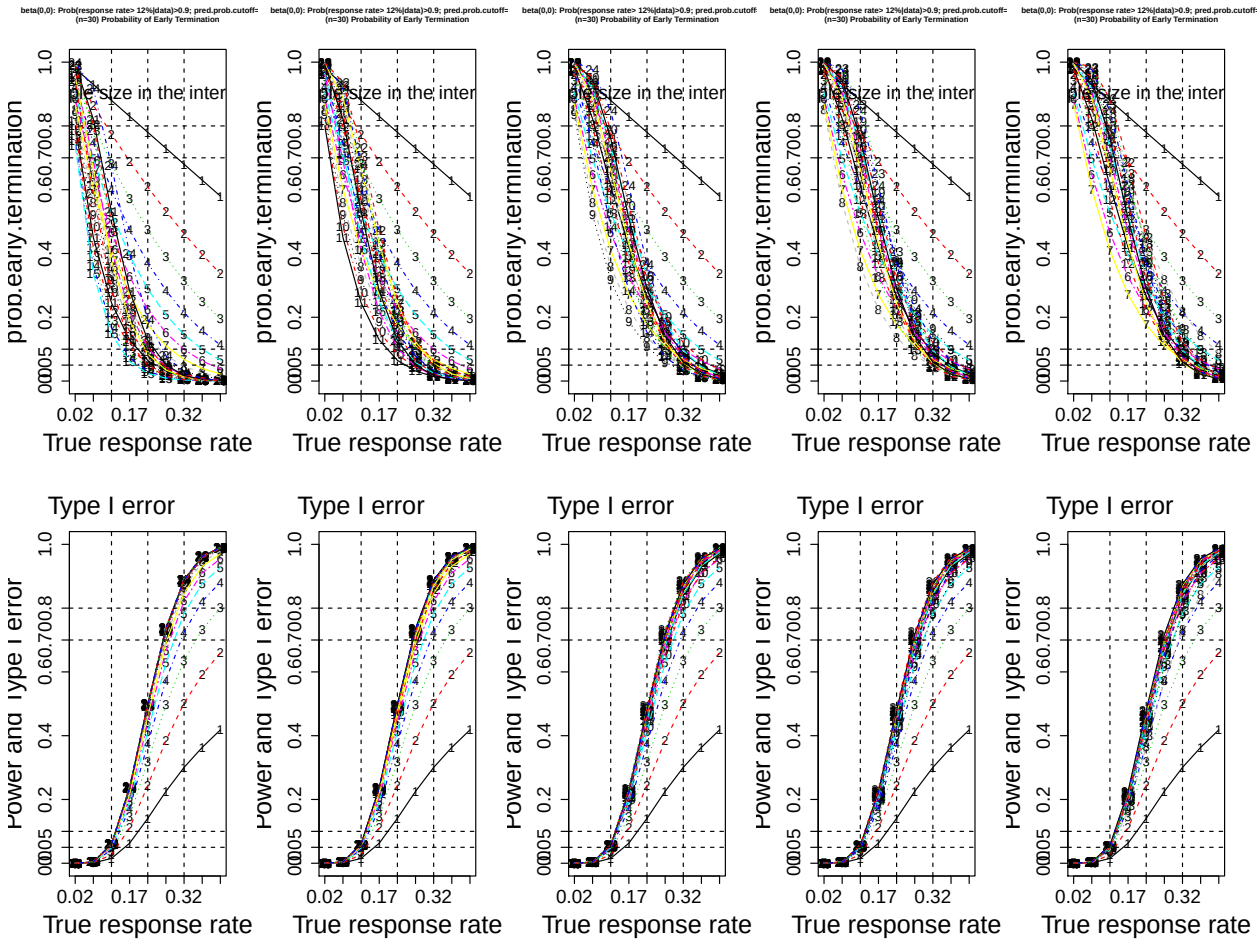
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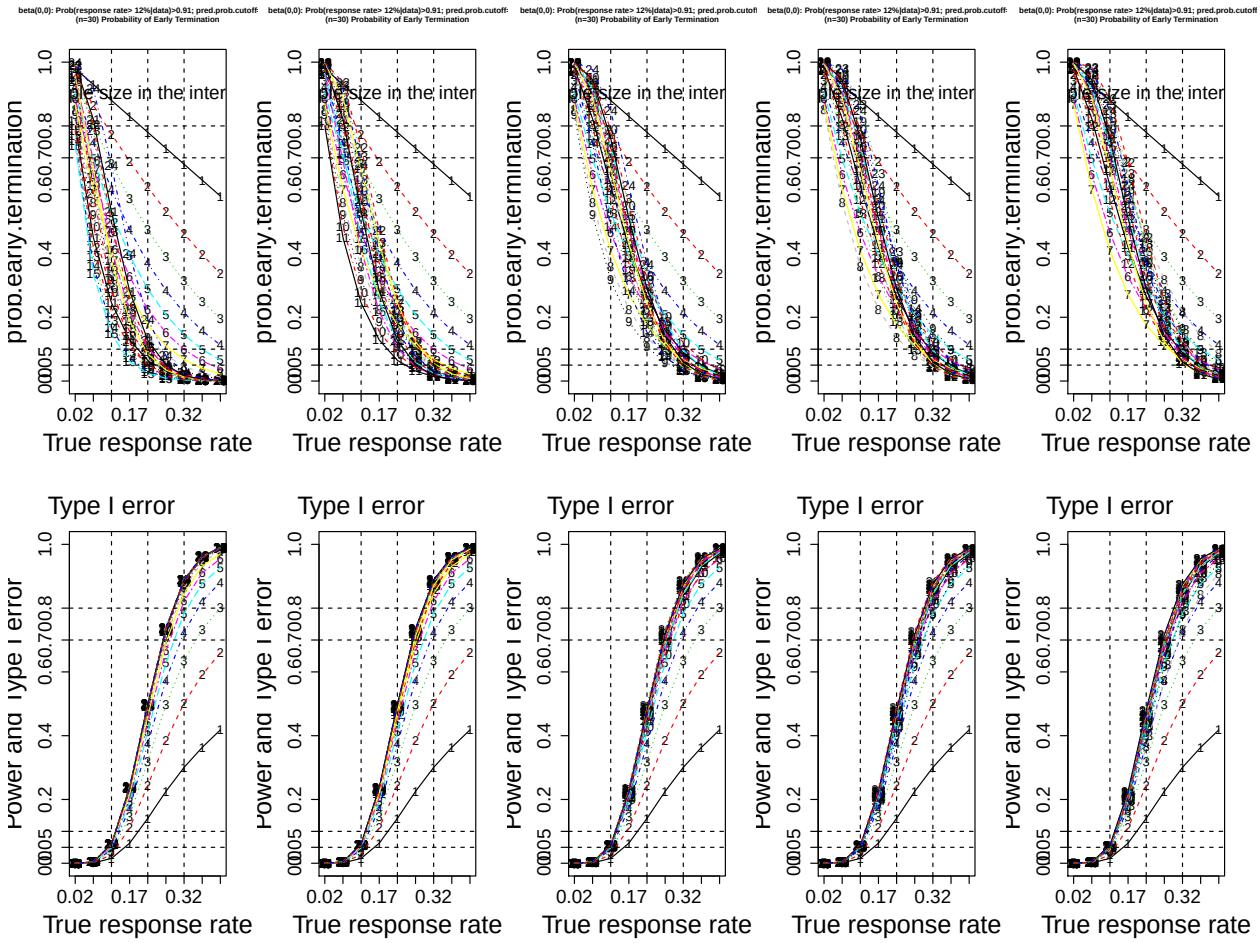
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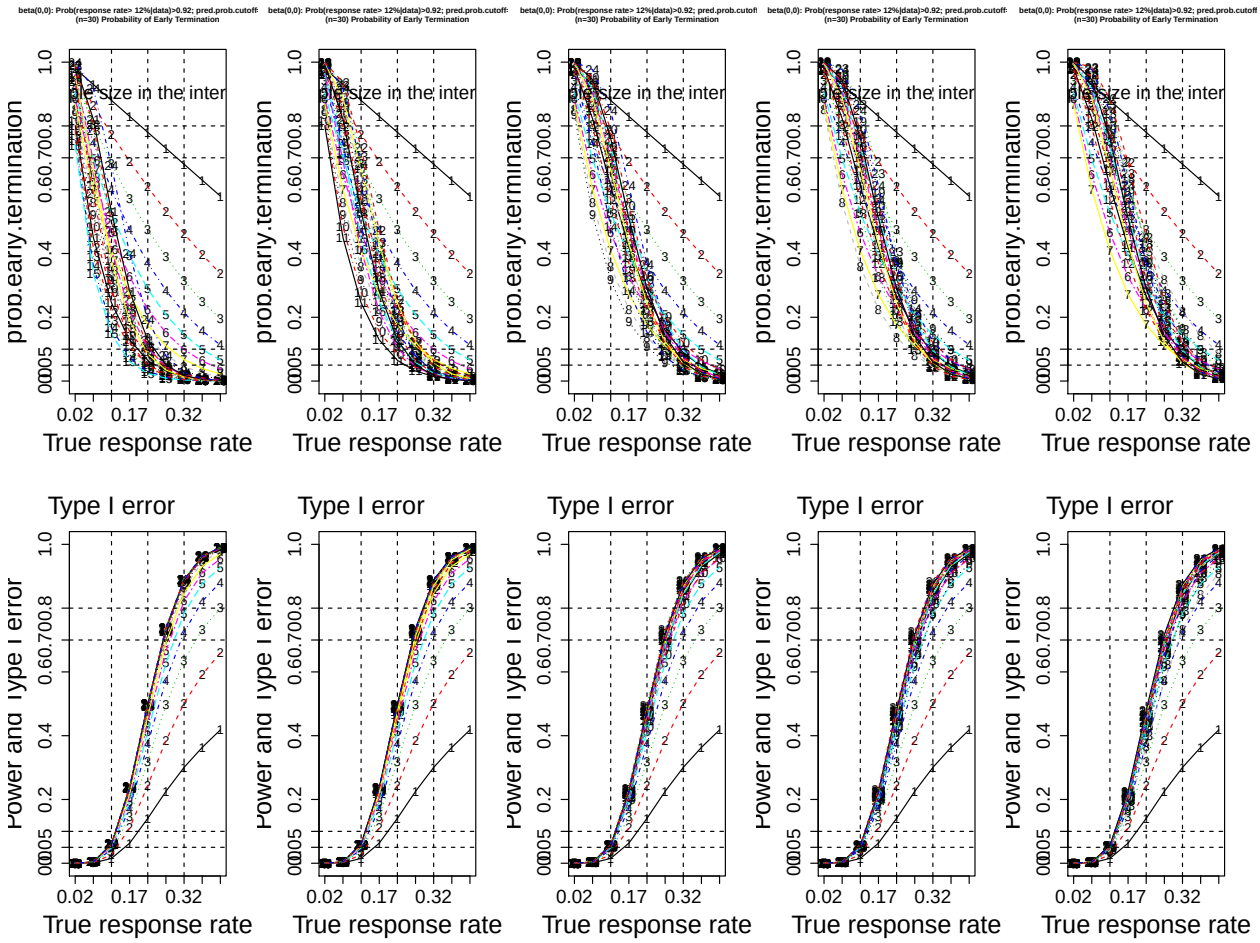
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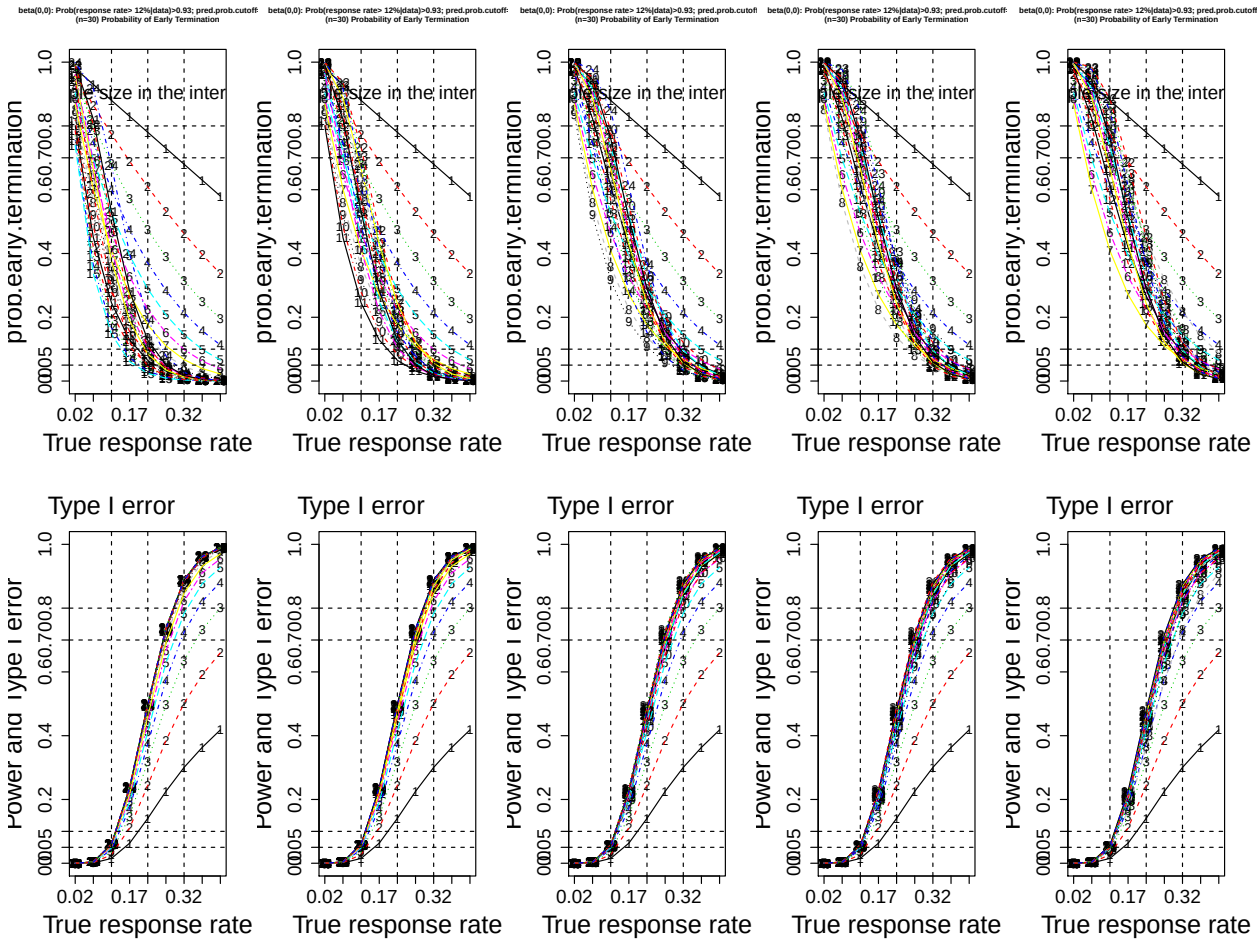
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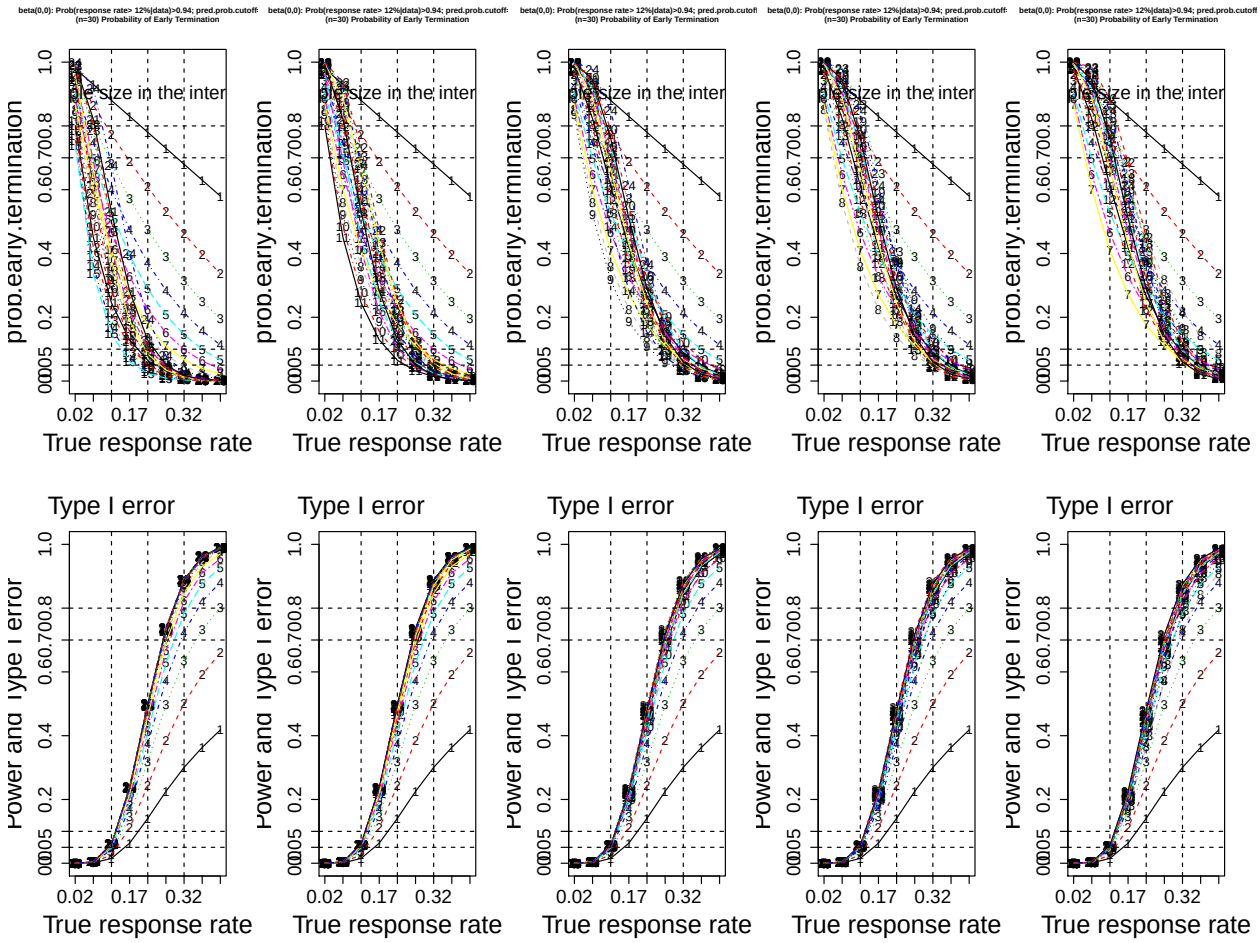
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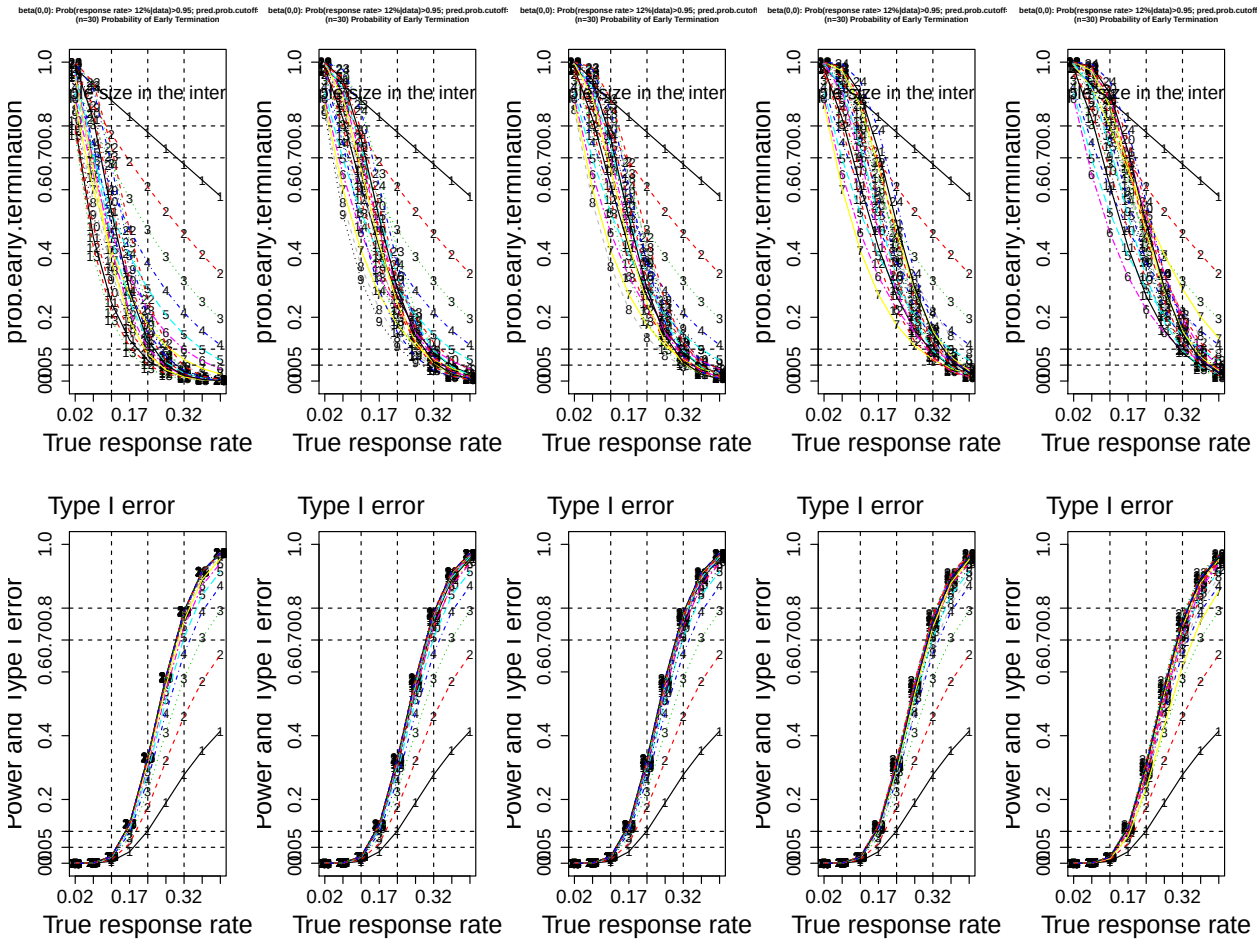
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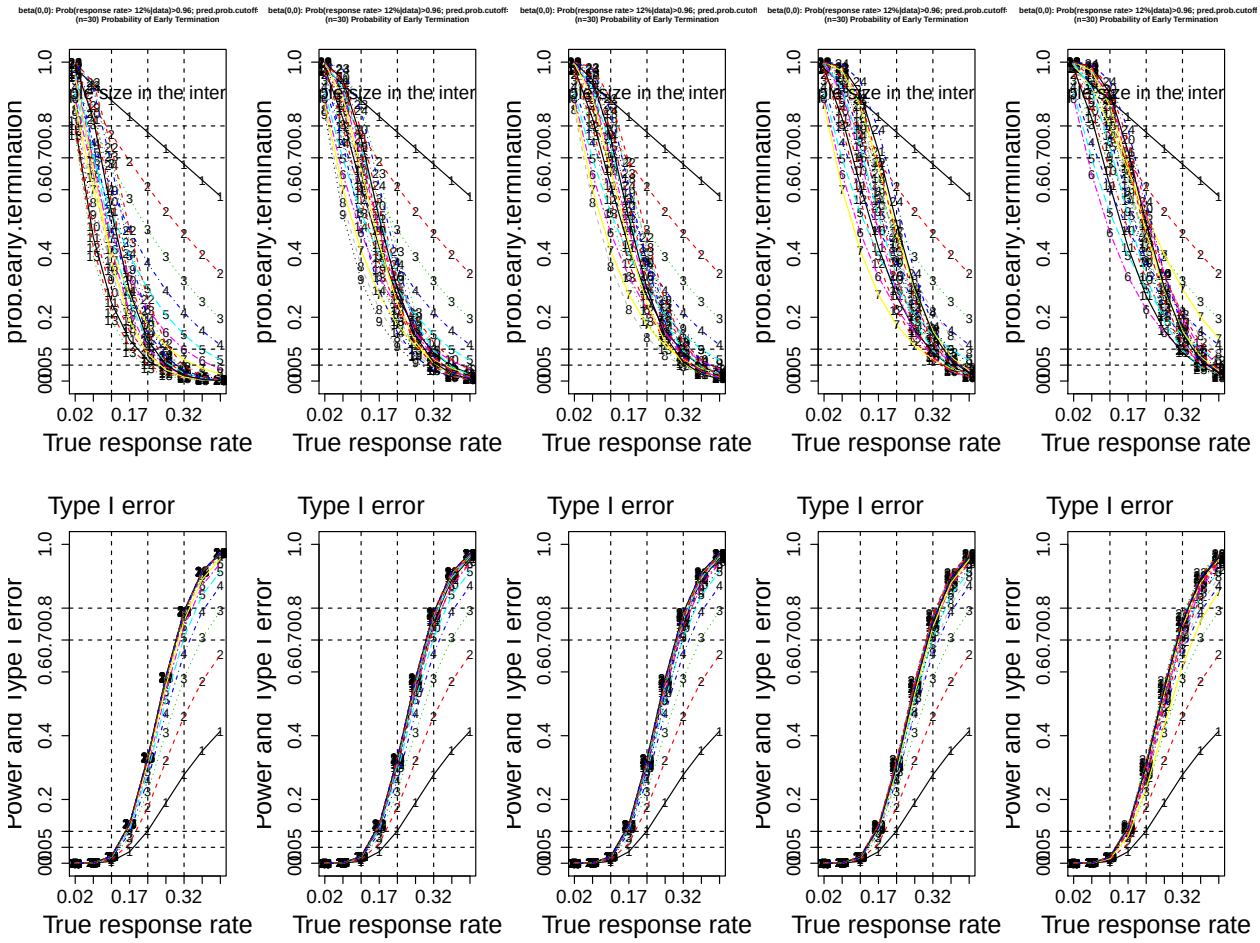
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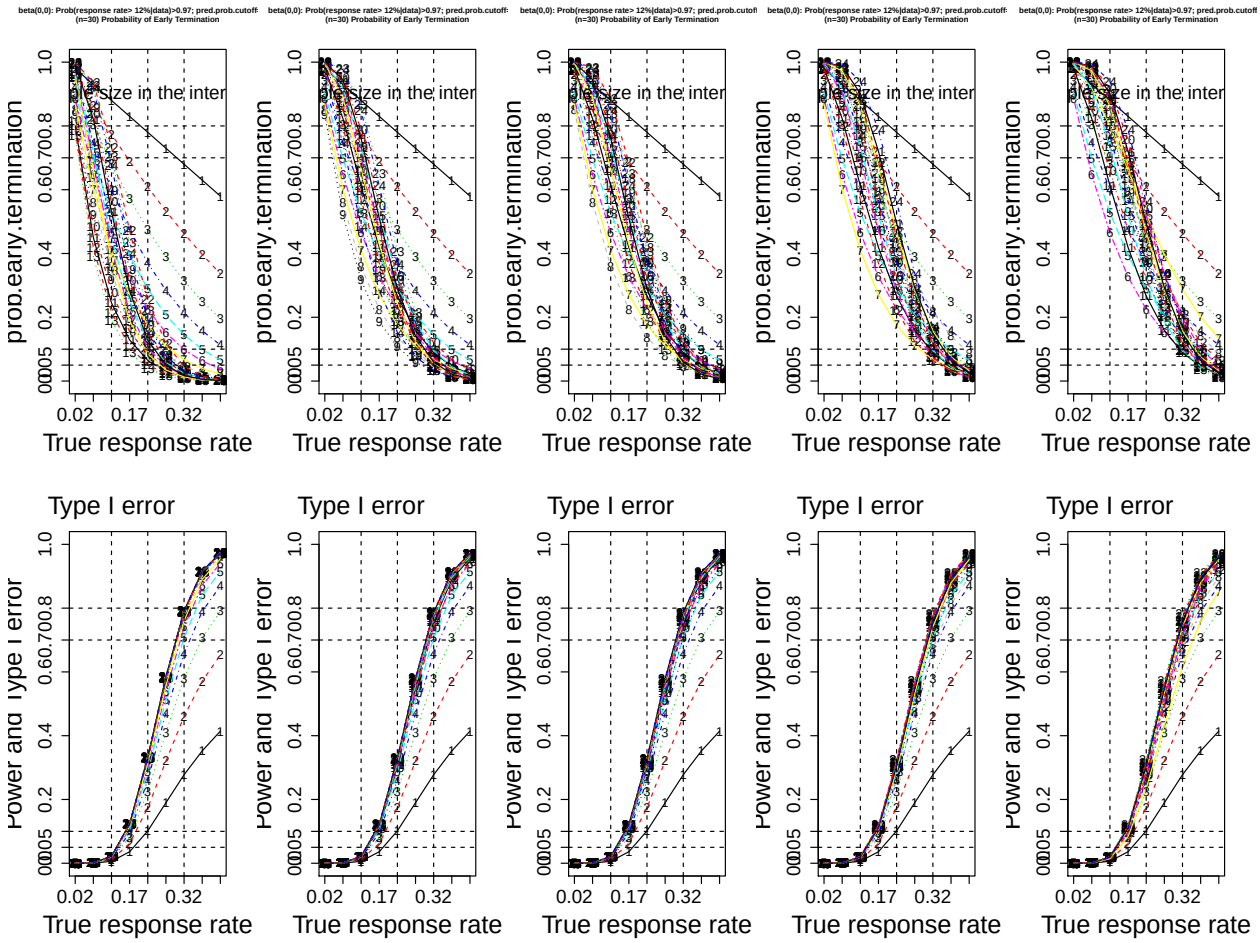
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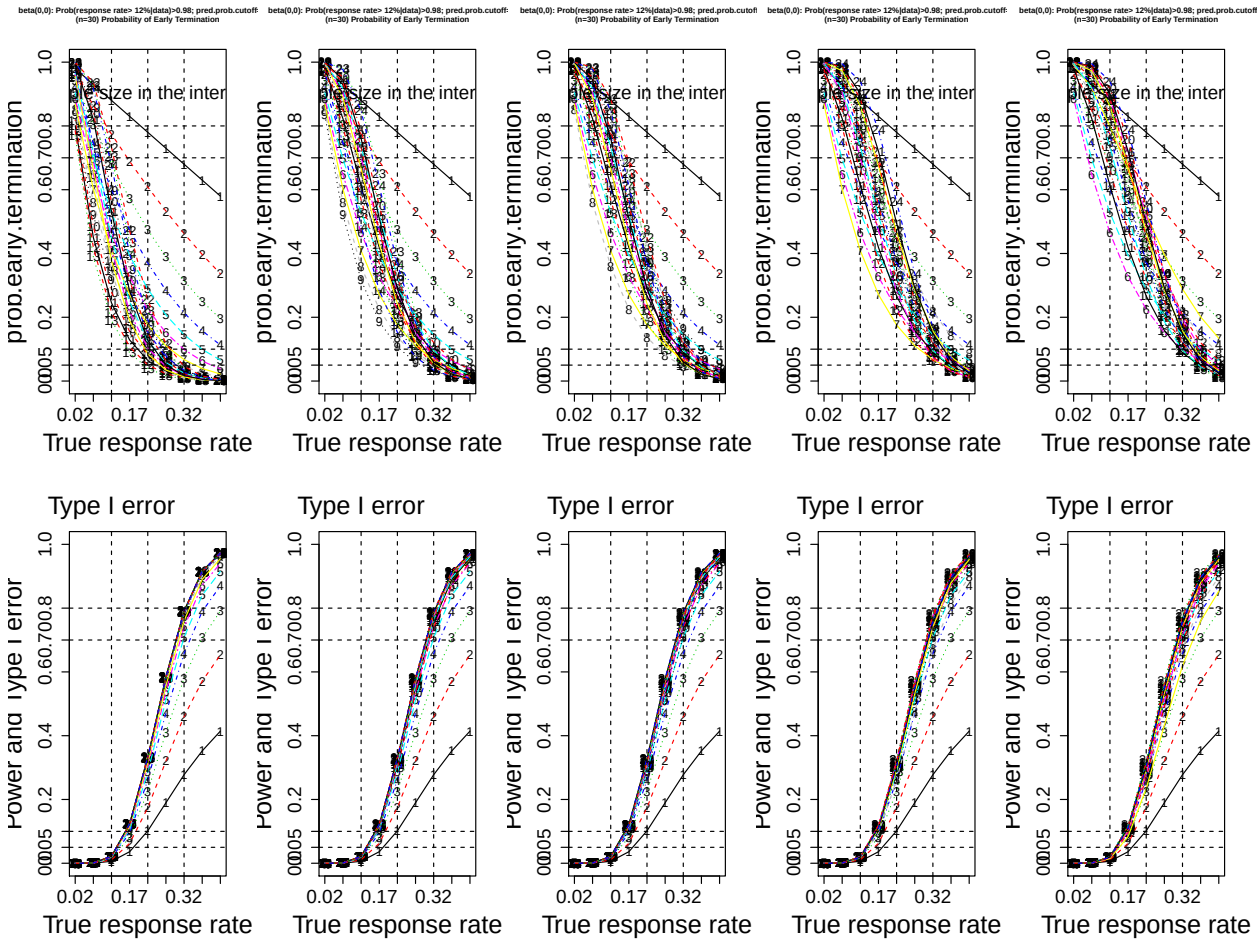
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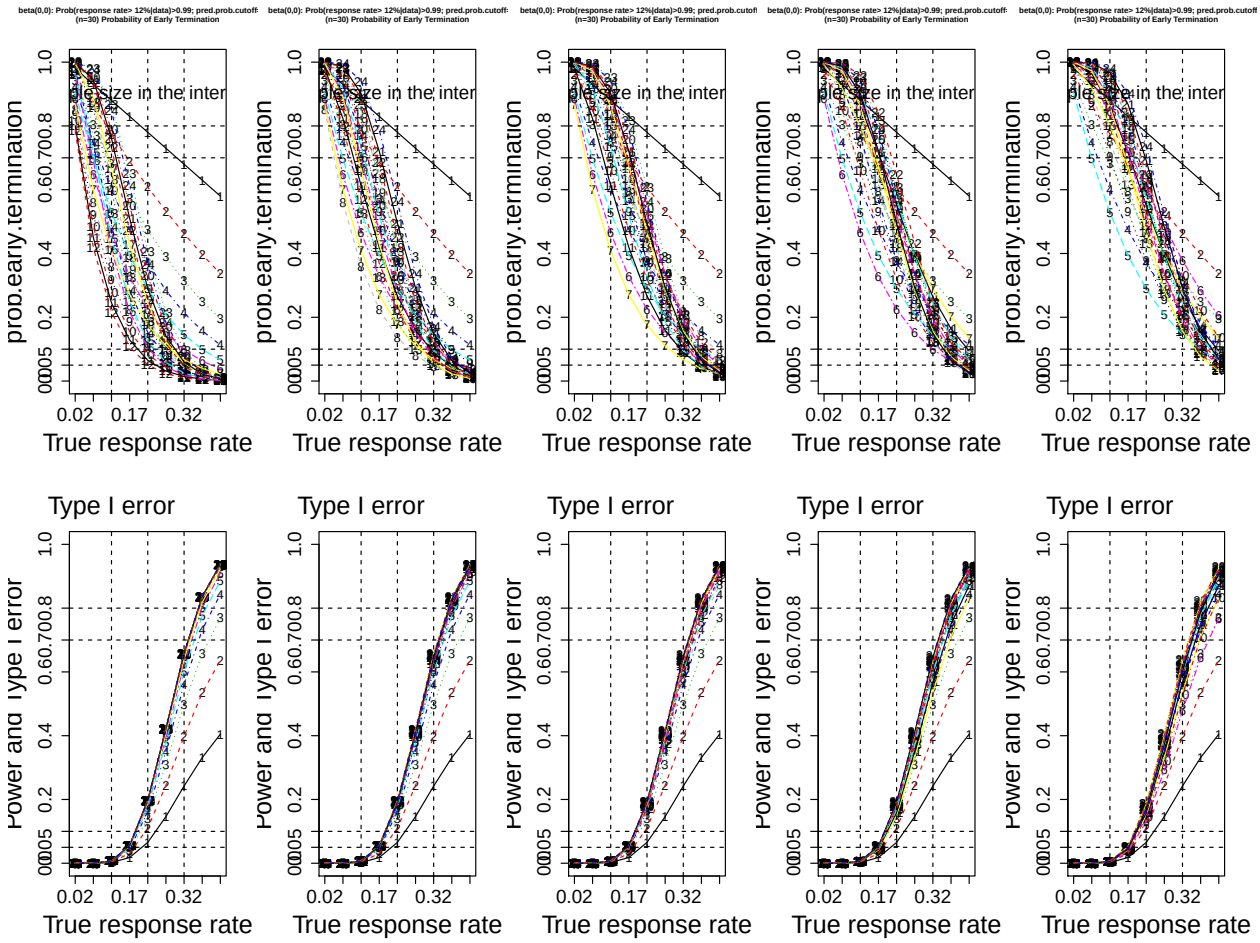
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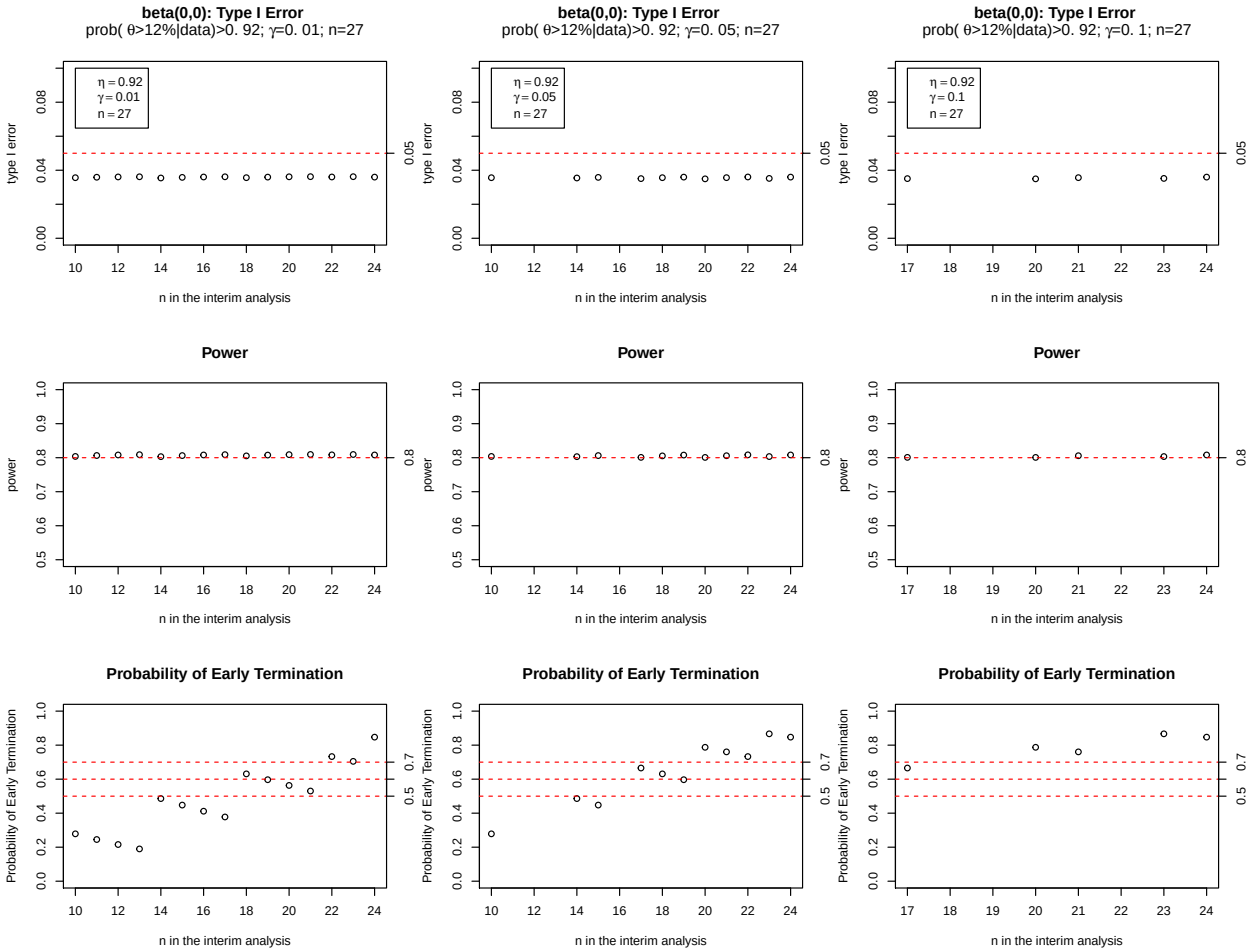
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η = 0.92
γ = 0.01
n = 27
type I error
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beta(0,0): Type I Error
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η = 0.92
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n in the interim analysis
beta(0,0): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 1; n=27
η = 0.92
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type I error
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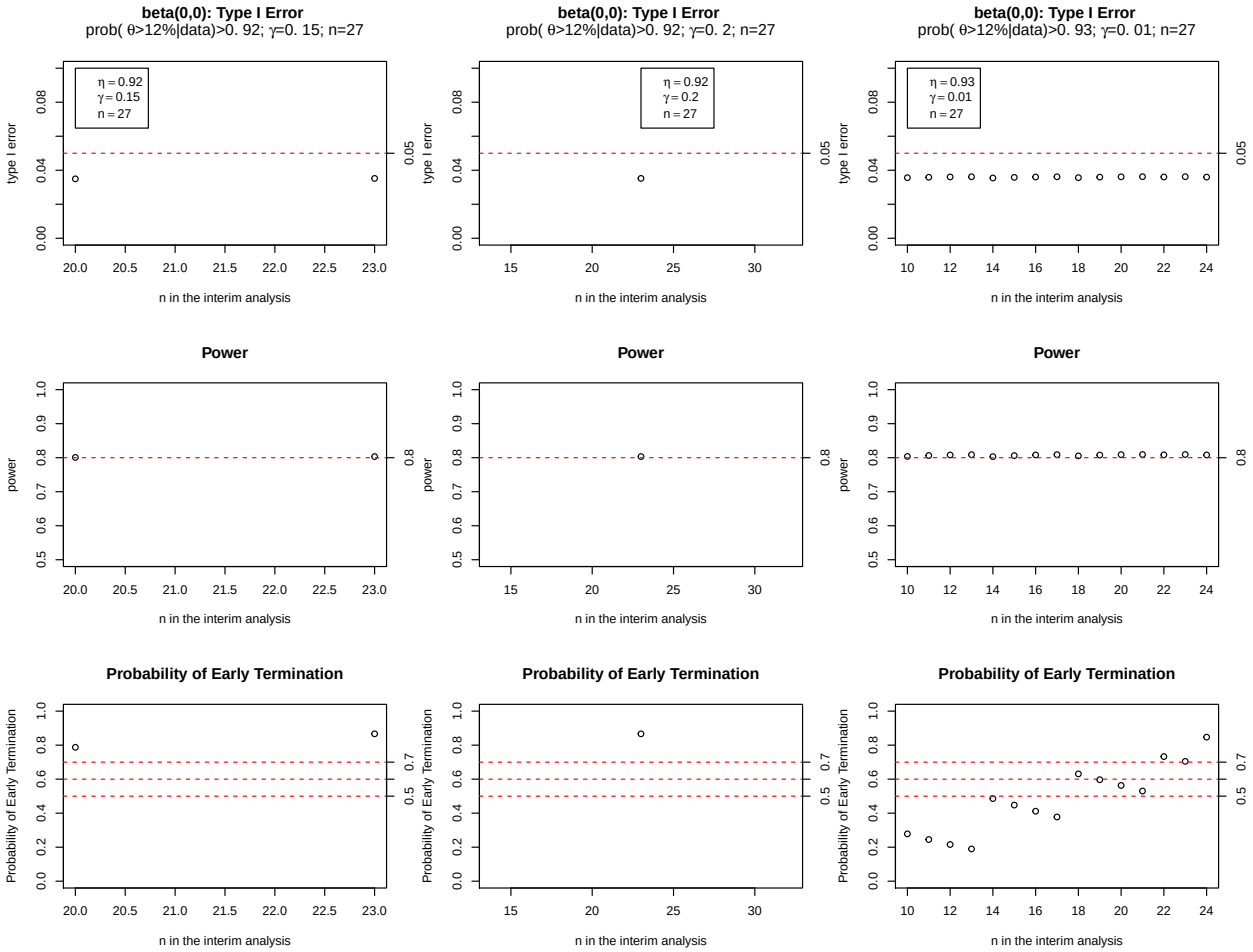
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n = 27
type I error
n in the interim analysis
beta(0,0): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 2; n=27
η = 0.92
γ = 0.2
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type I error
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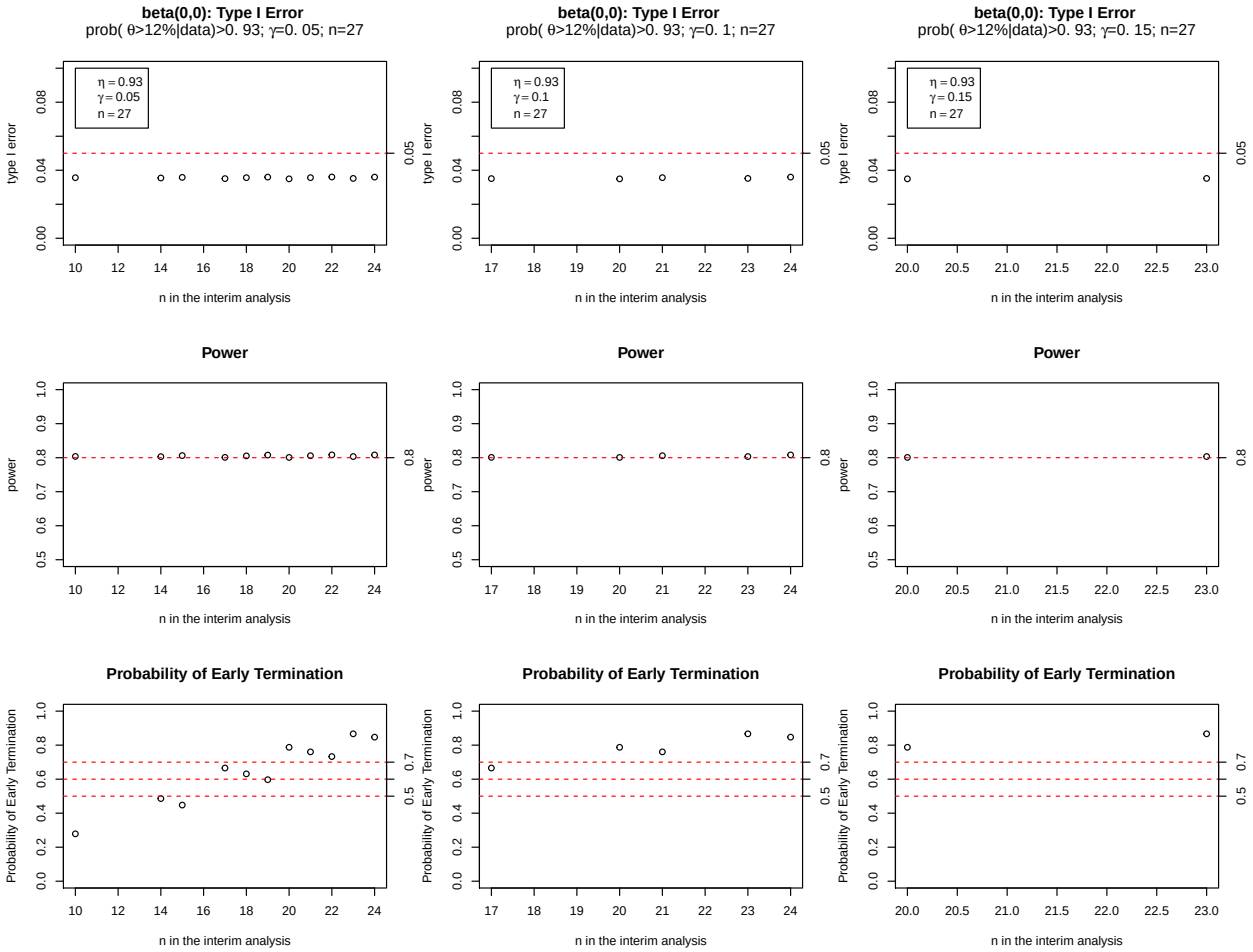
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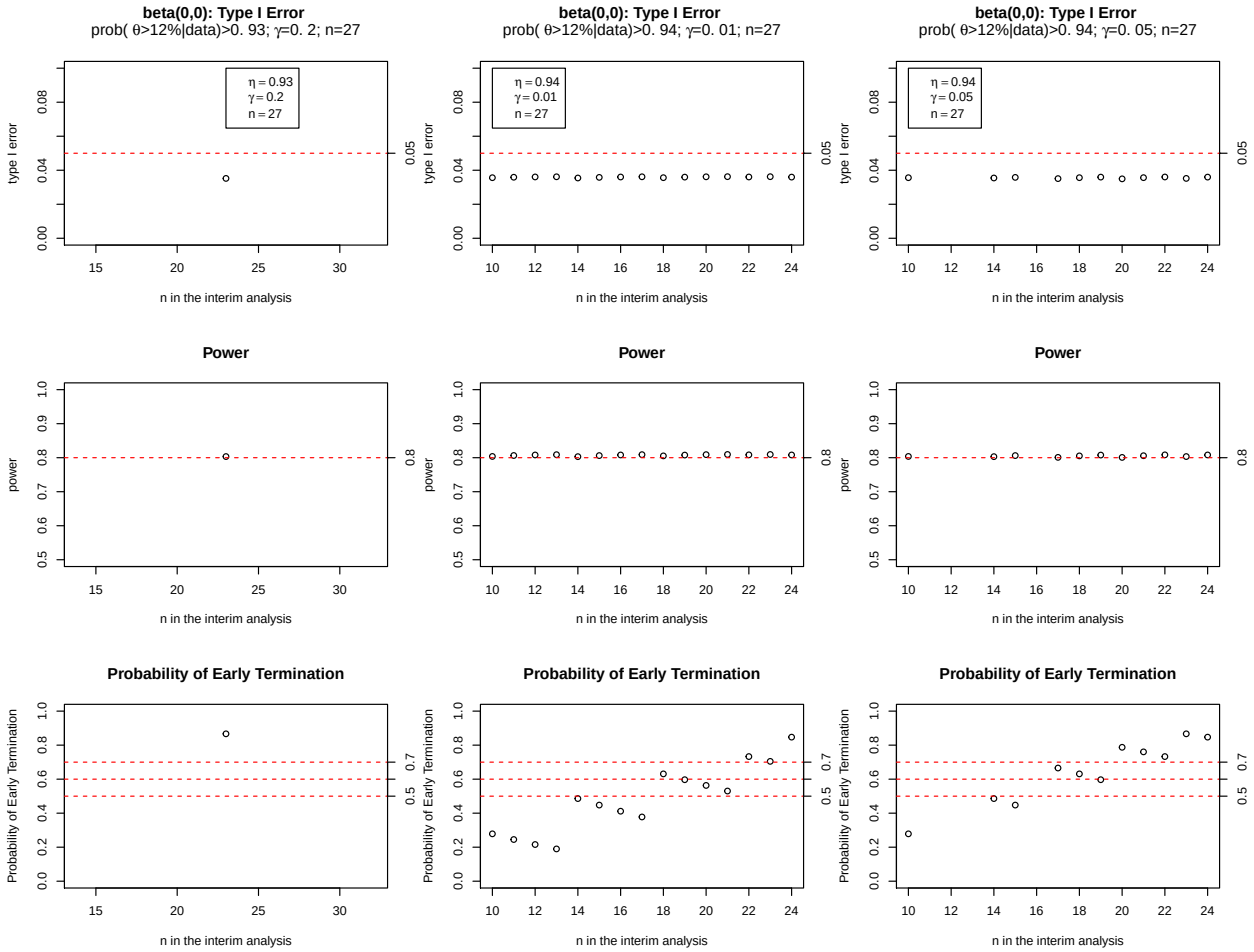
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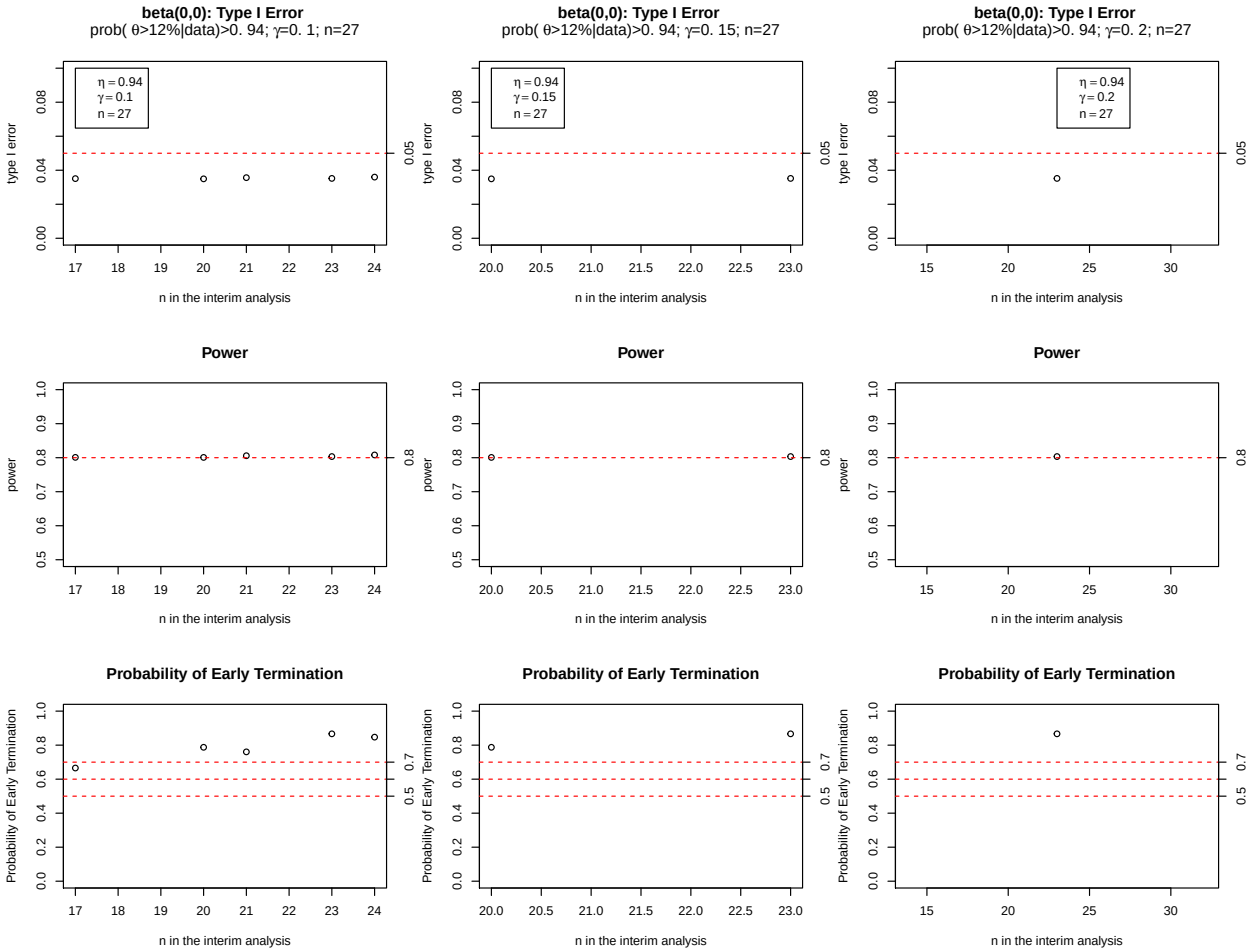
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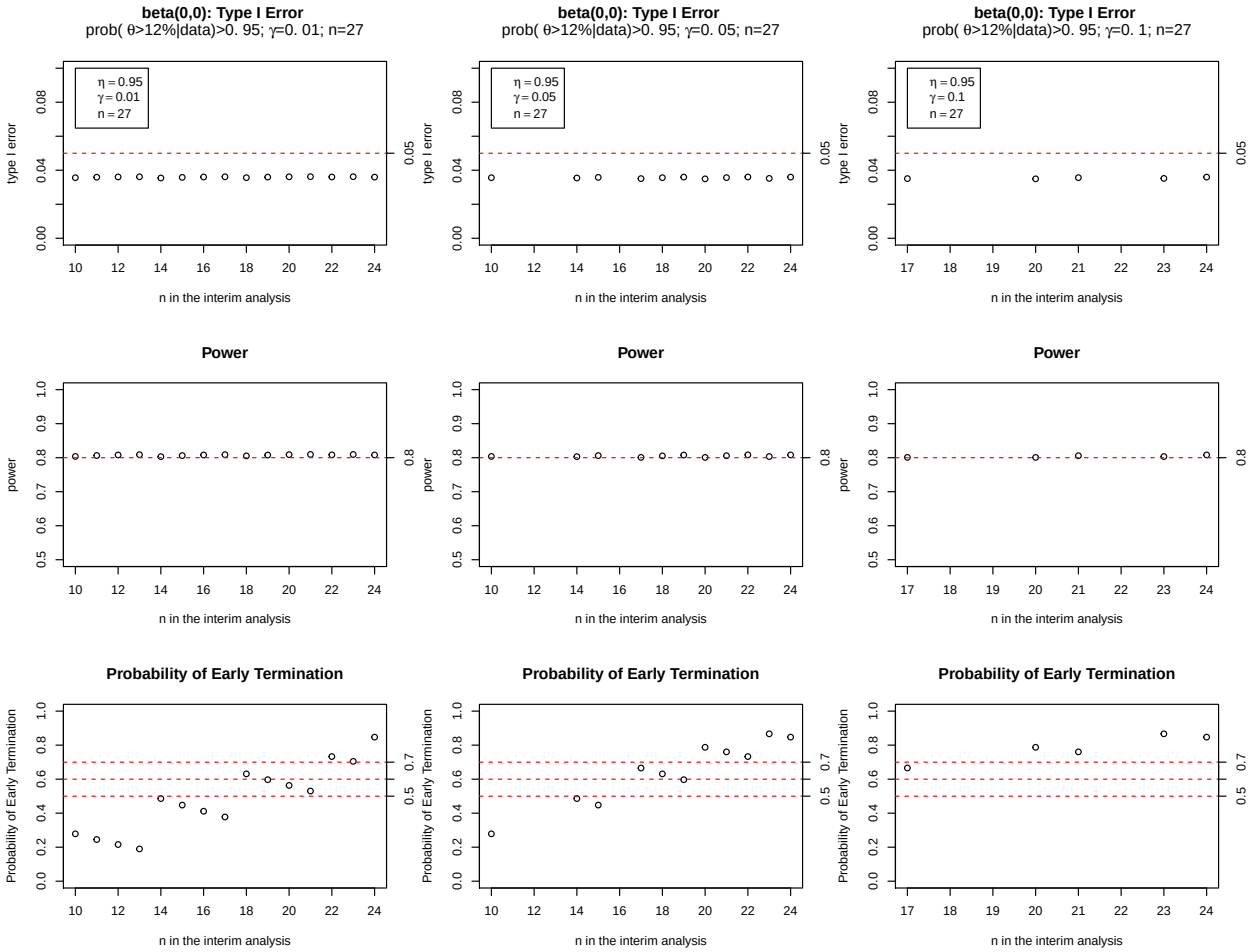
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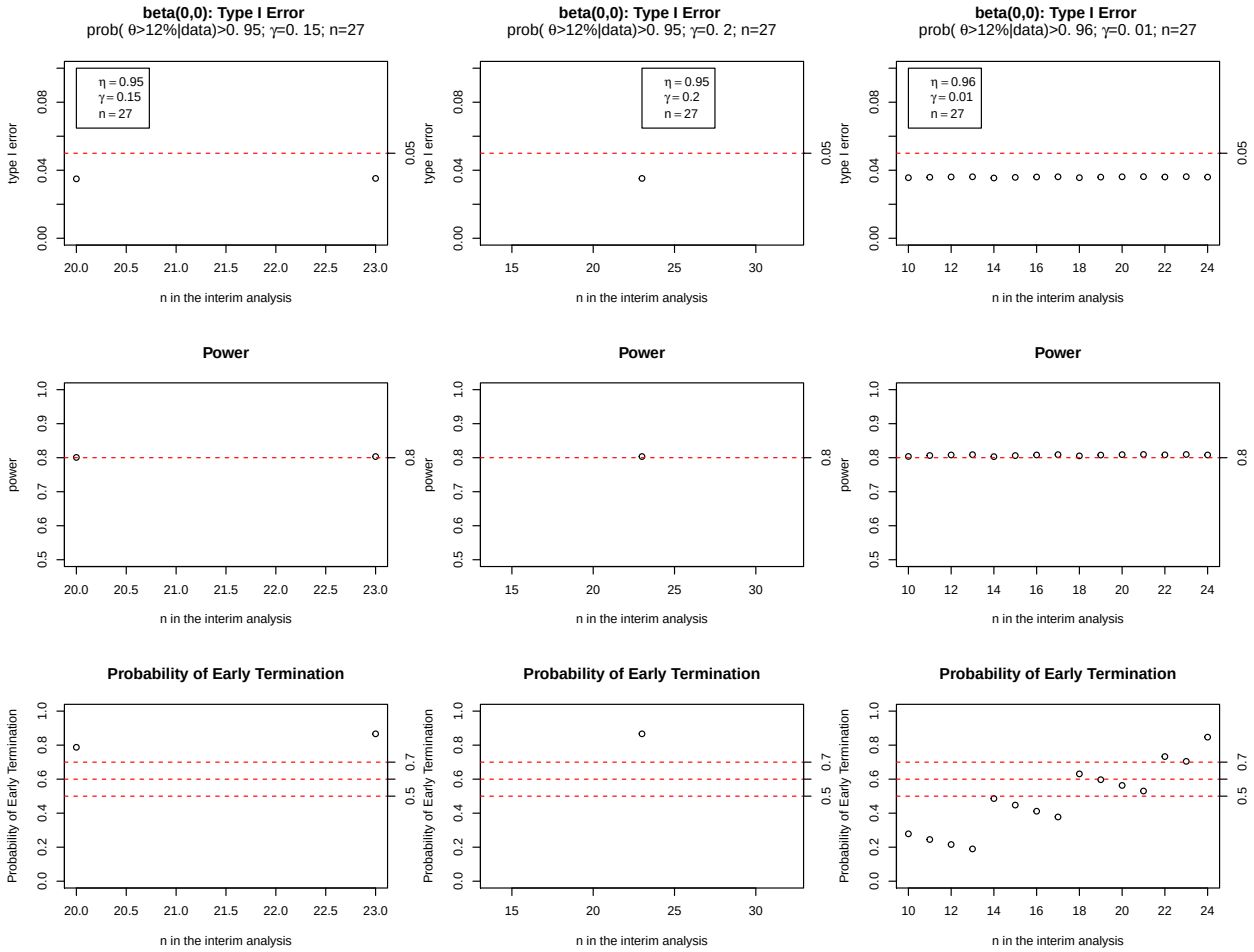
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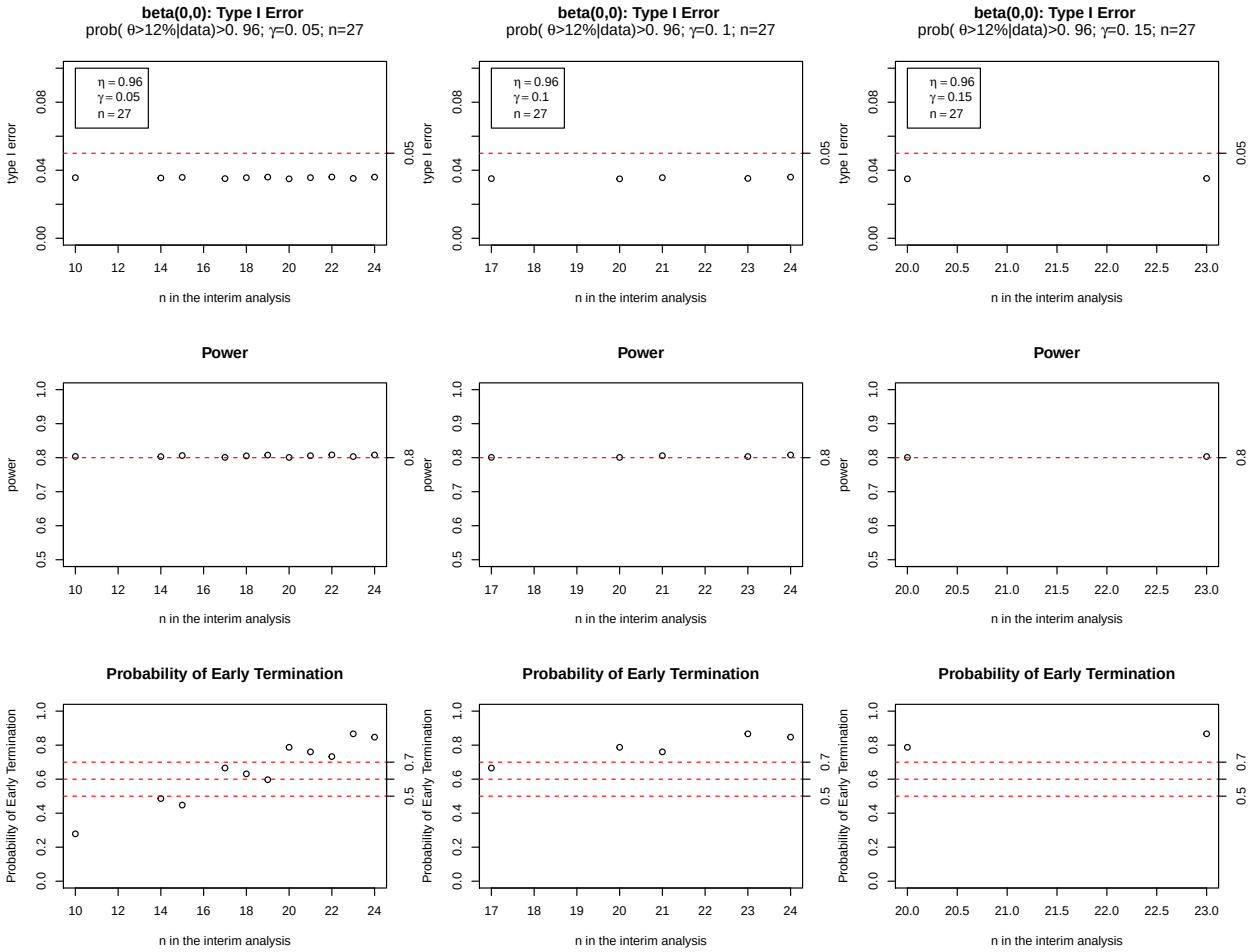
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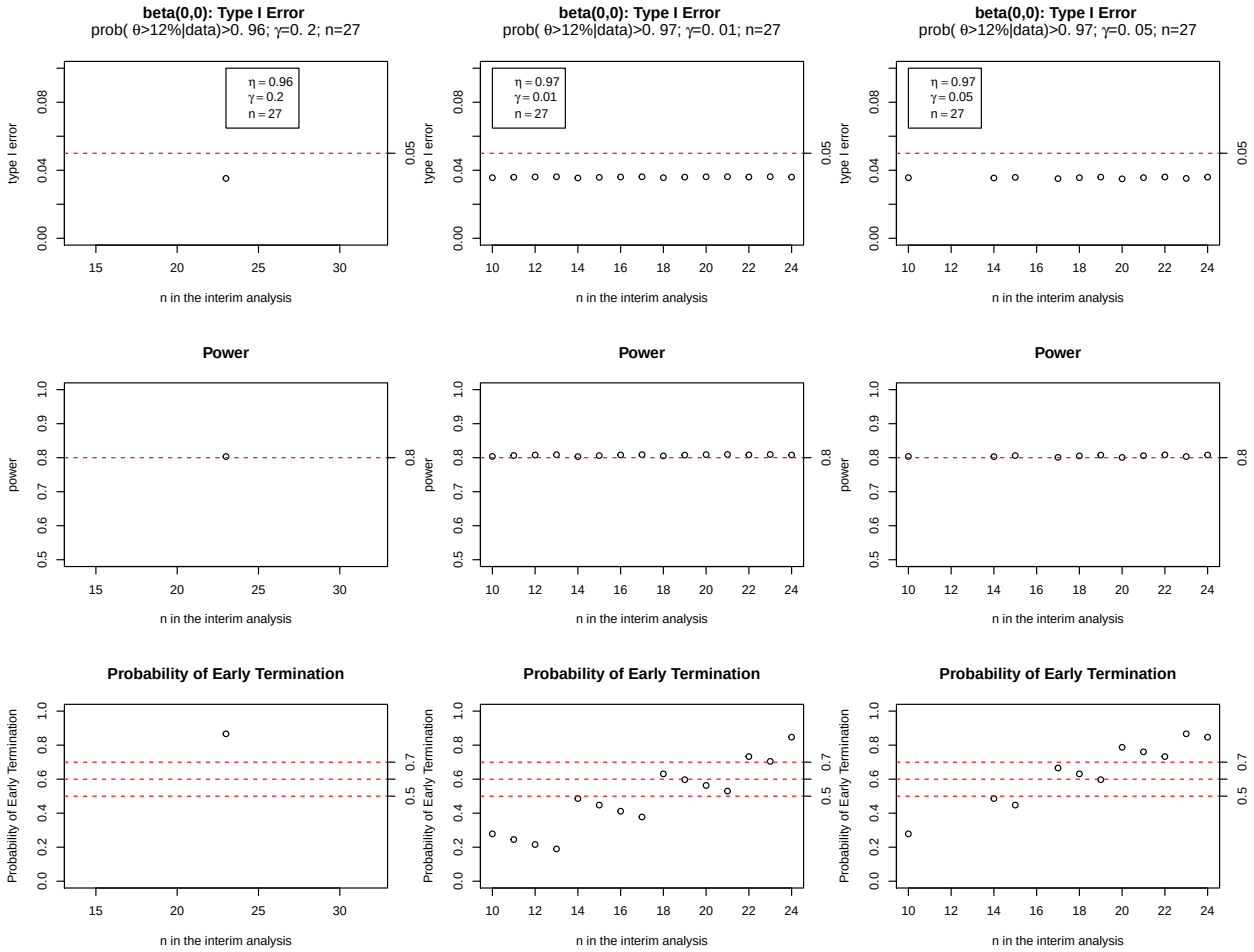
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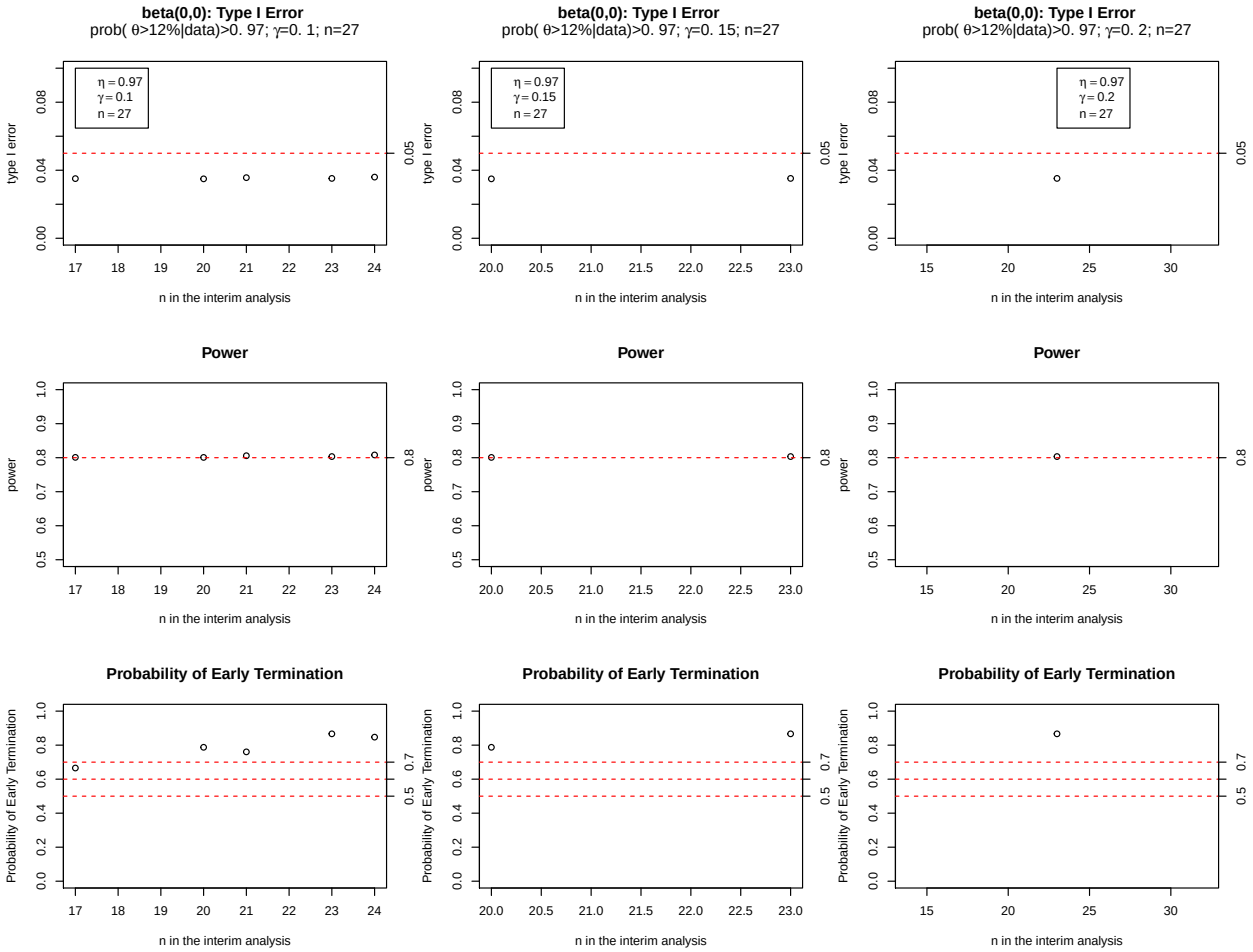
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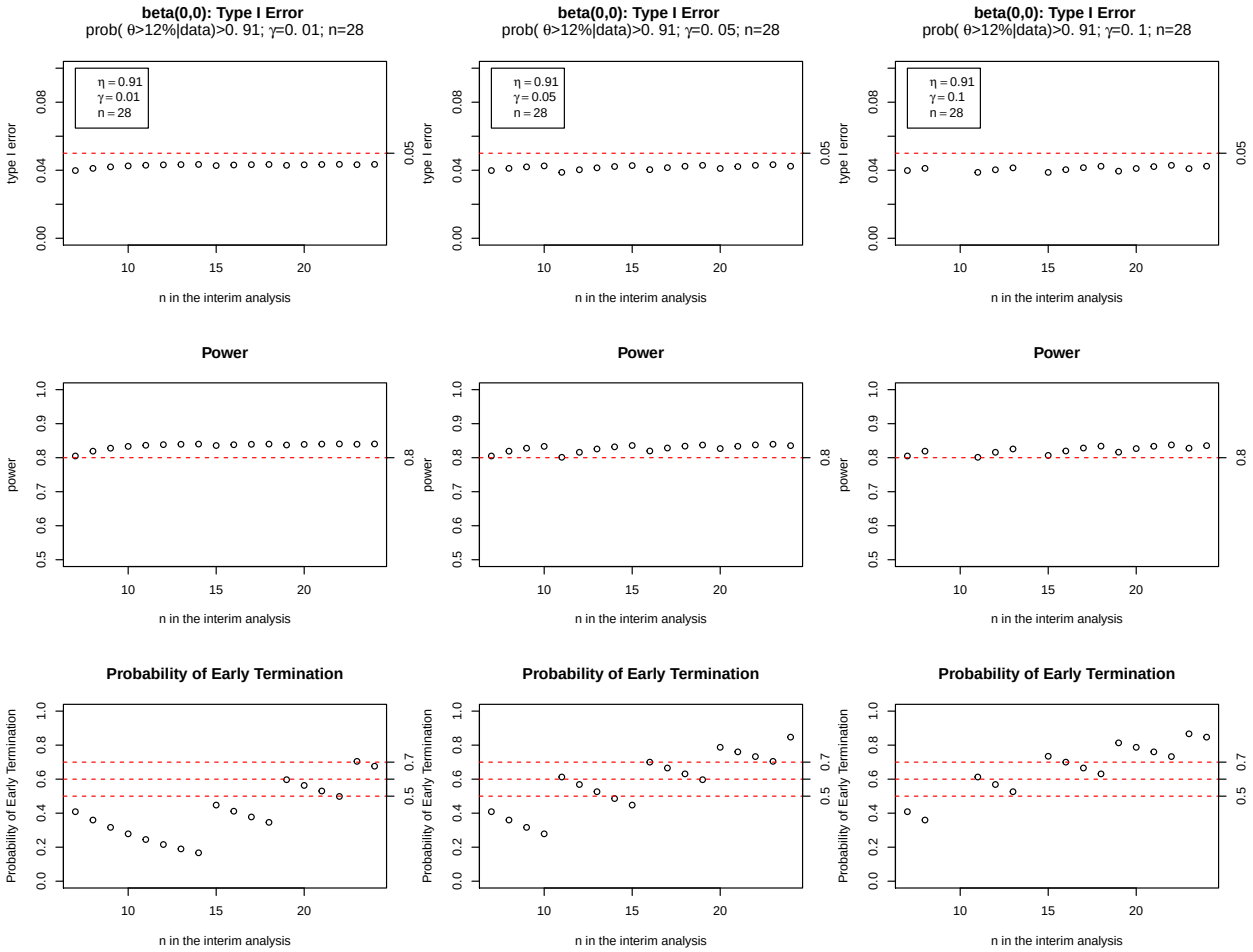
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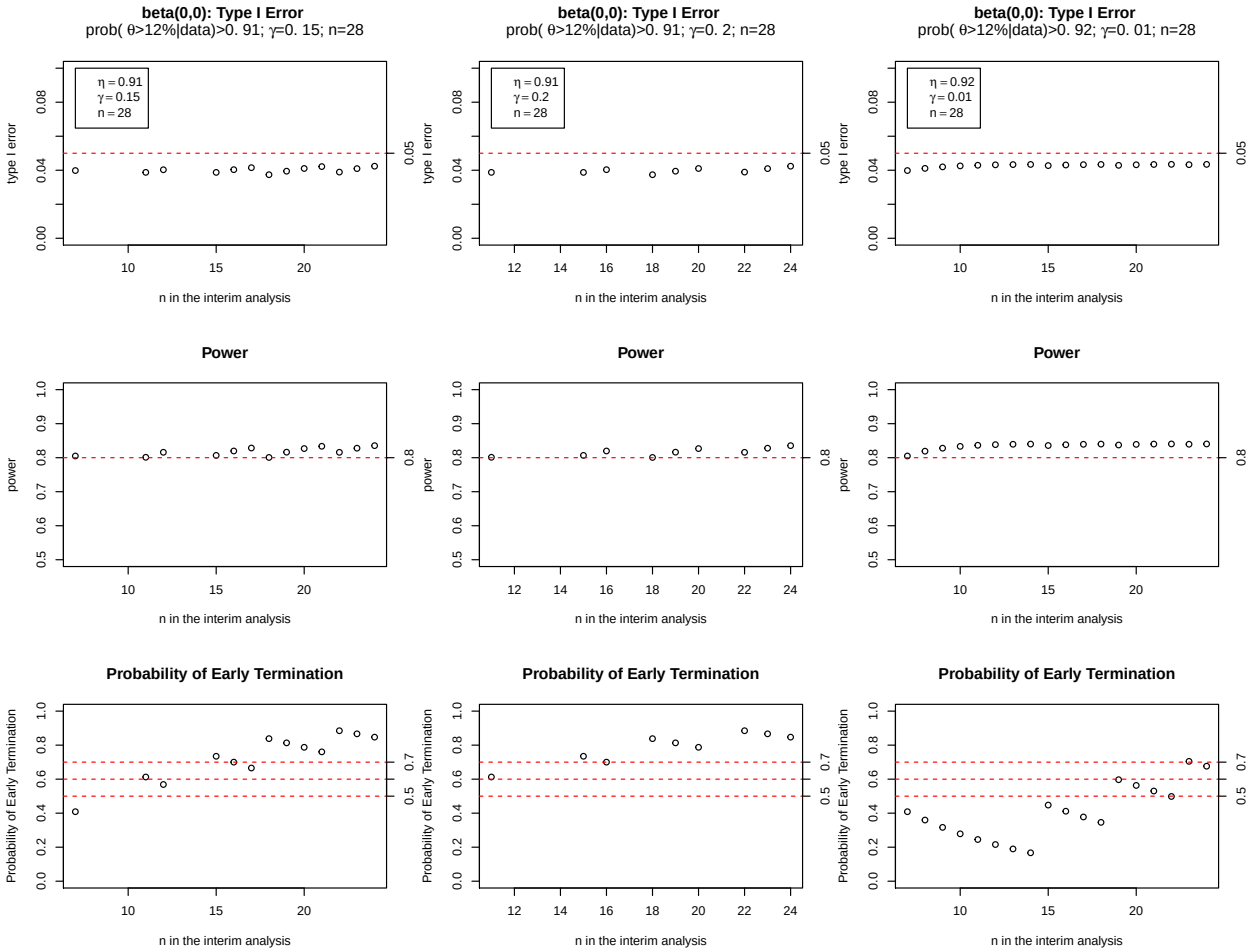
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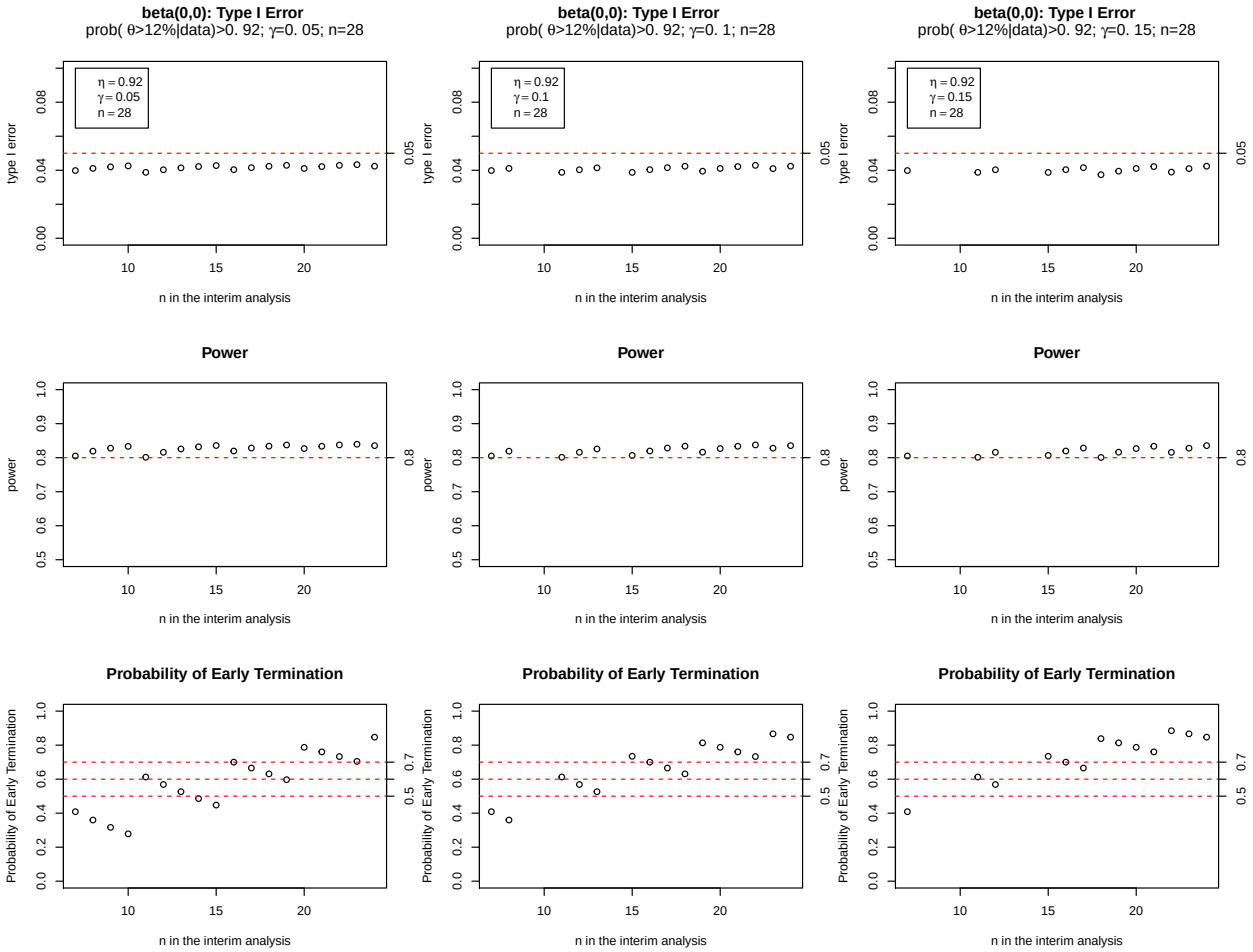
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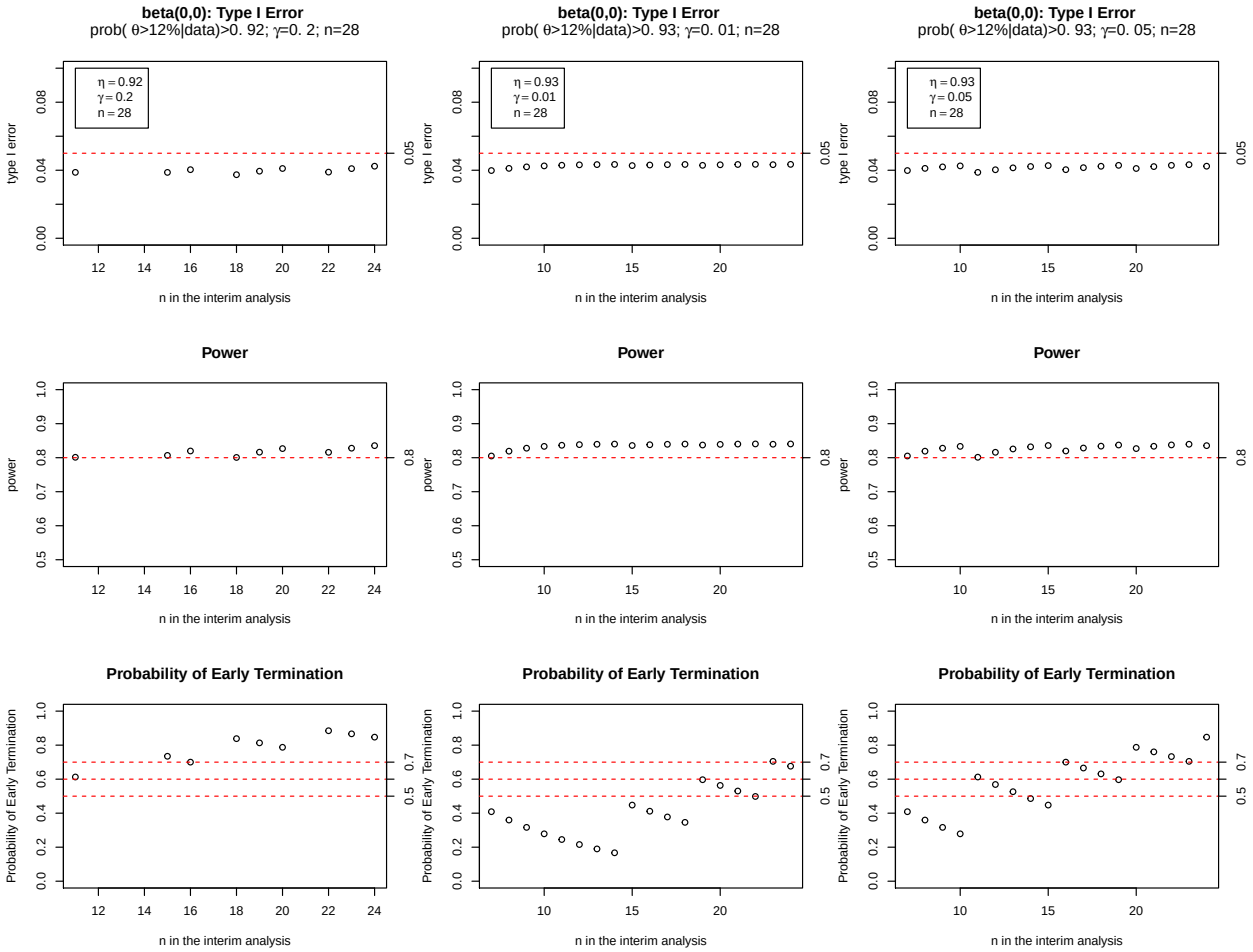
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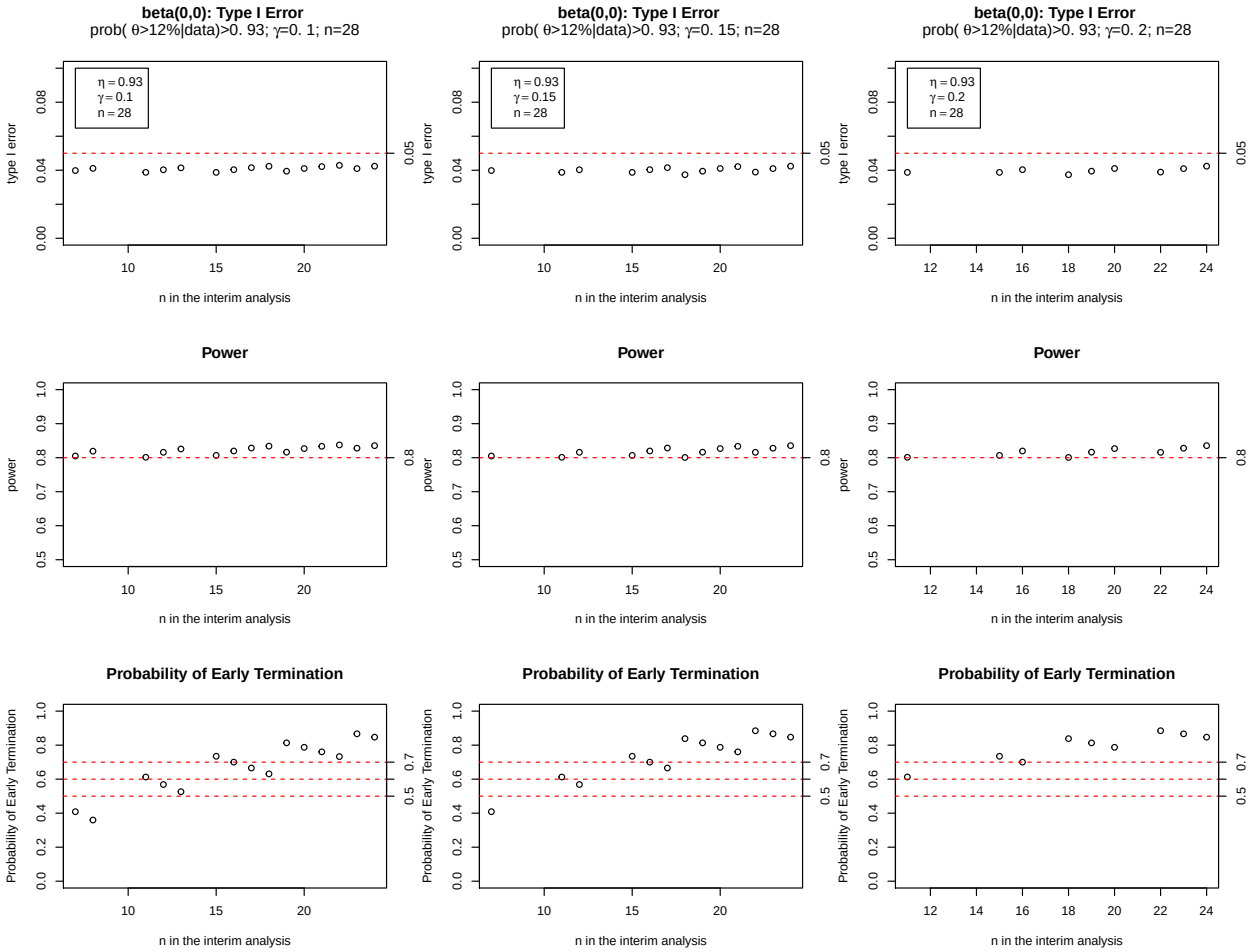
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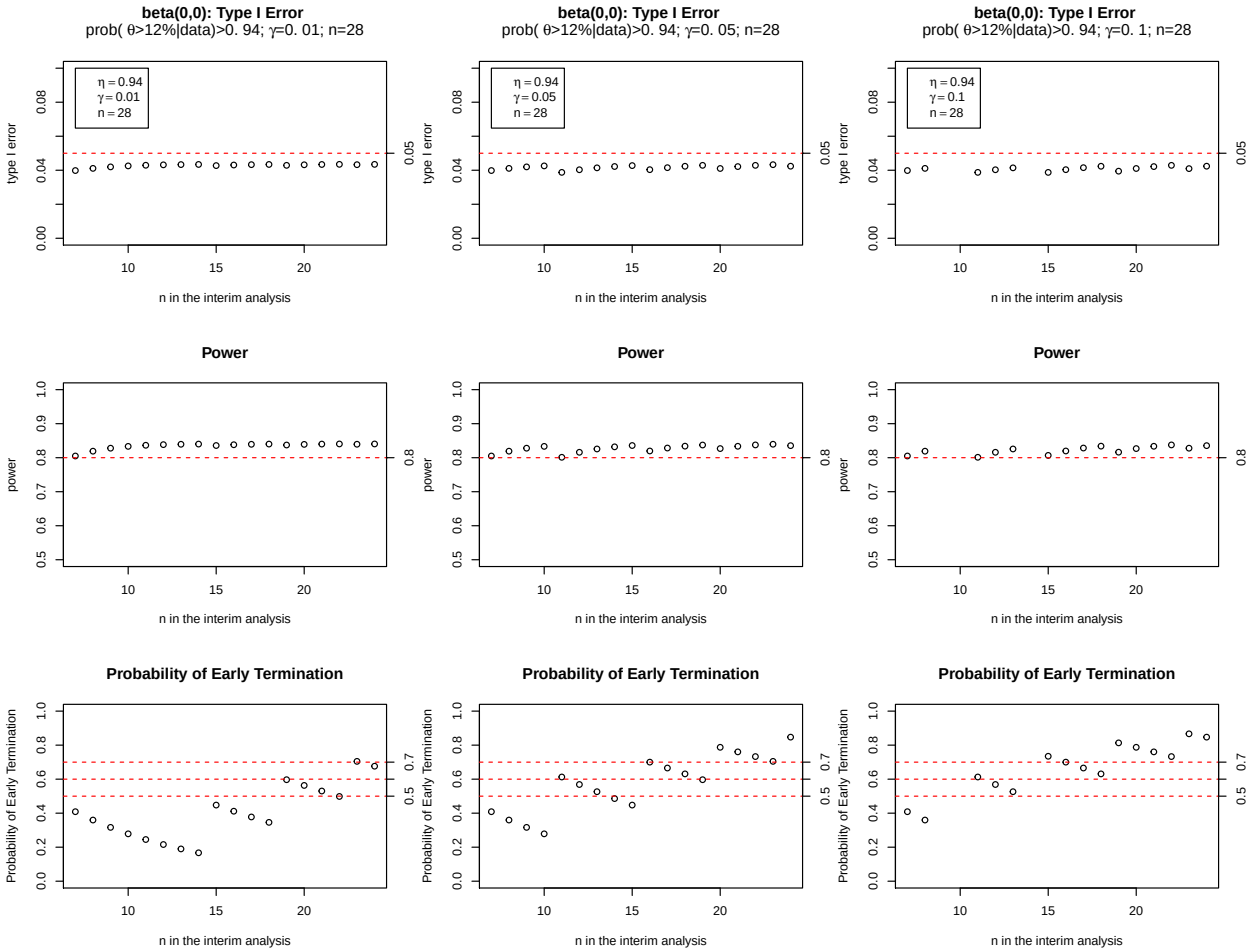
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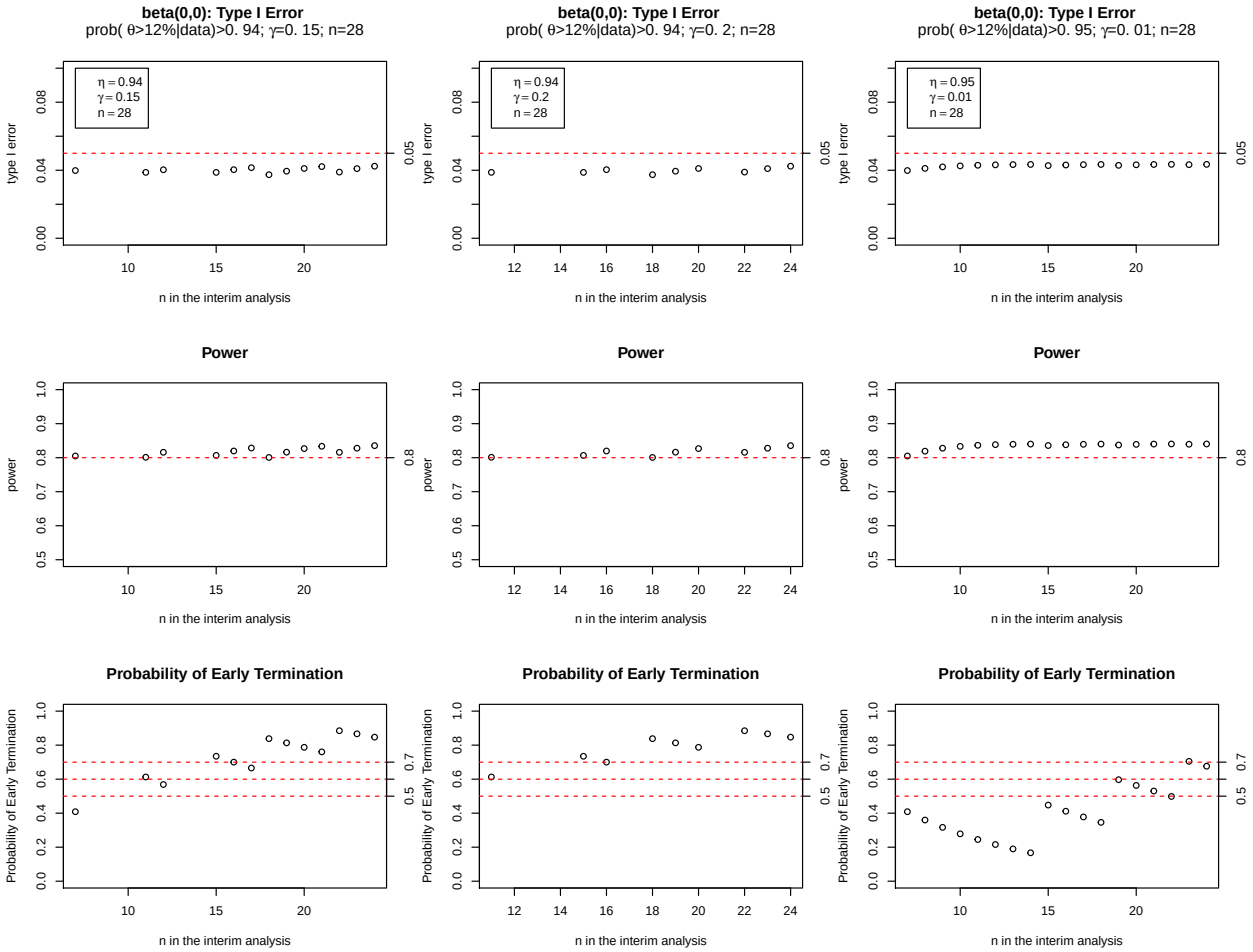
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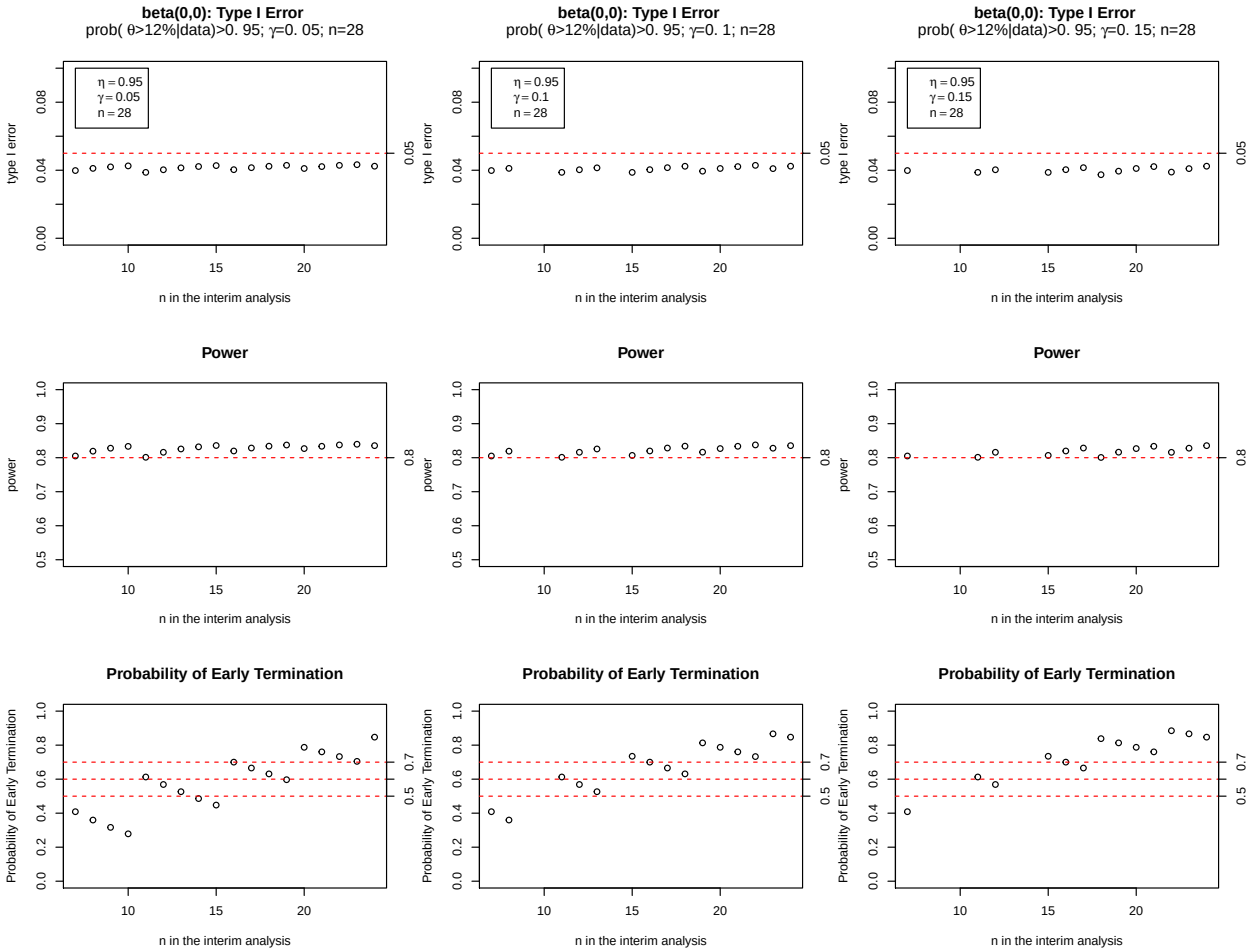
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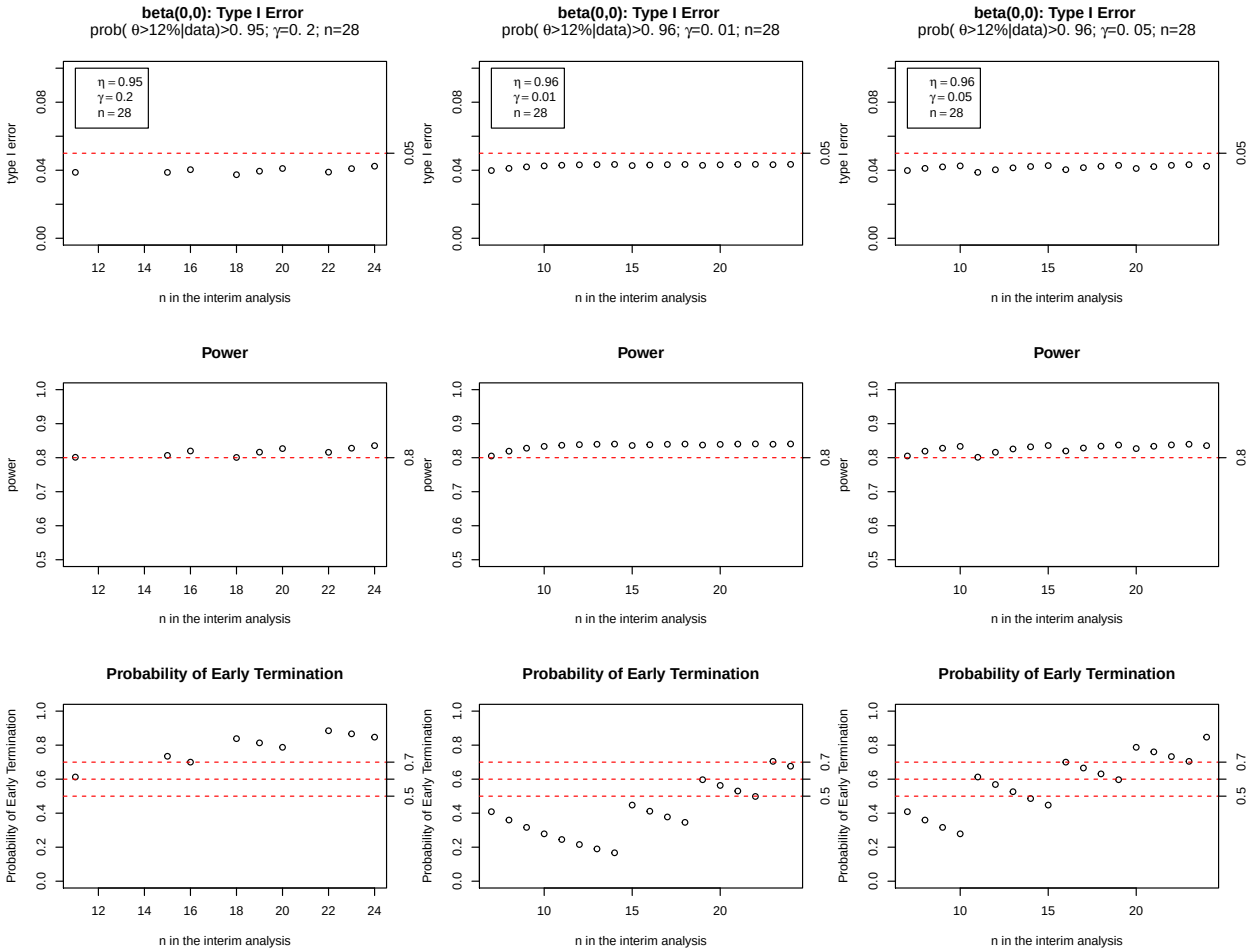
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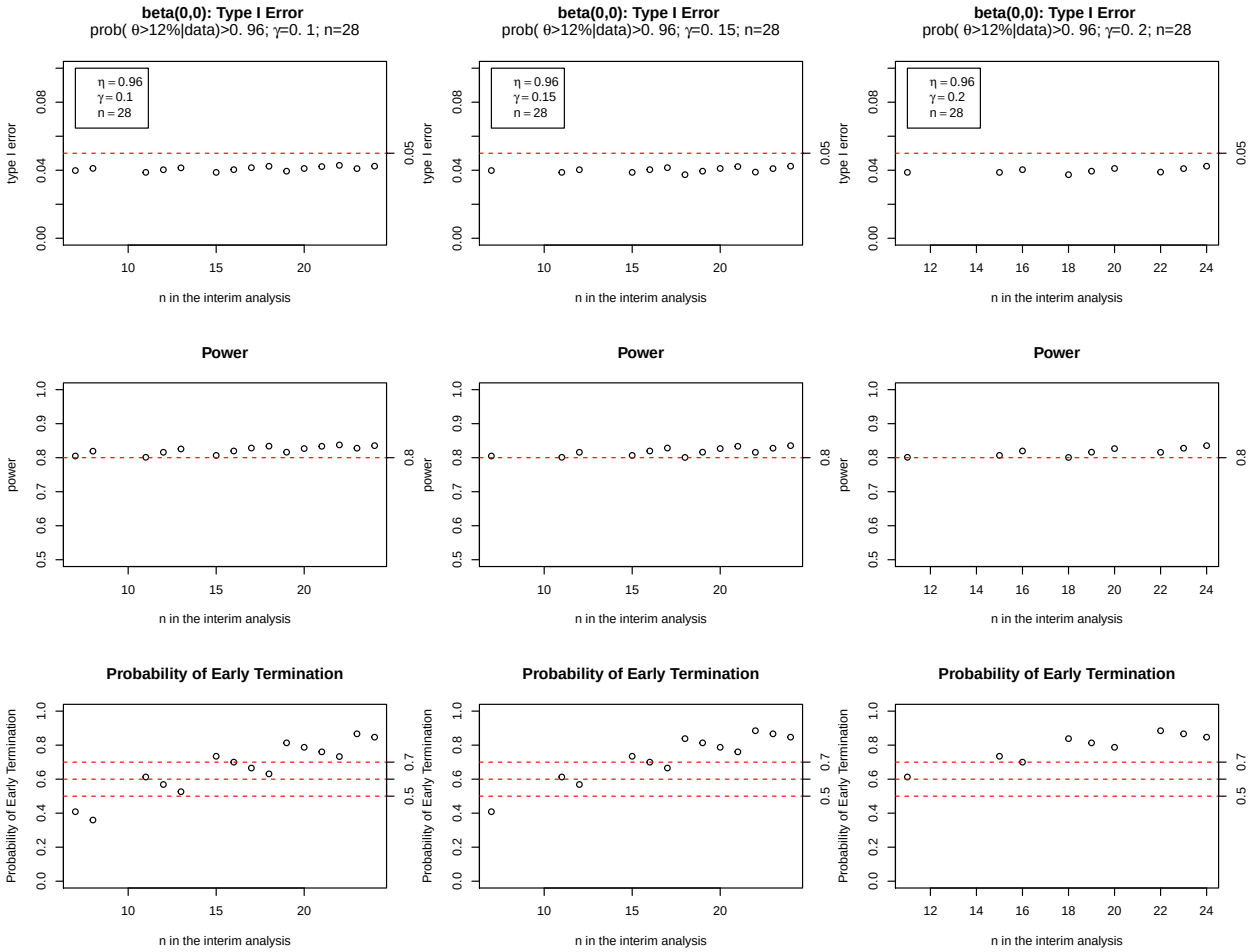
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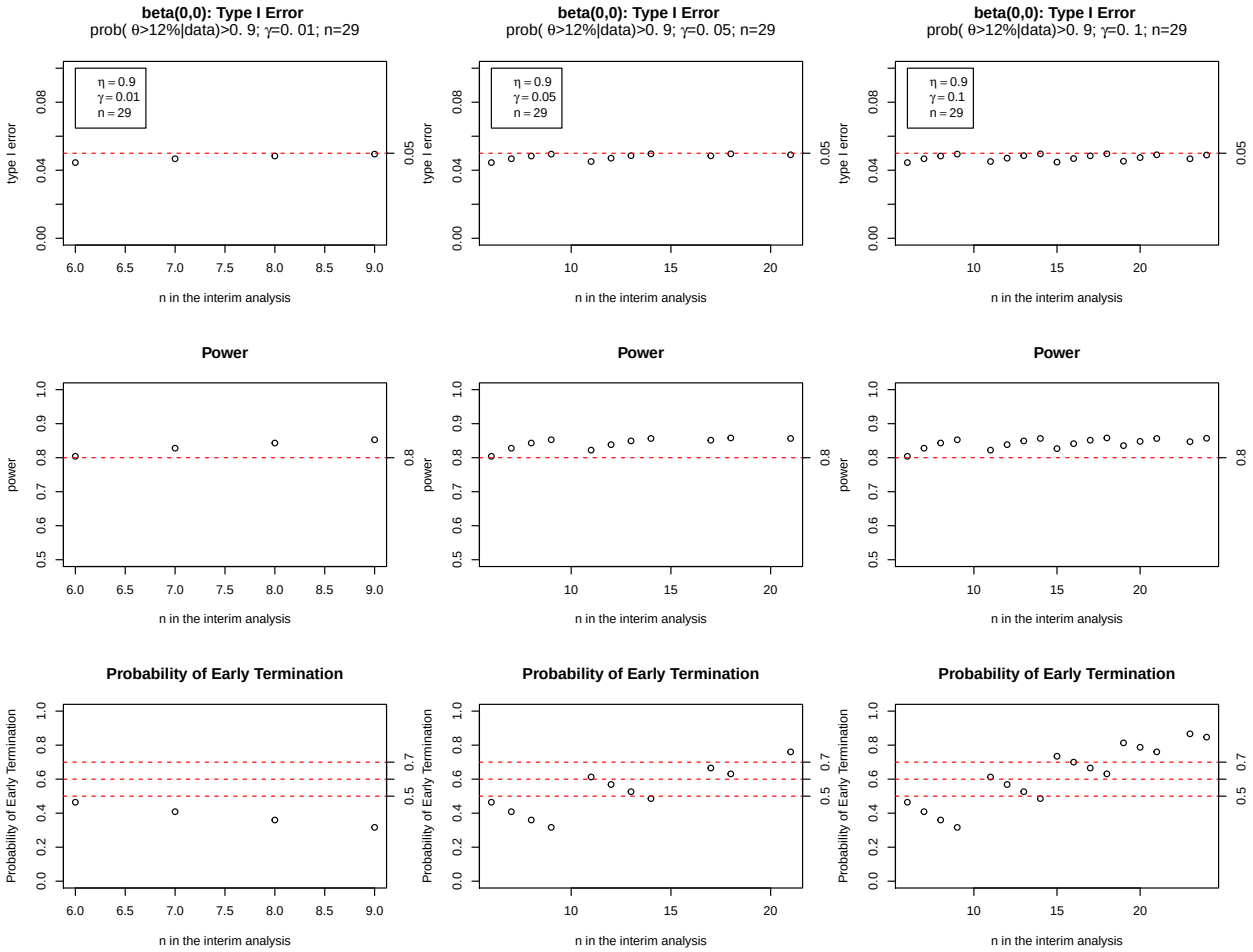
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γ = 0.01
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type I error
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beta(0,0): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 05; n=29
η = 0.9
γ = 0.05
n = 29
type I error
n in the interim analysis
beta(0,0): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 1; n=29
η = 0.9
γ = 0.1
n = 29
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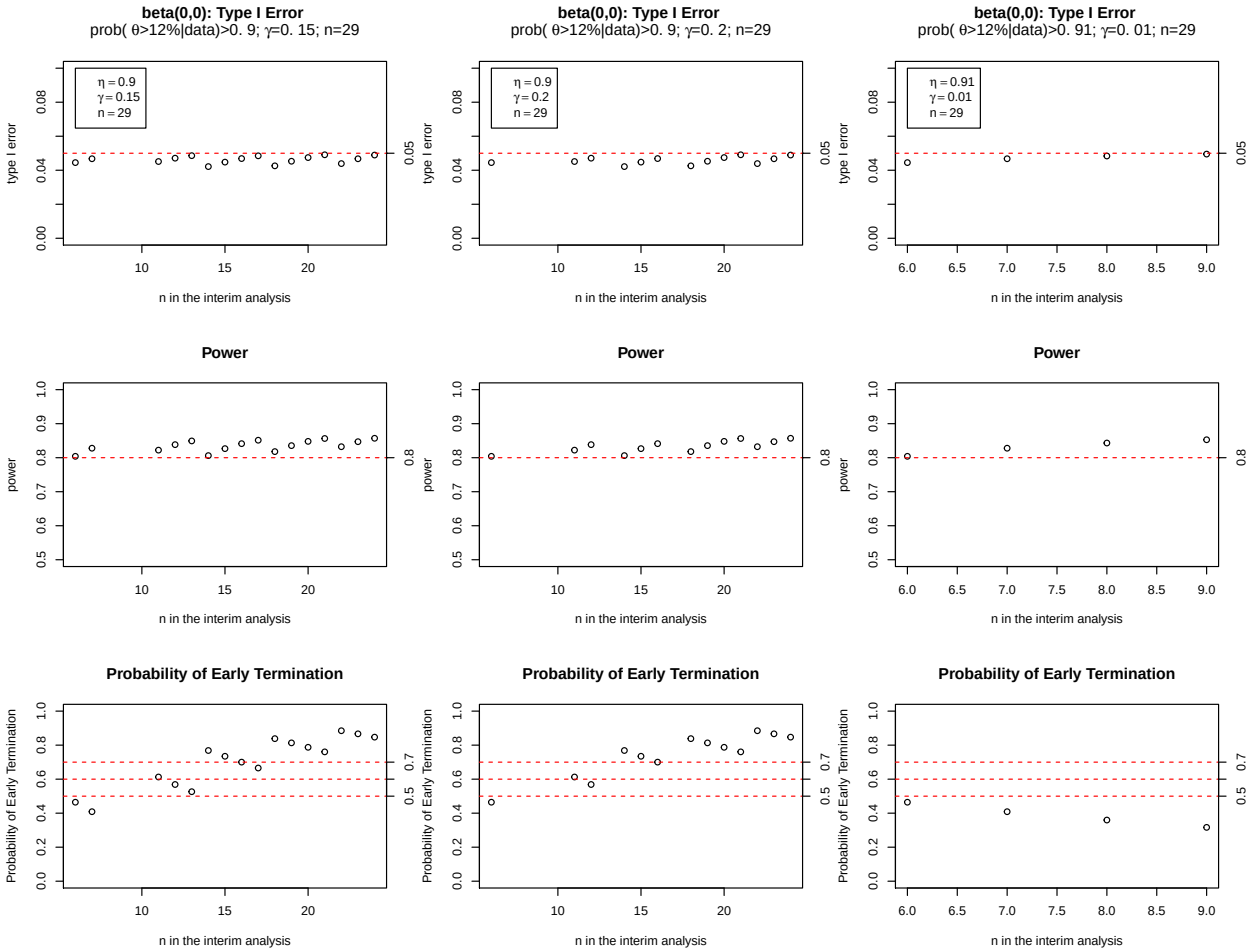
beta(0,0): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 15; n=29
η = 0.9
γ = 0.15
n = 29
type I error
n in the interim analysis
beta(0,0): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 2; n=29
η = 0.9
γ = 0.2
n = 29
type I error
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beta(0,0): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 01; n=29
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γ = 0.01
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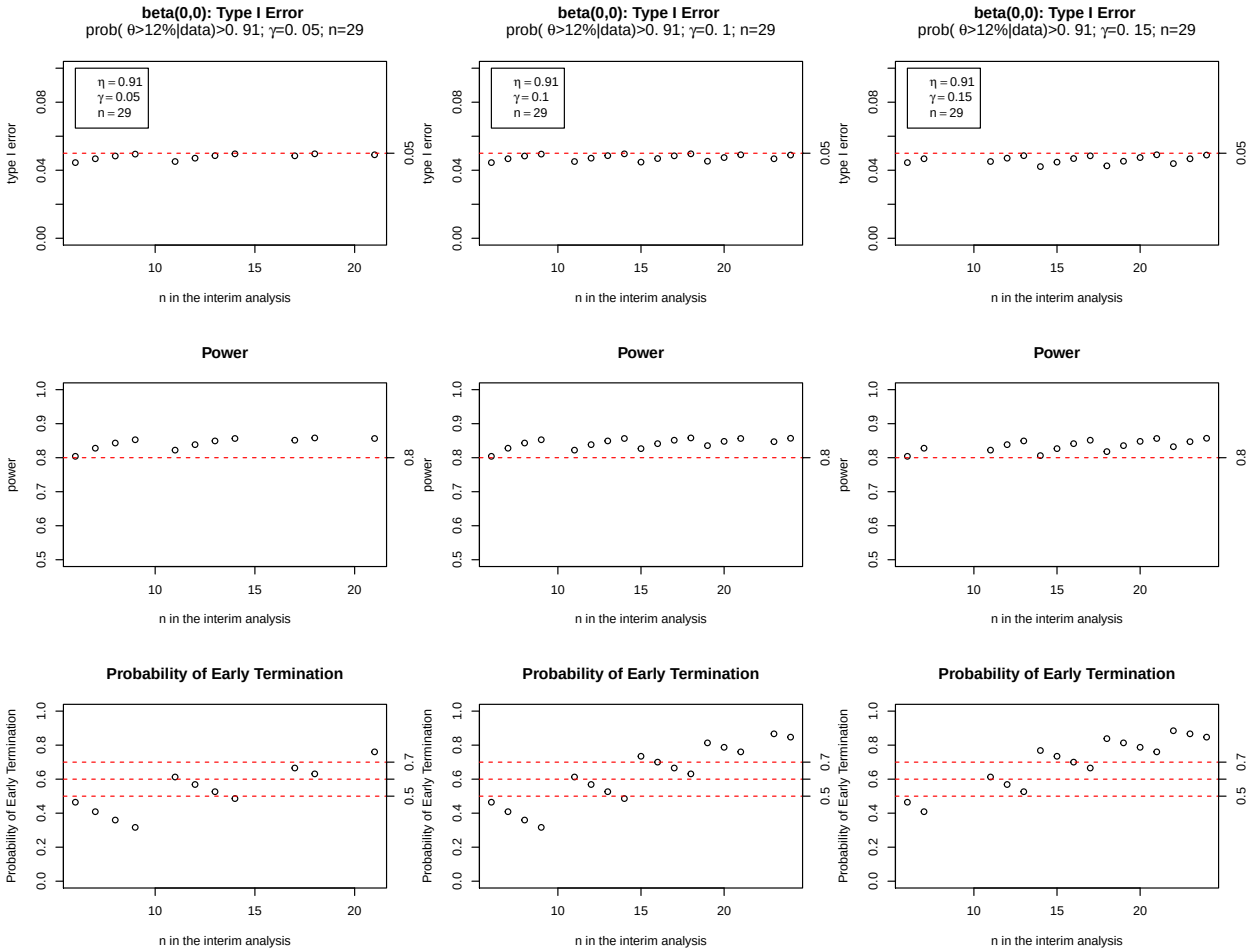
beta(0,0): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 05; n=29
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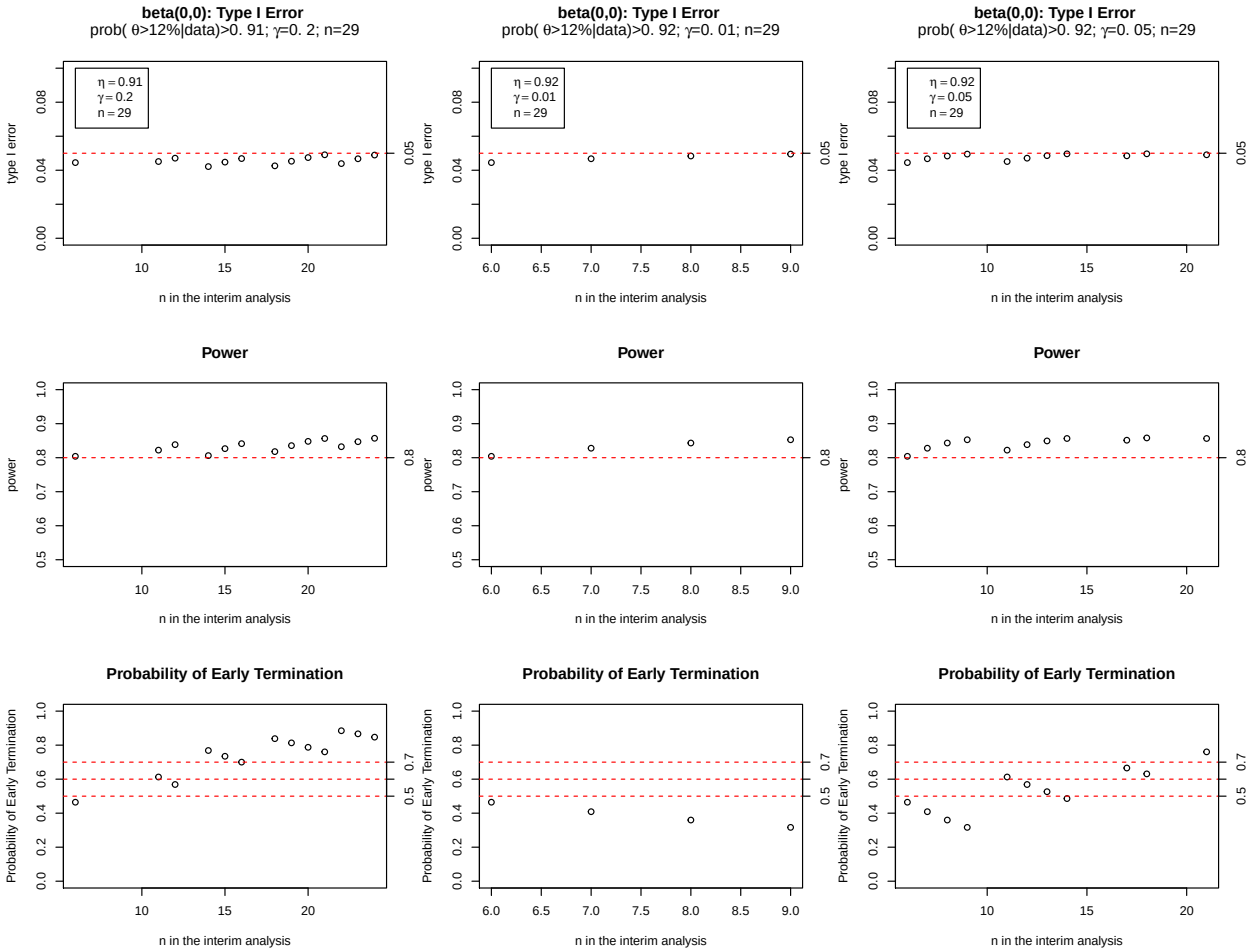
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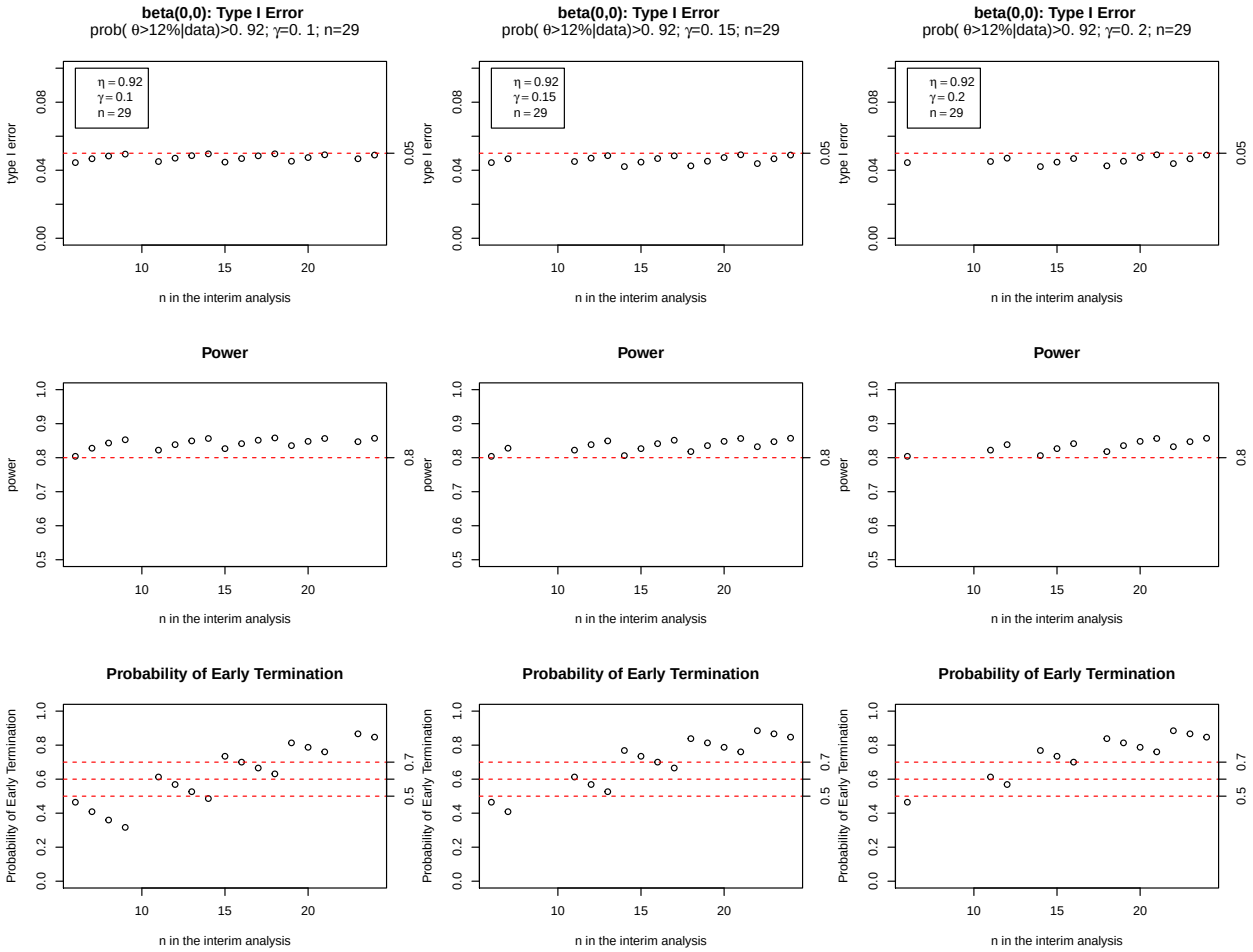
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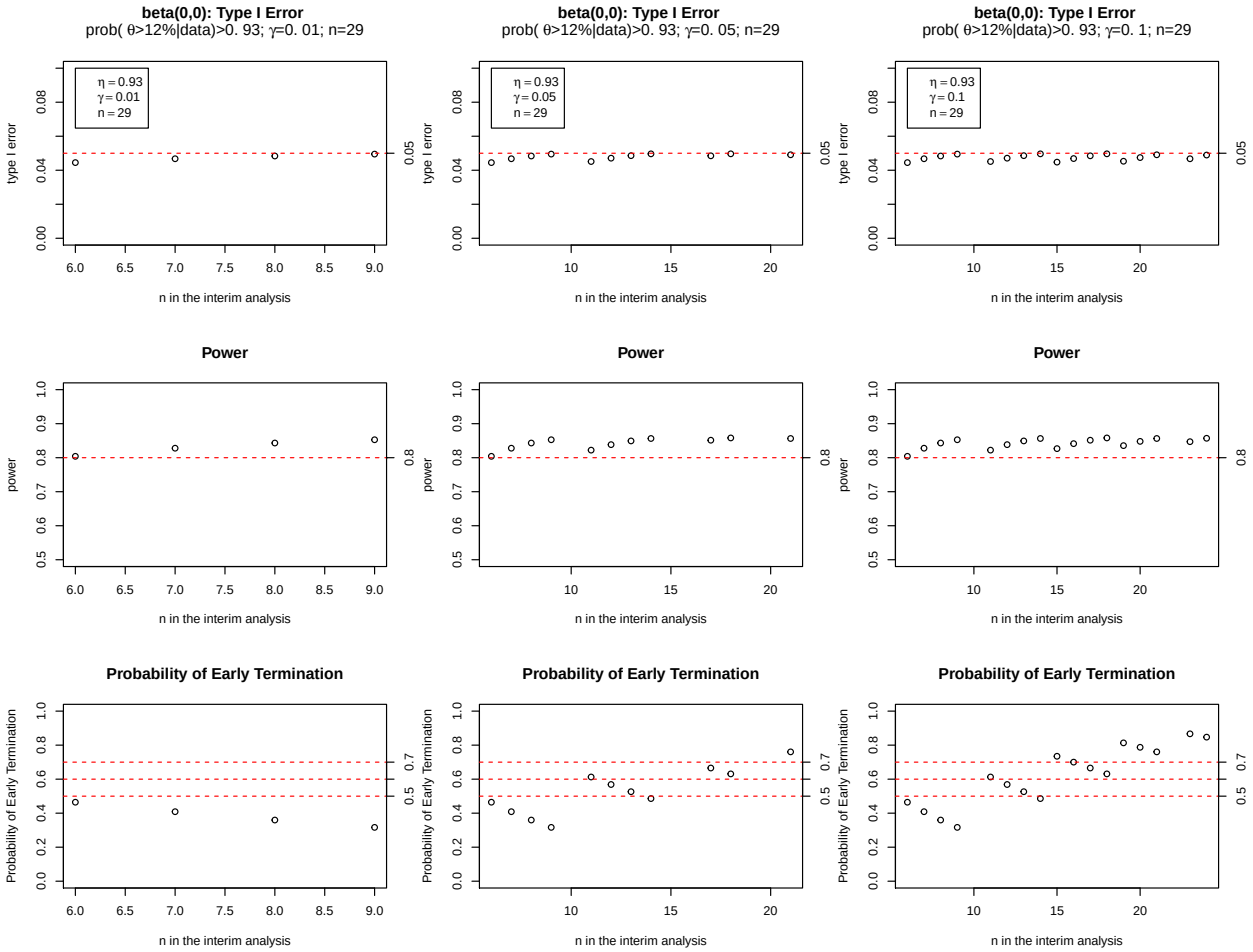
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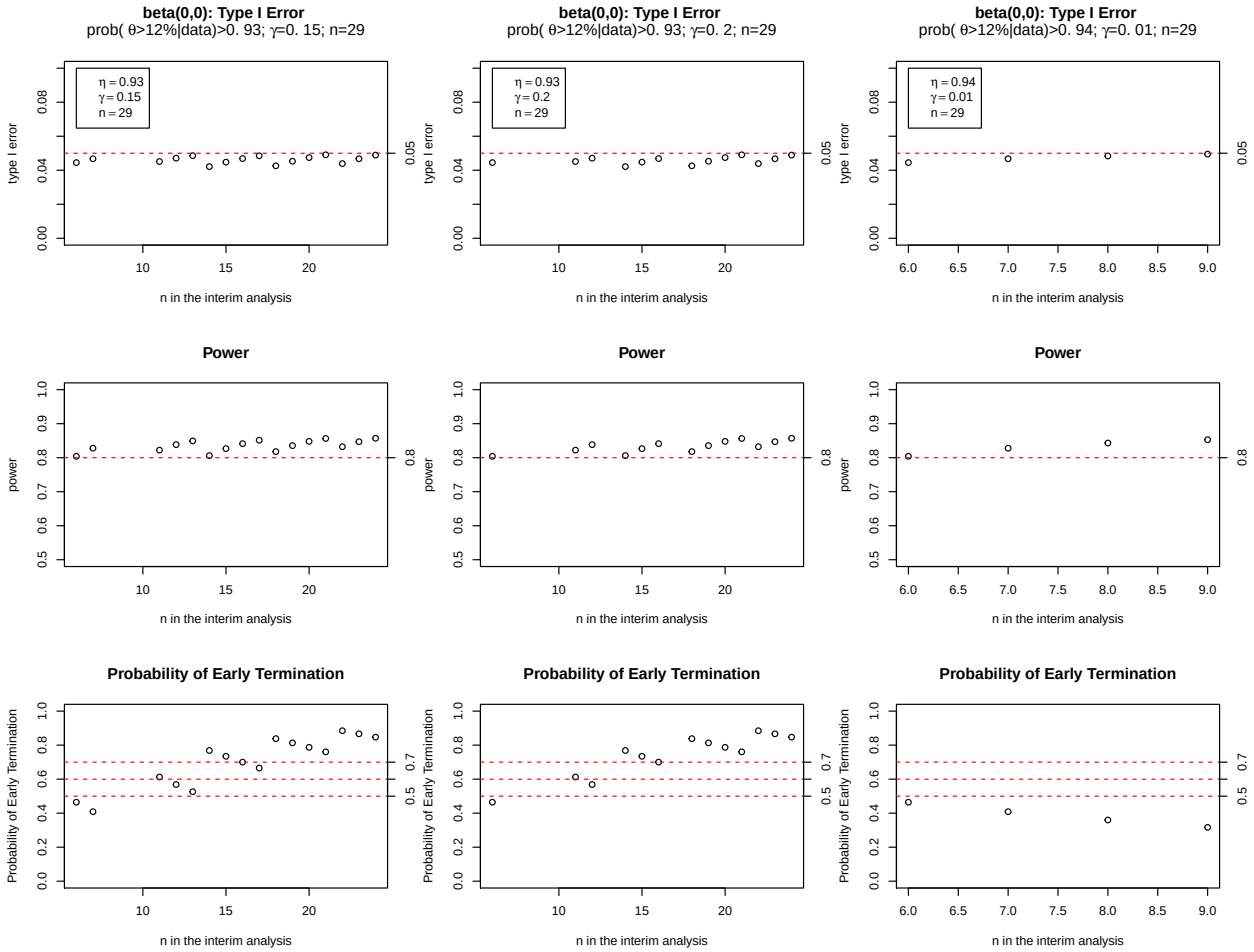
beta(0,0): Type I Error
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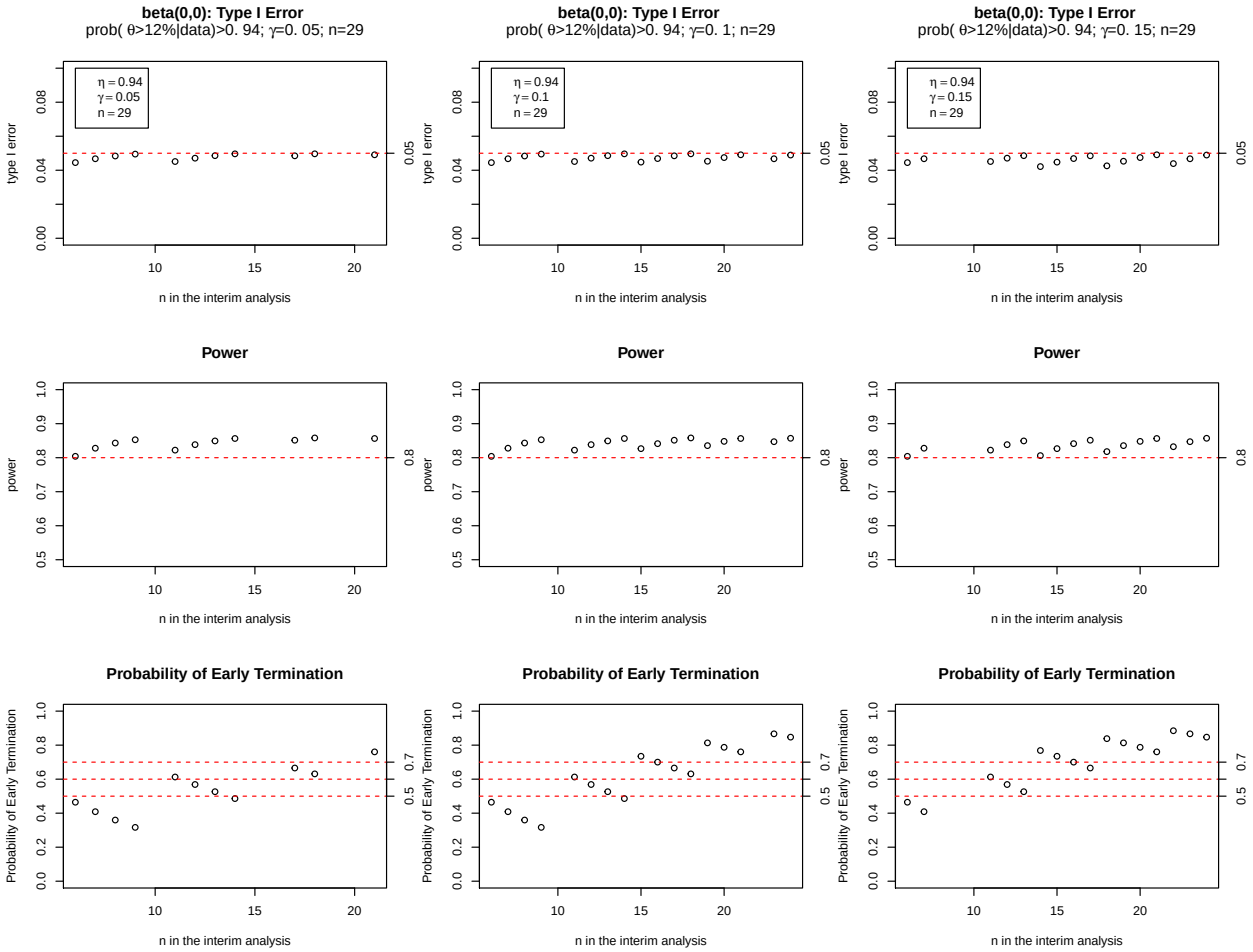
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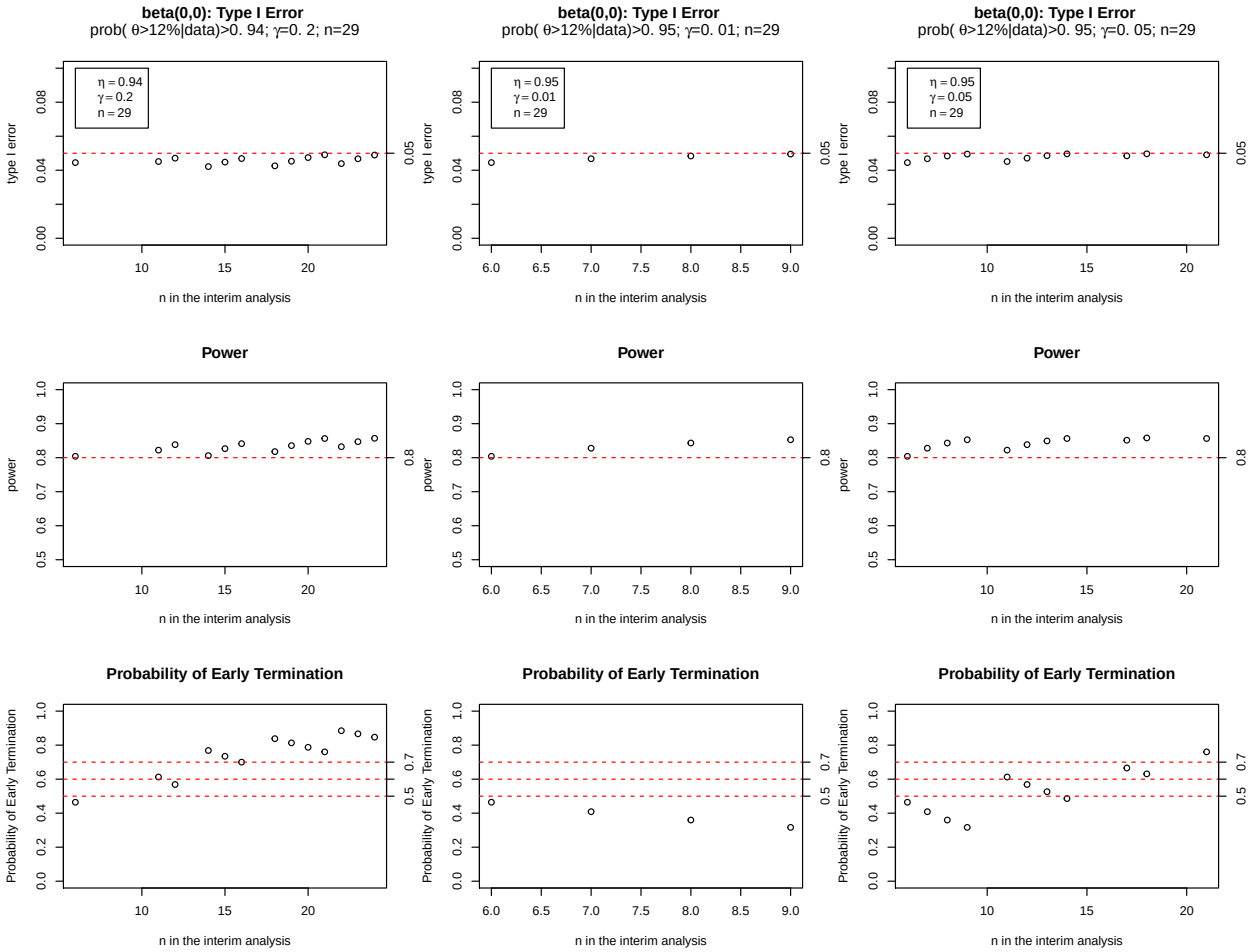
beta(0,0): Type I Error
prob(θ>12%|data)>0. 94; γ=0. 2; n=29
η = 0.94
γ = 0.2
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type I error
n in the interim analysis
beta(0,0): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 01; n=29
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beta(0,0): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 05; n=29
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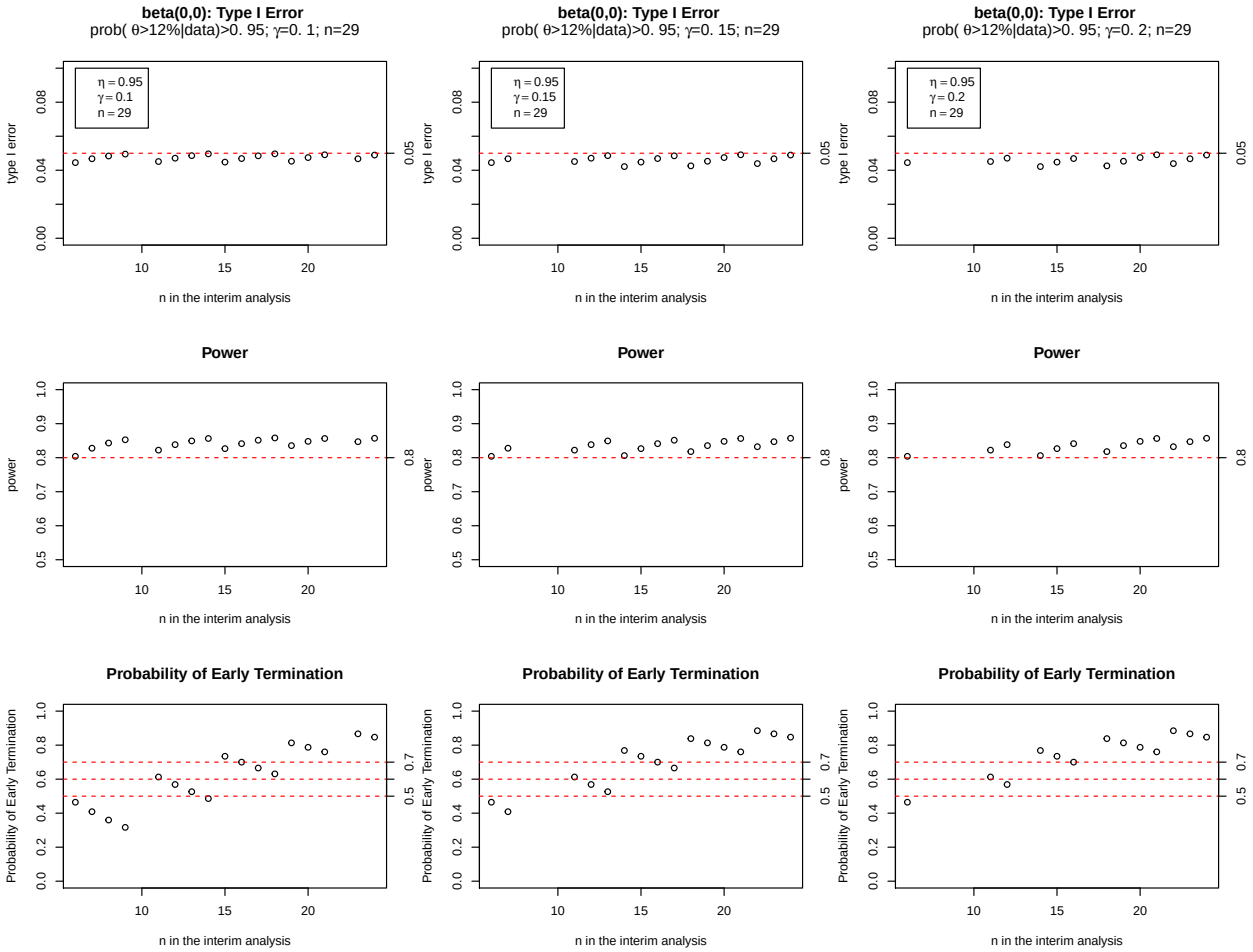
beta(0,0): Type I Error
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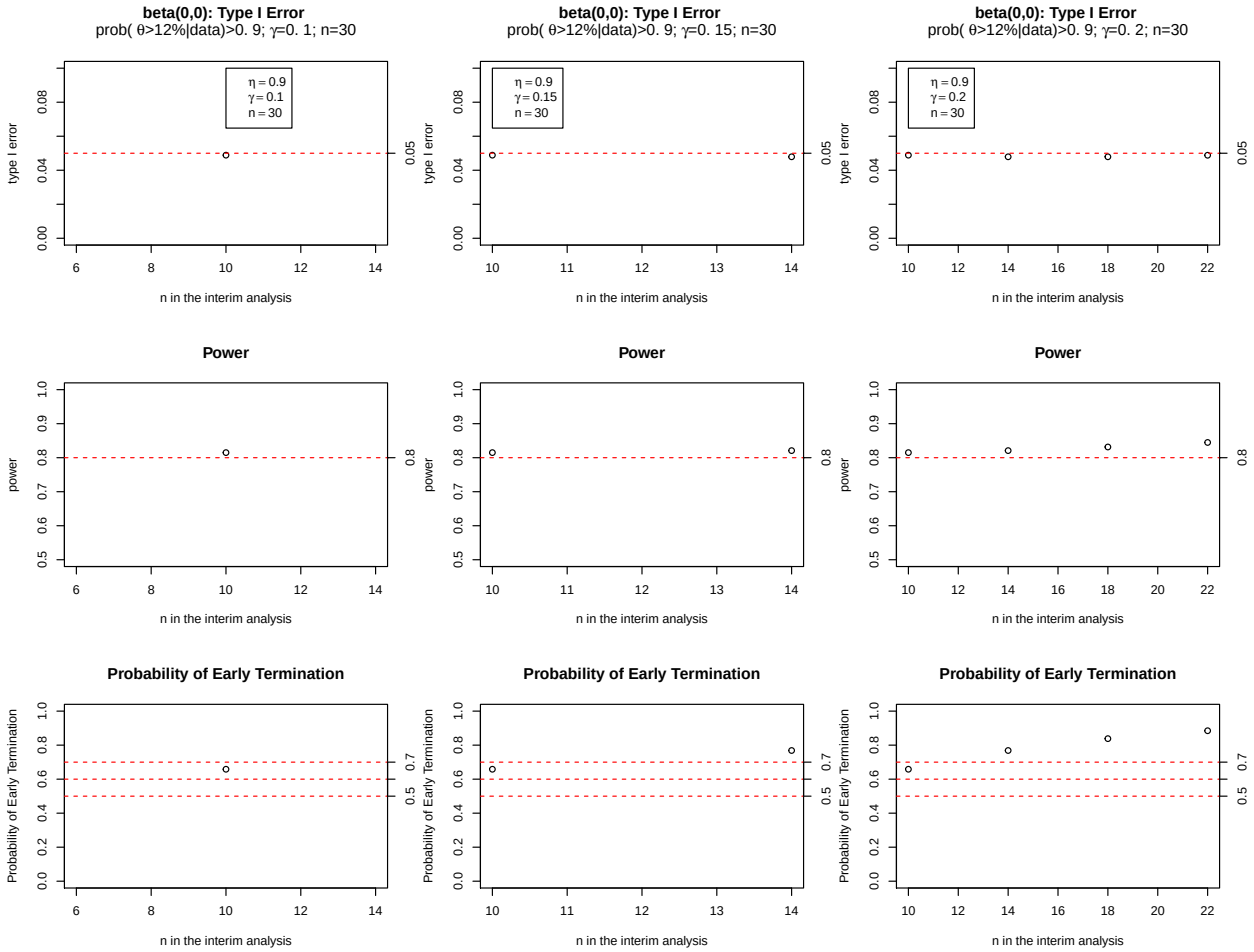
beta(0,0): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 1; n=30
η = 0.9
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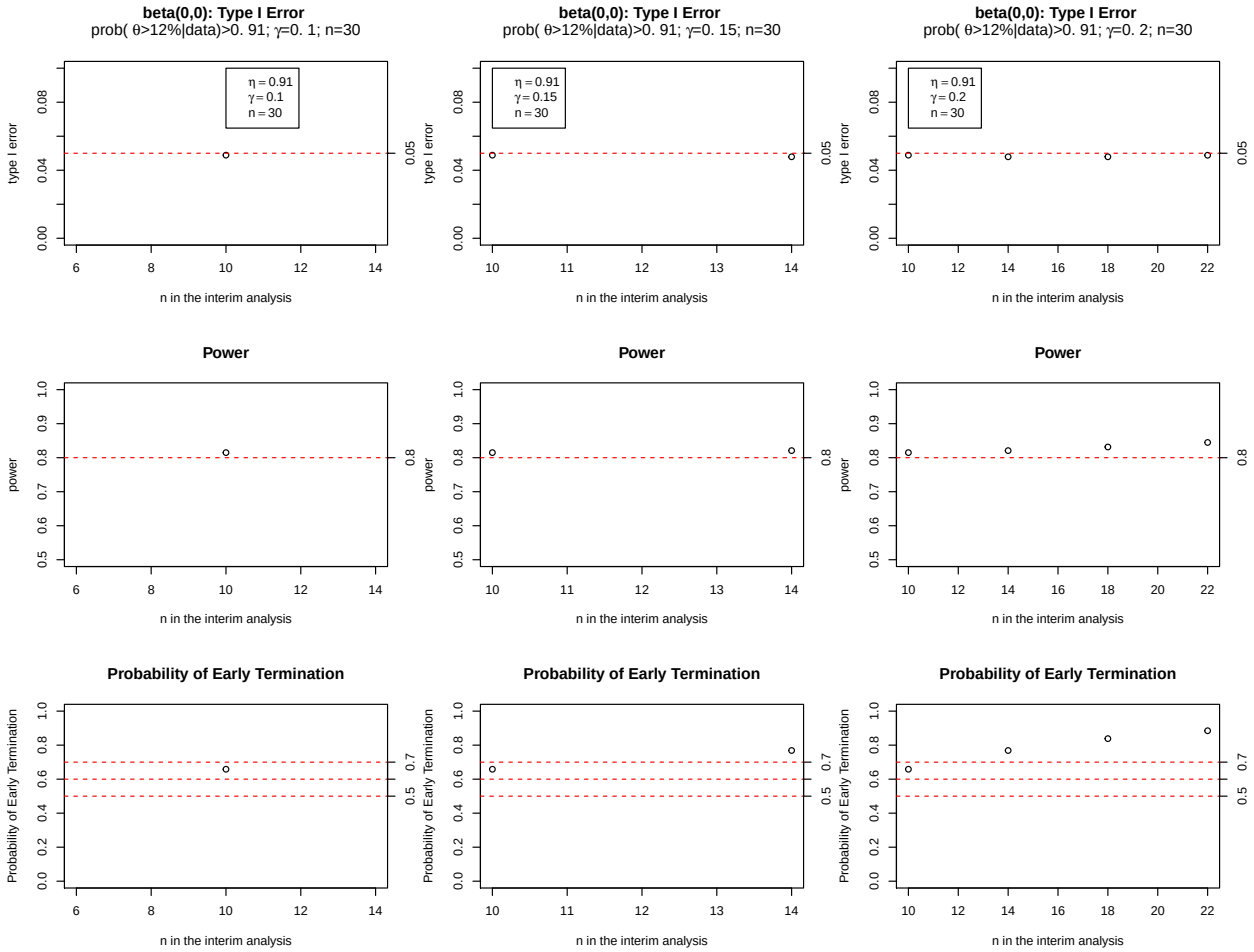
beta(0,0): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 1; n=30
η = 0.91
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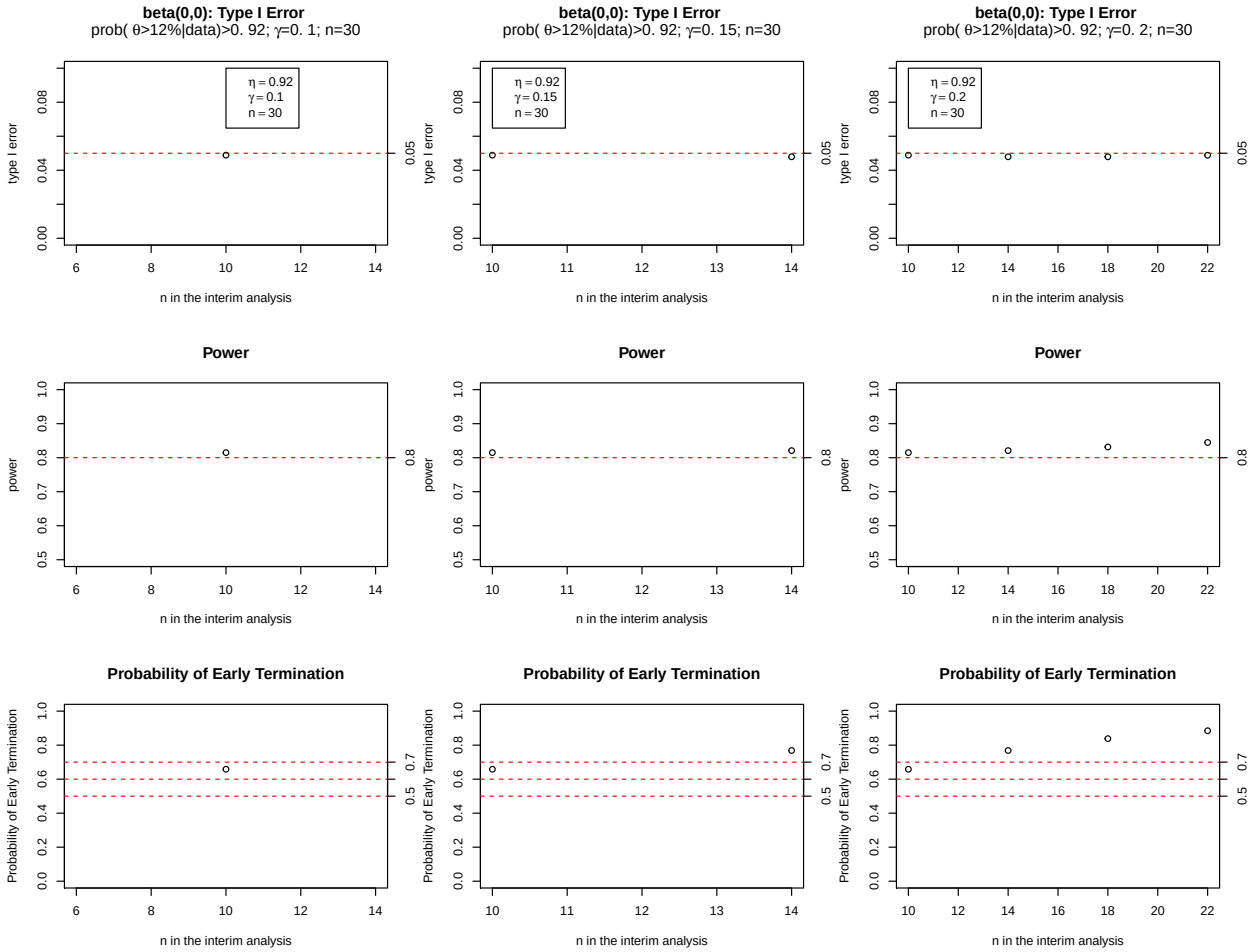
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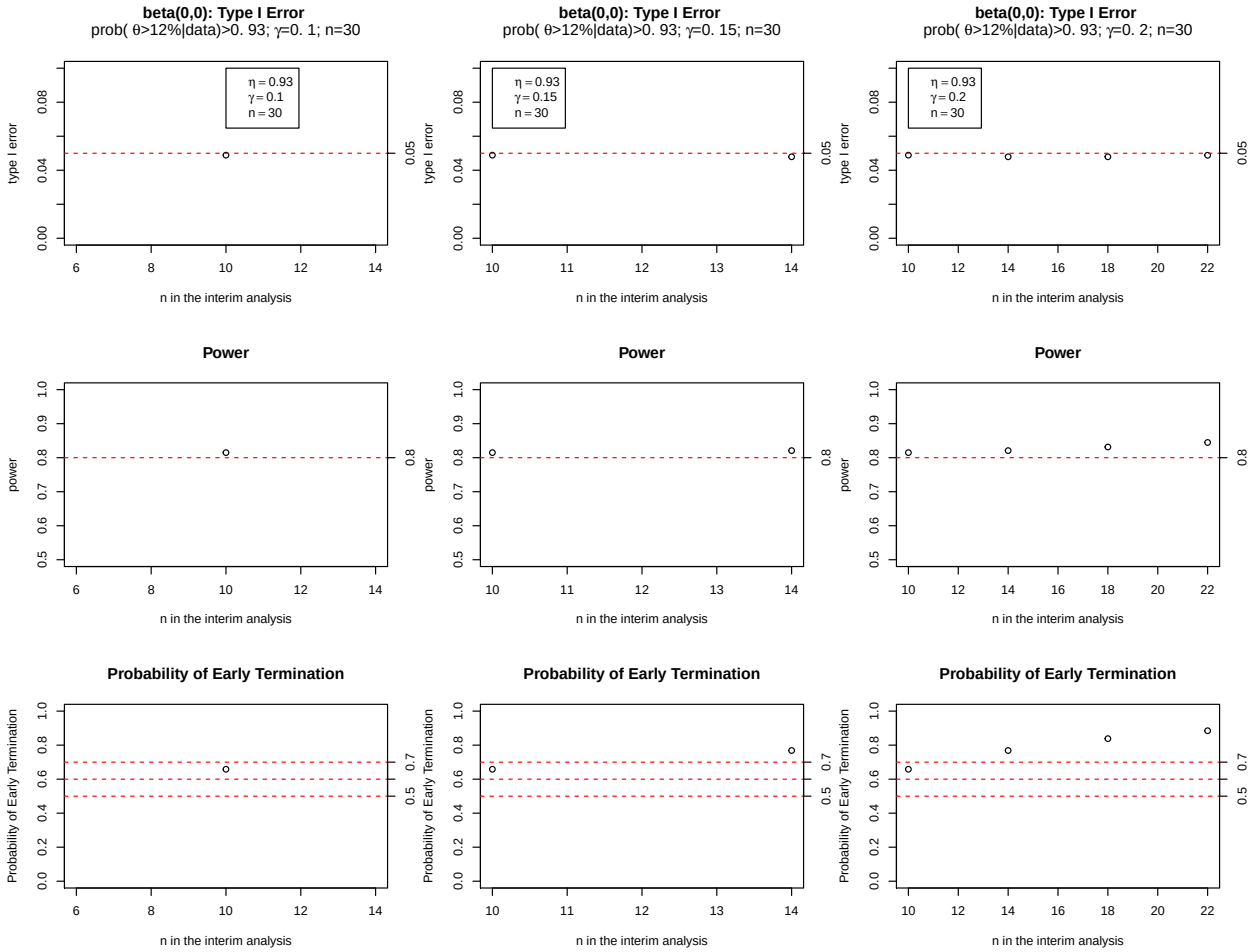
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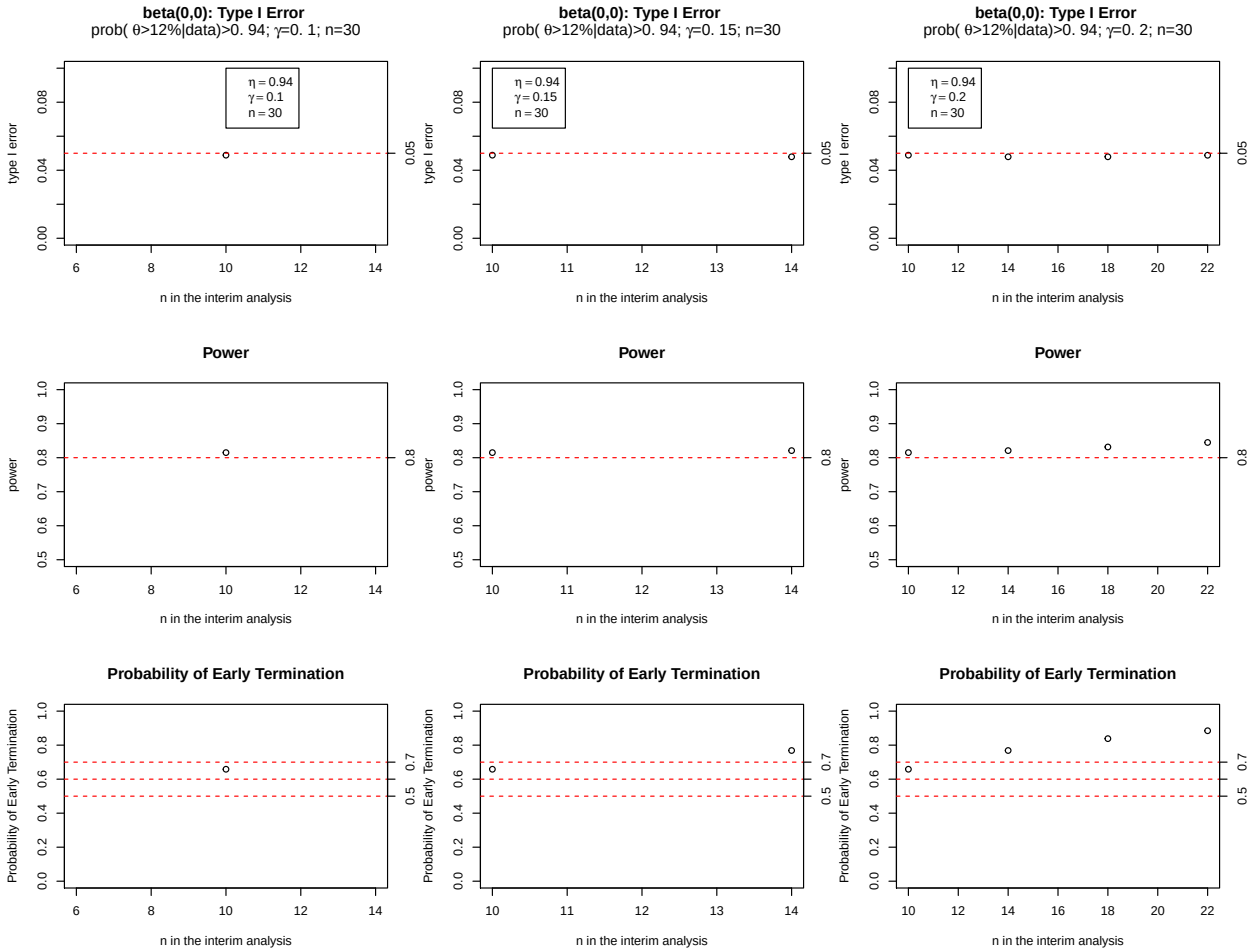
beta(0,0): Type I Error
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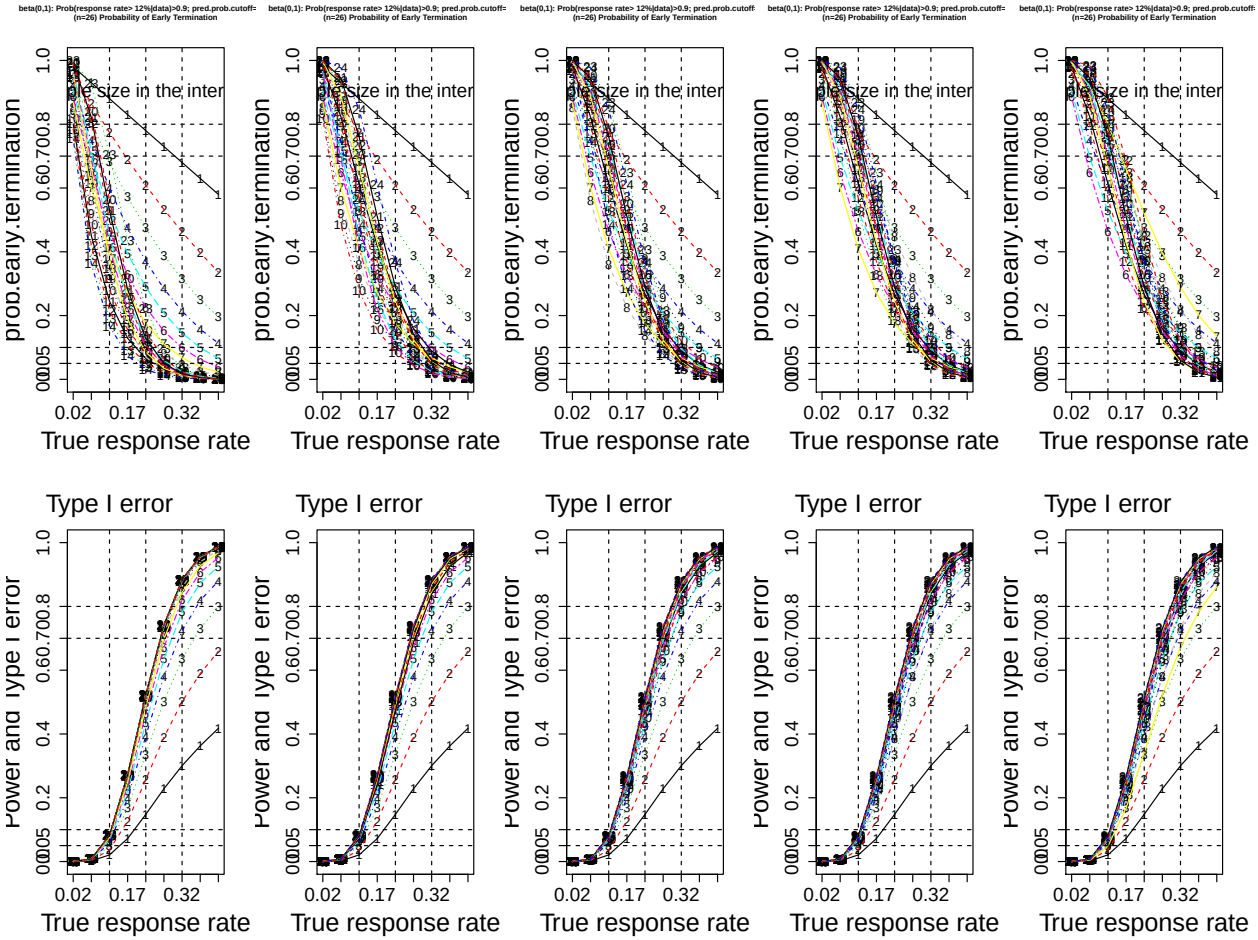
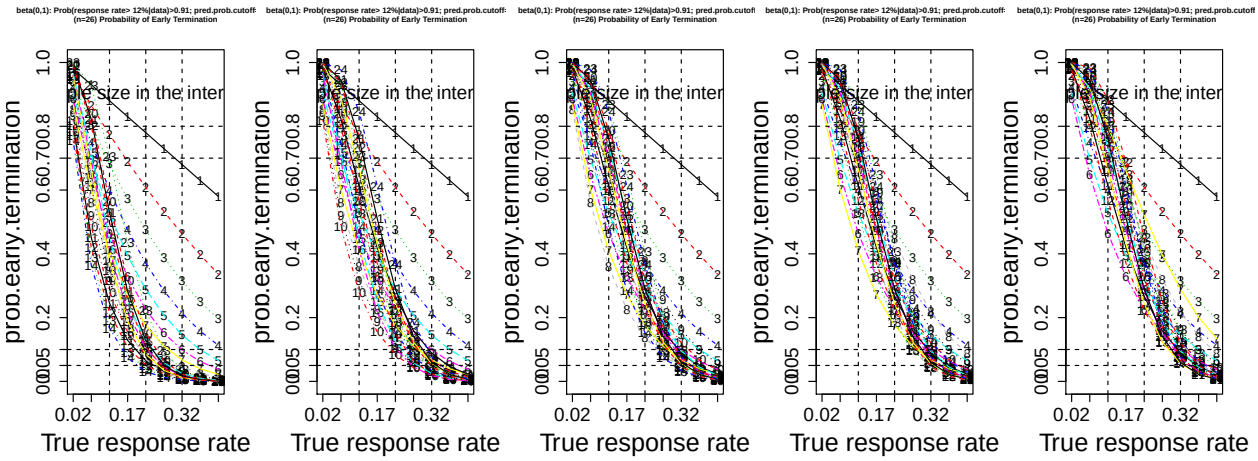
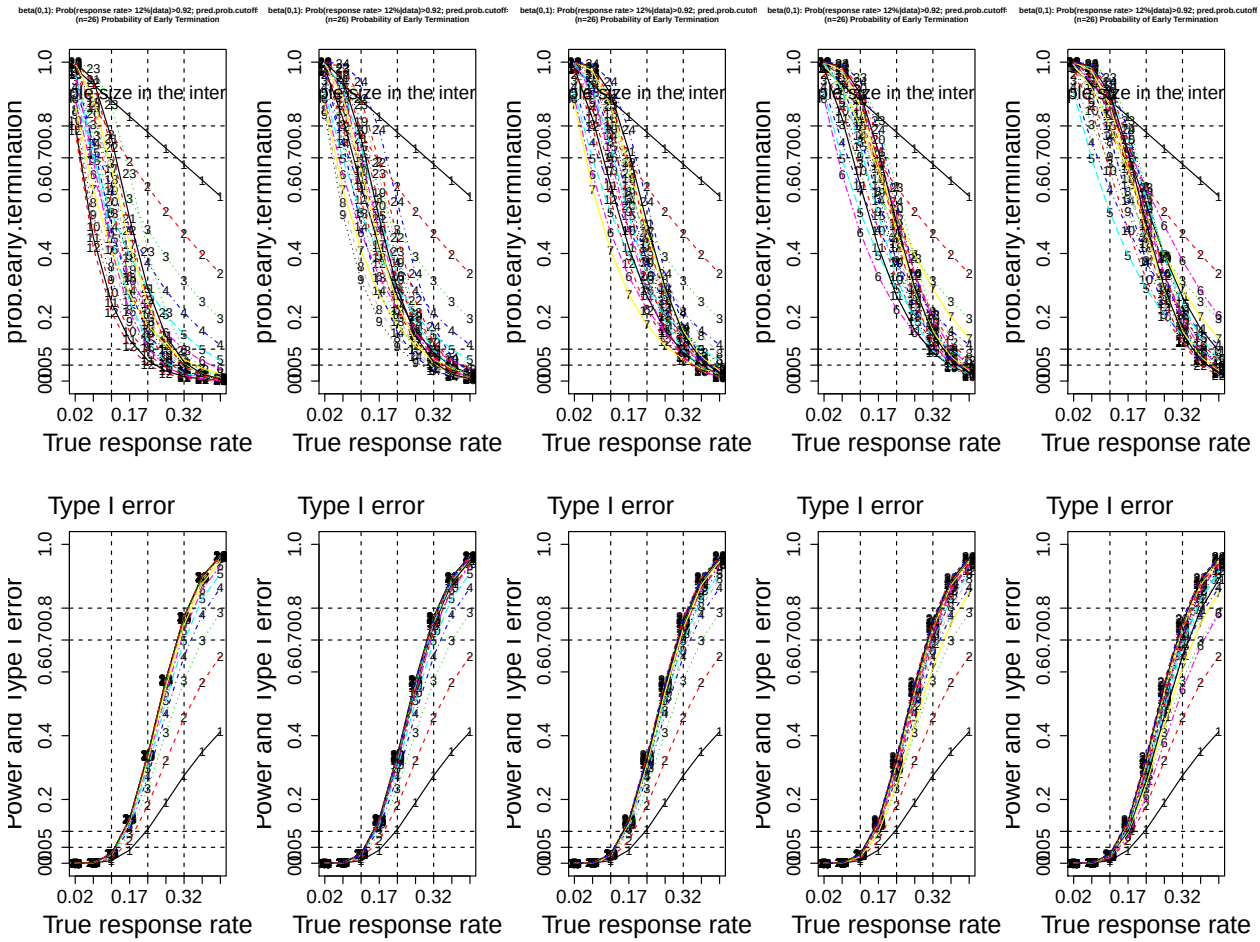
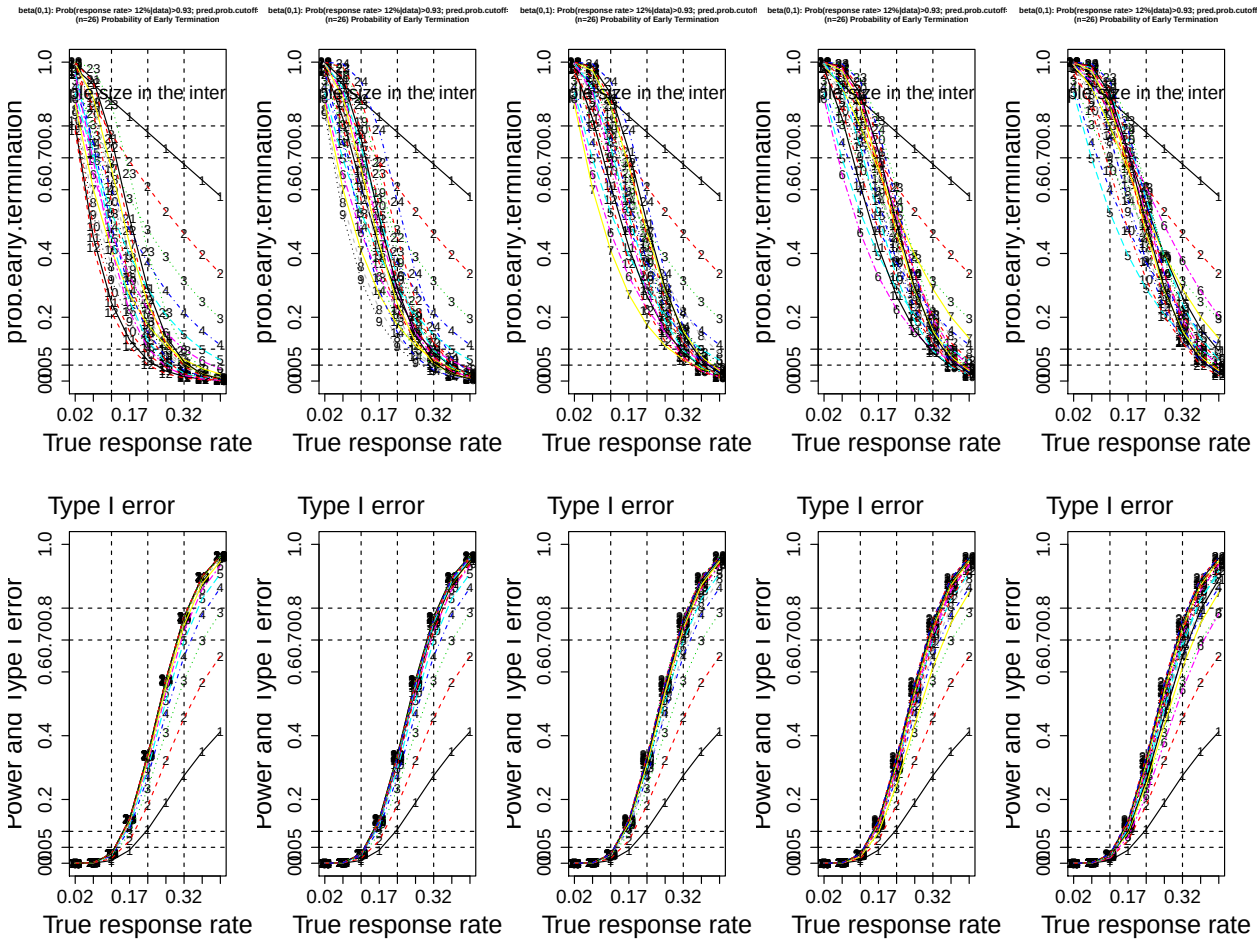
Prior Distribution: beta(0,1)






beta(0,1): Prob(response rate> 12%|data)>0.92; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
0.32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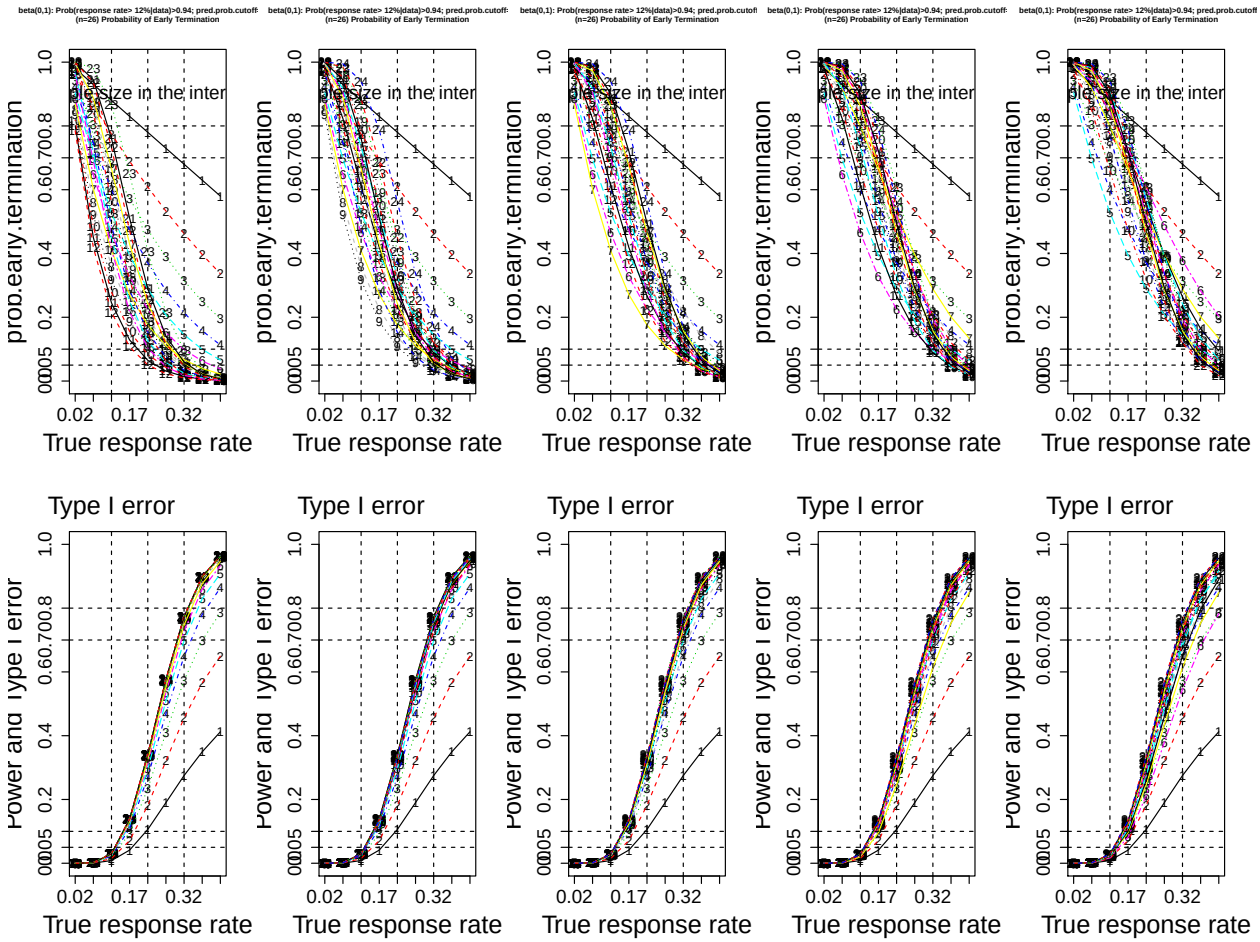
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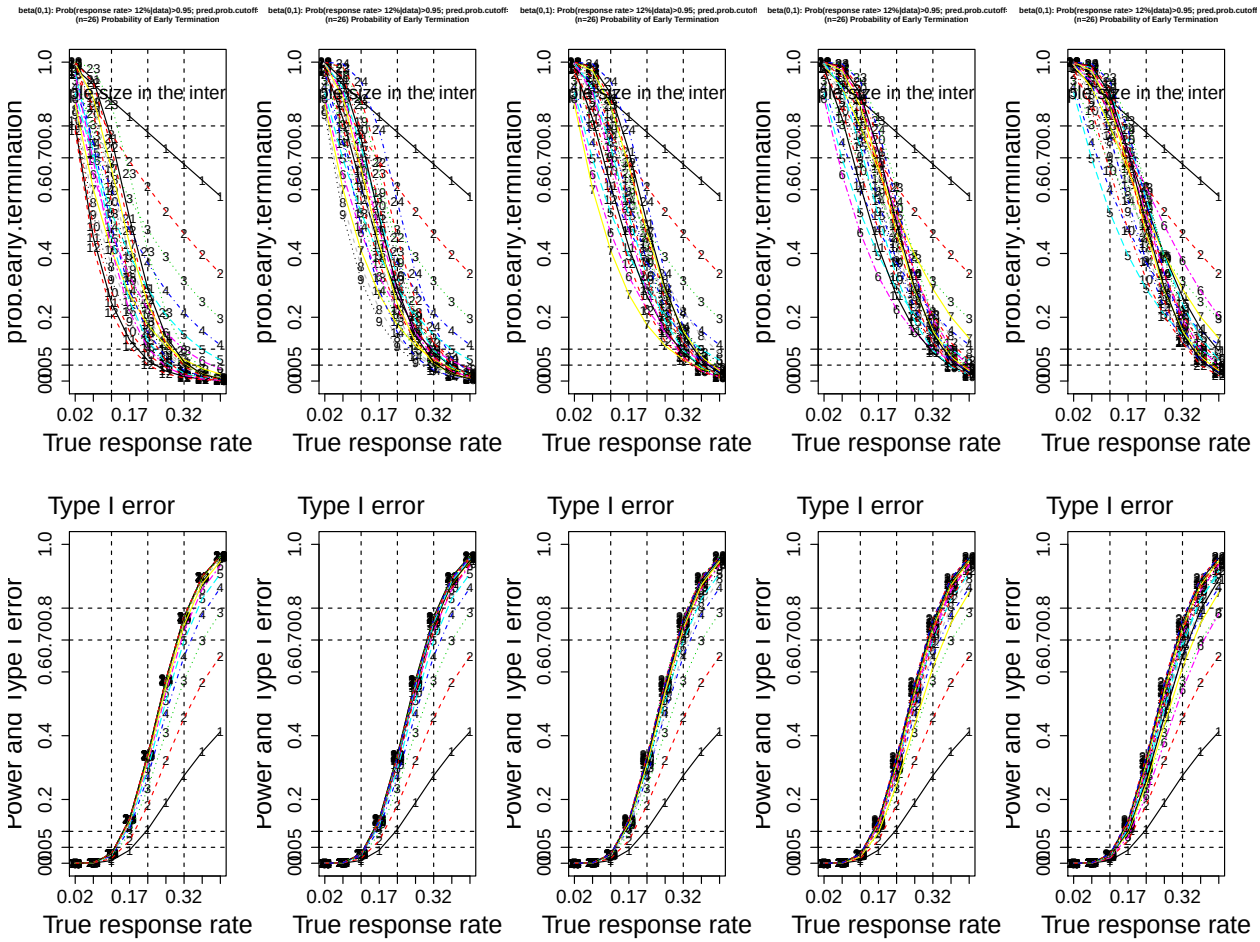
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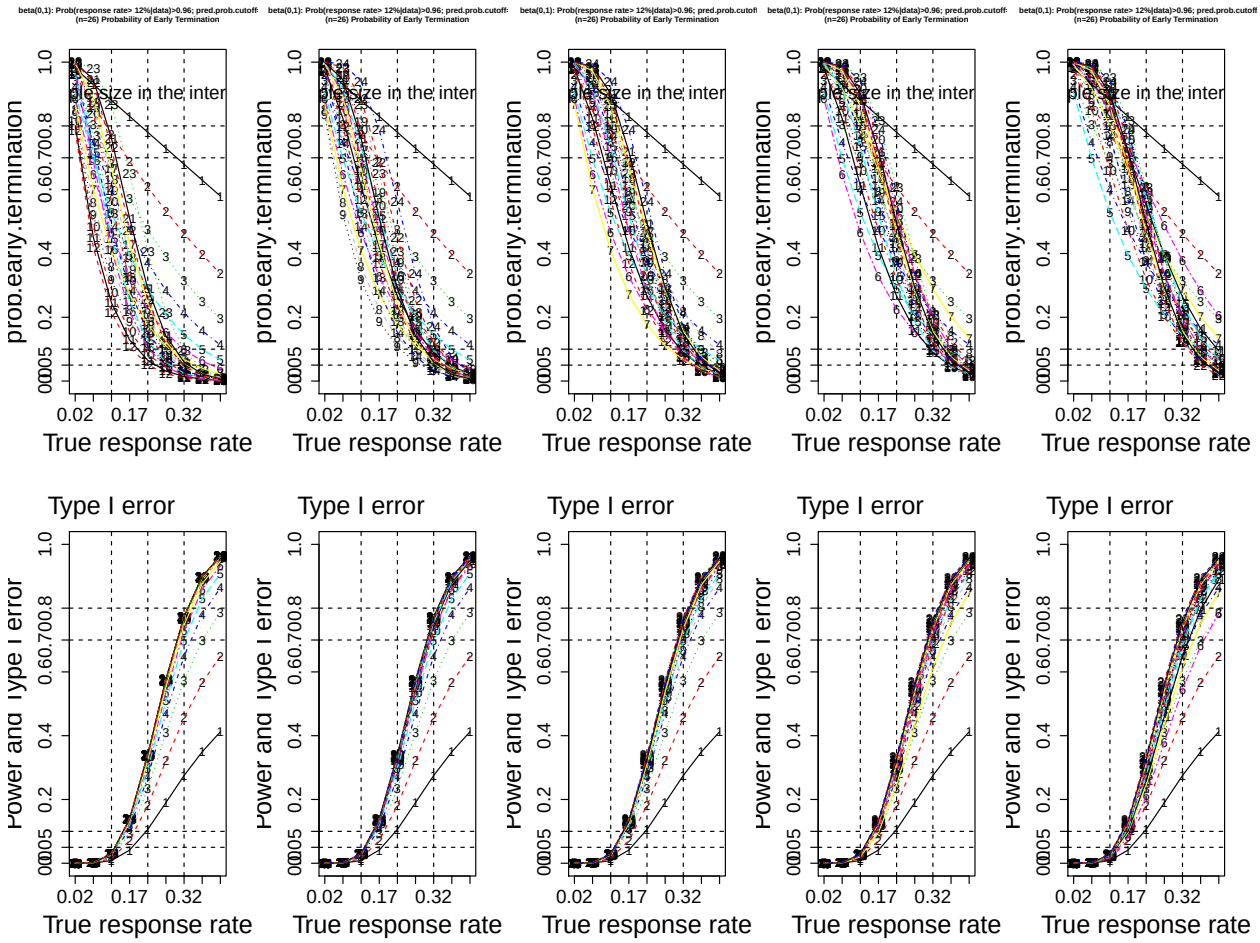
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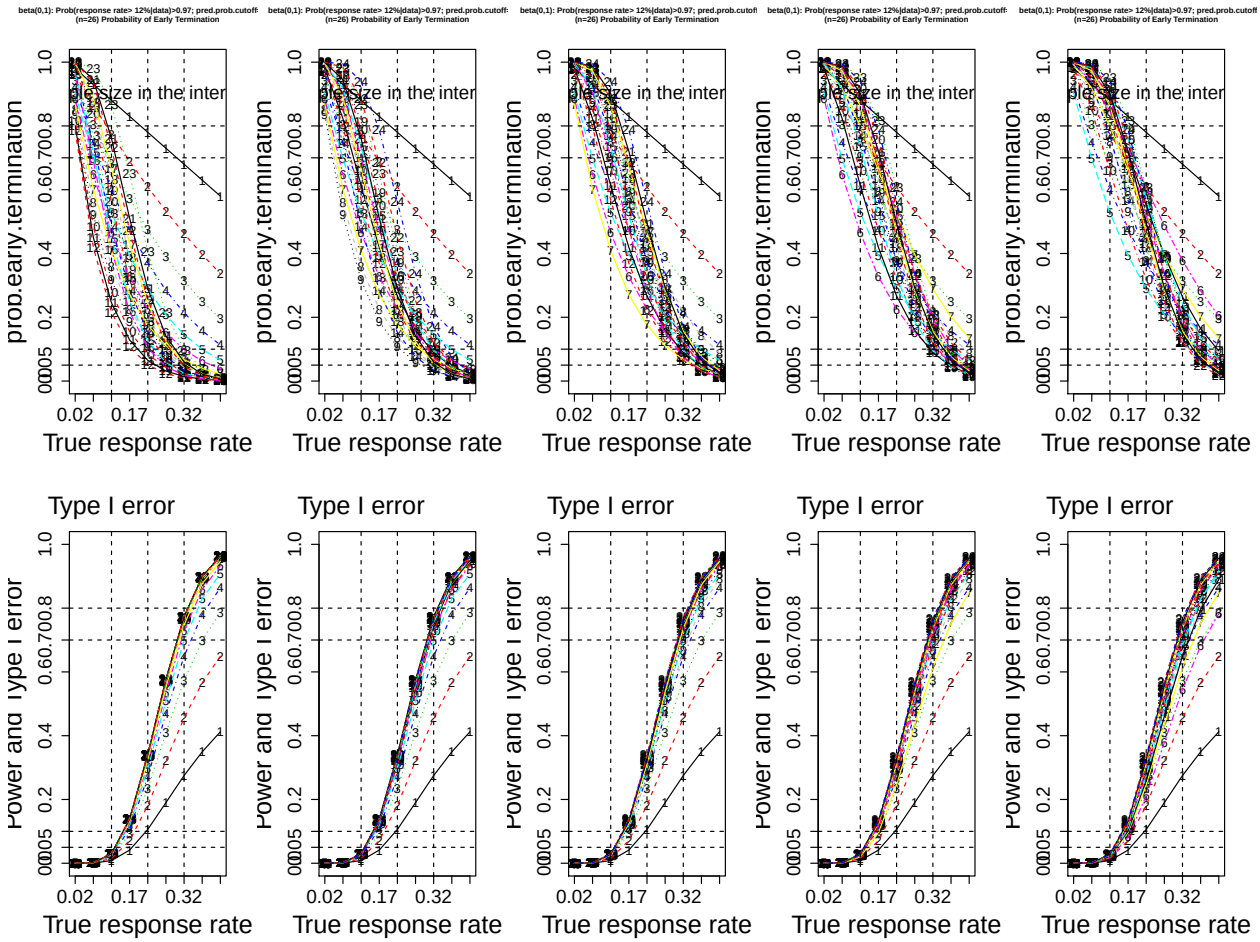
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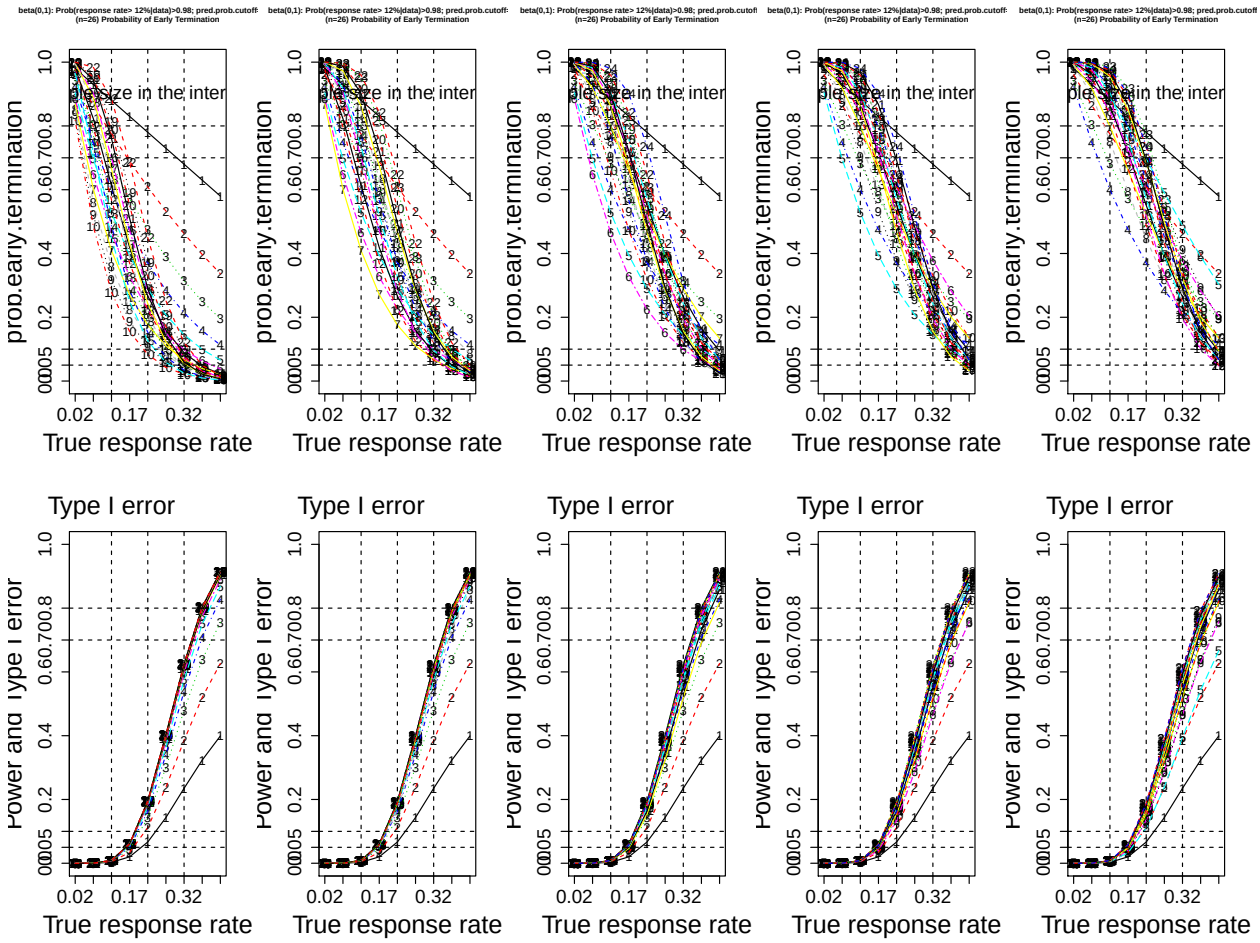
0.32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(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
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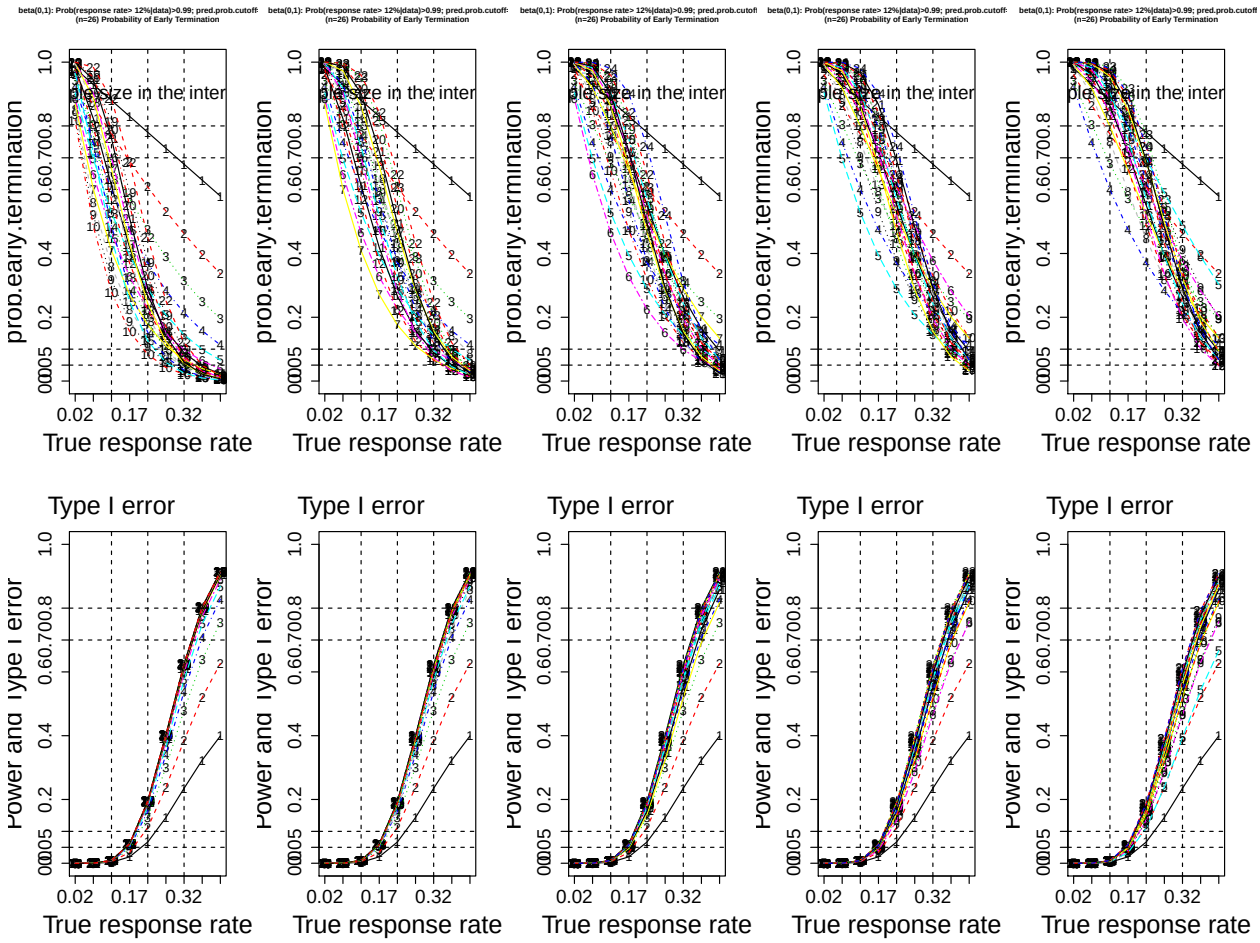
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prob.early.termination
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Power and Type I error
True response rate
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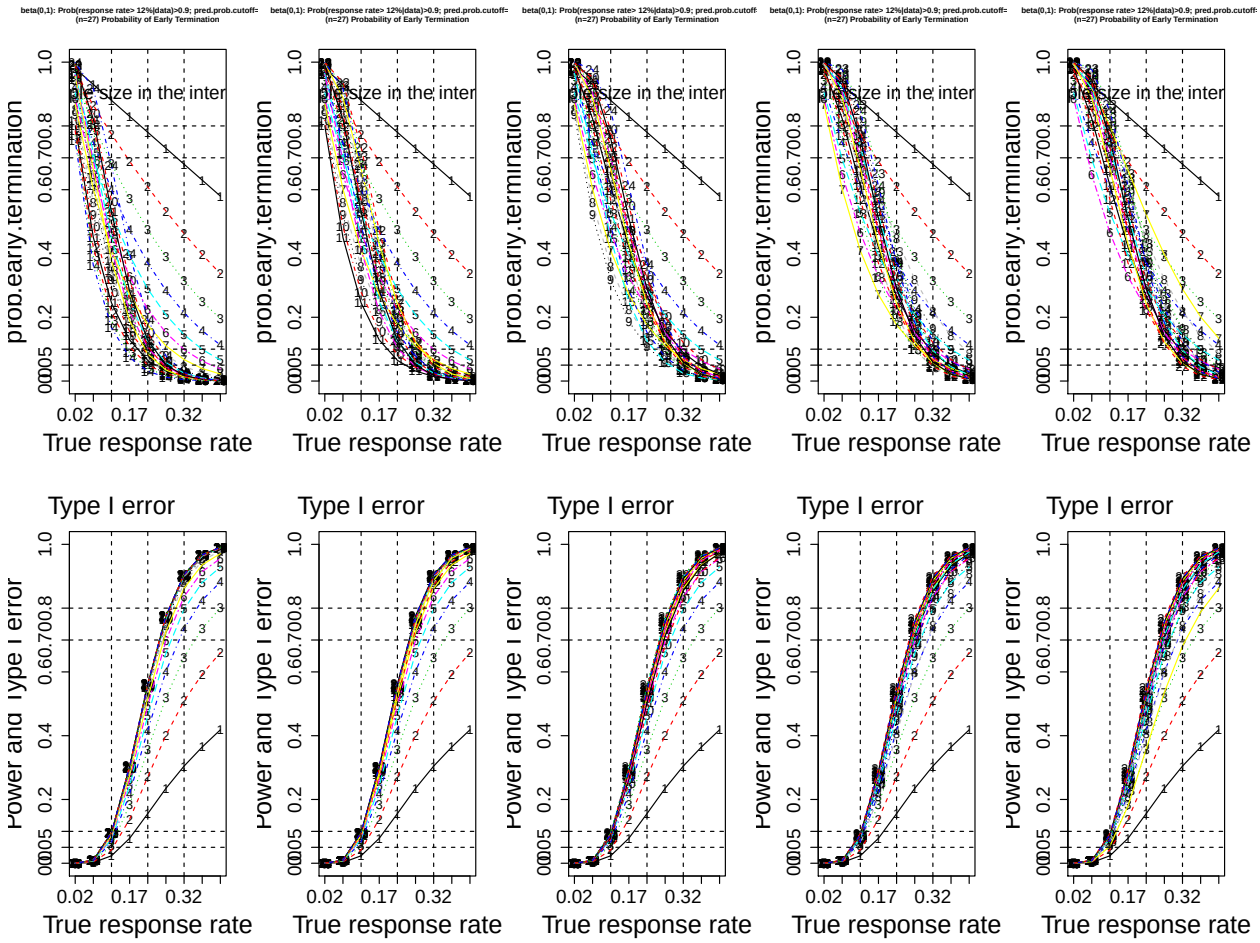
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prob.early.termination
Type I error
Power and Type I error
True response rate
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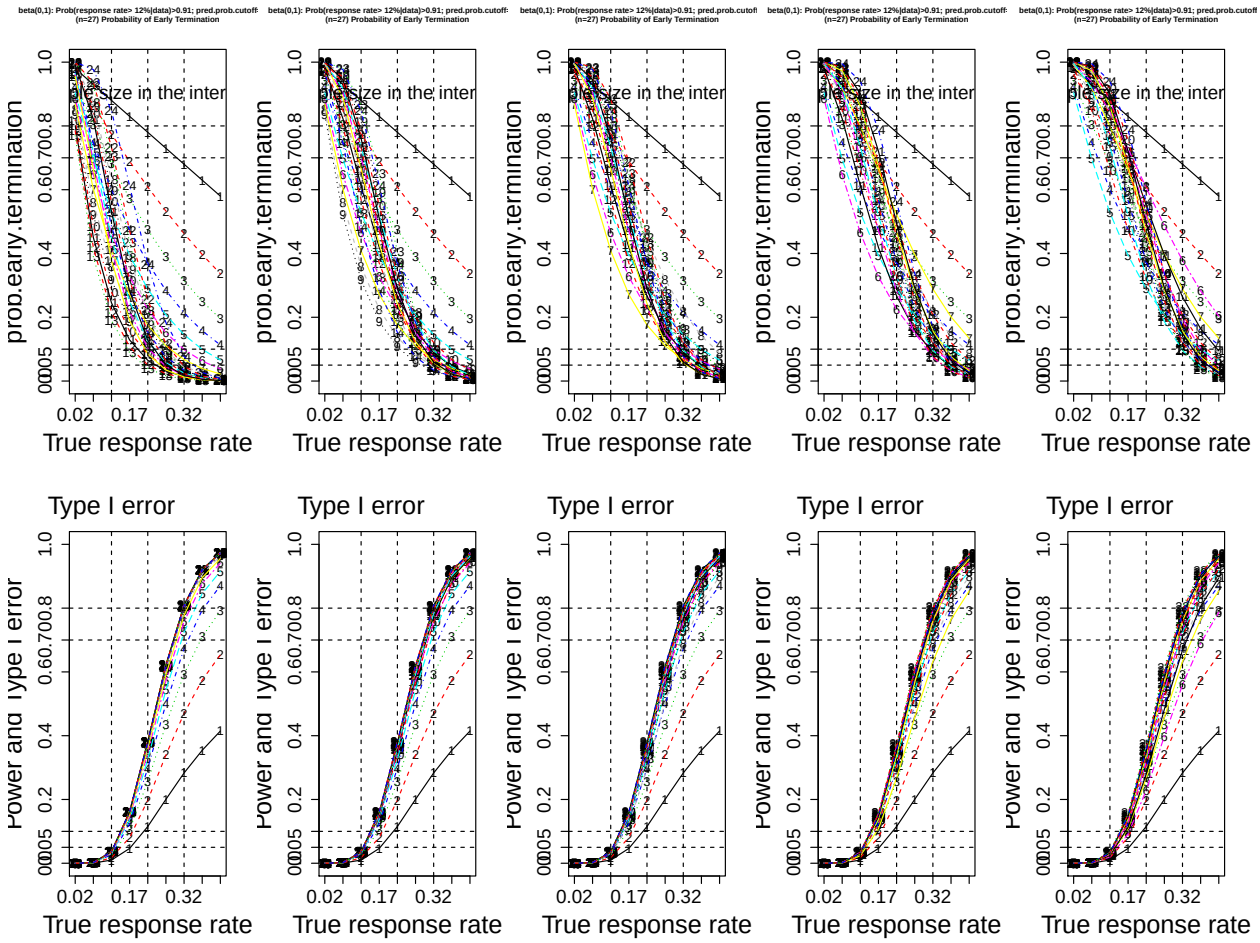
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Power and Type I error
True response rate
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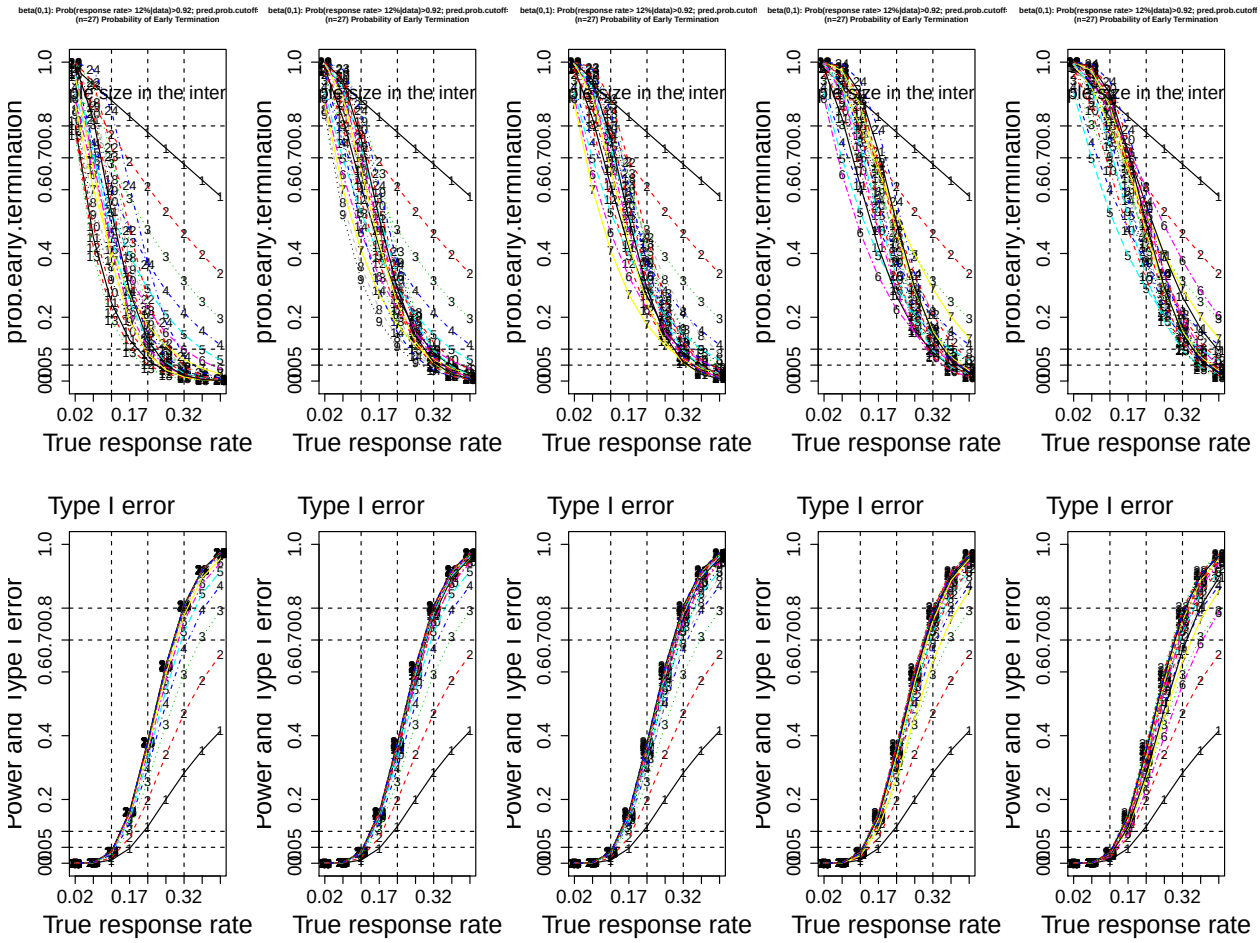
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(n=27) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
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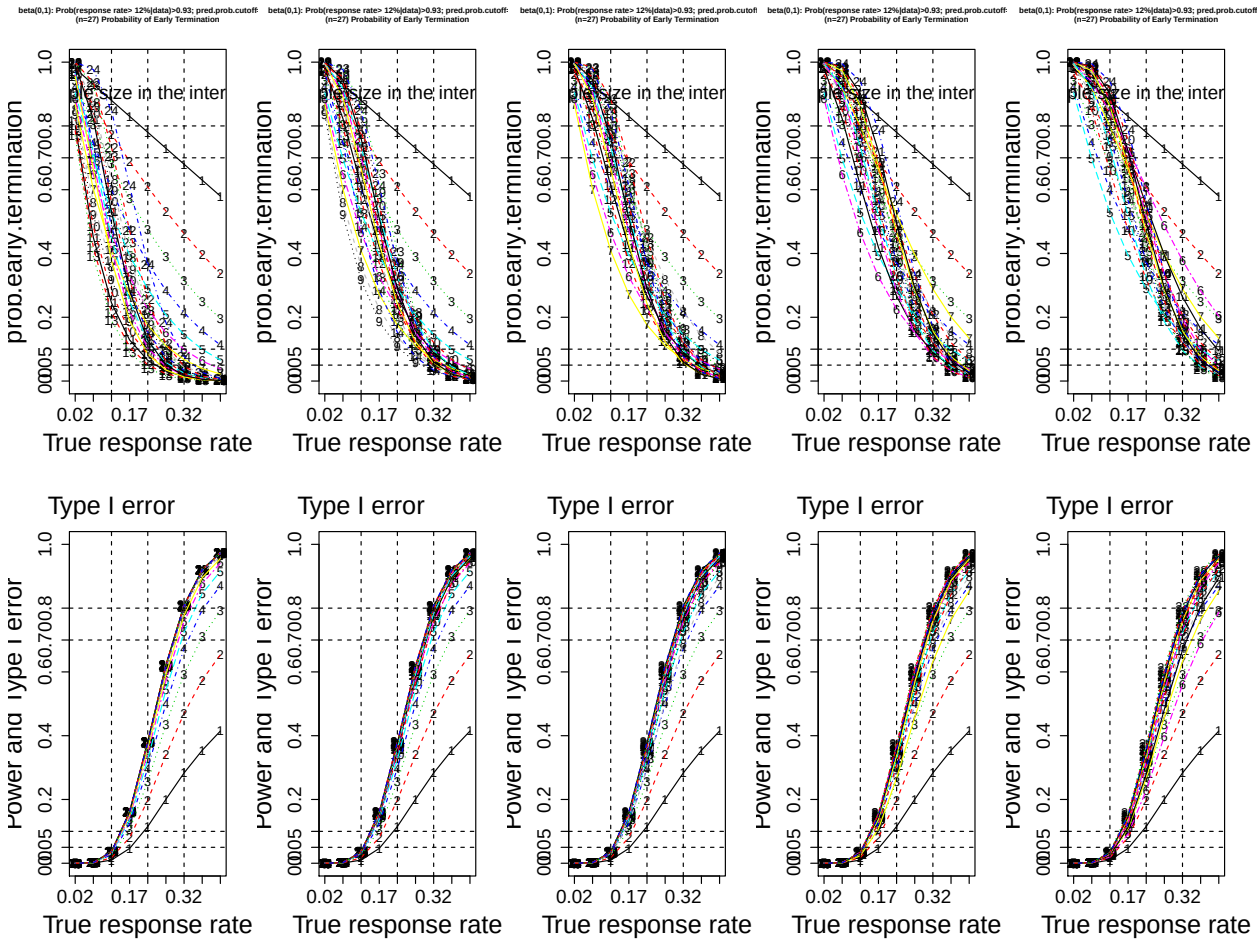
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prob.early.termination
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Power and Type I error
True response rate
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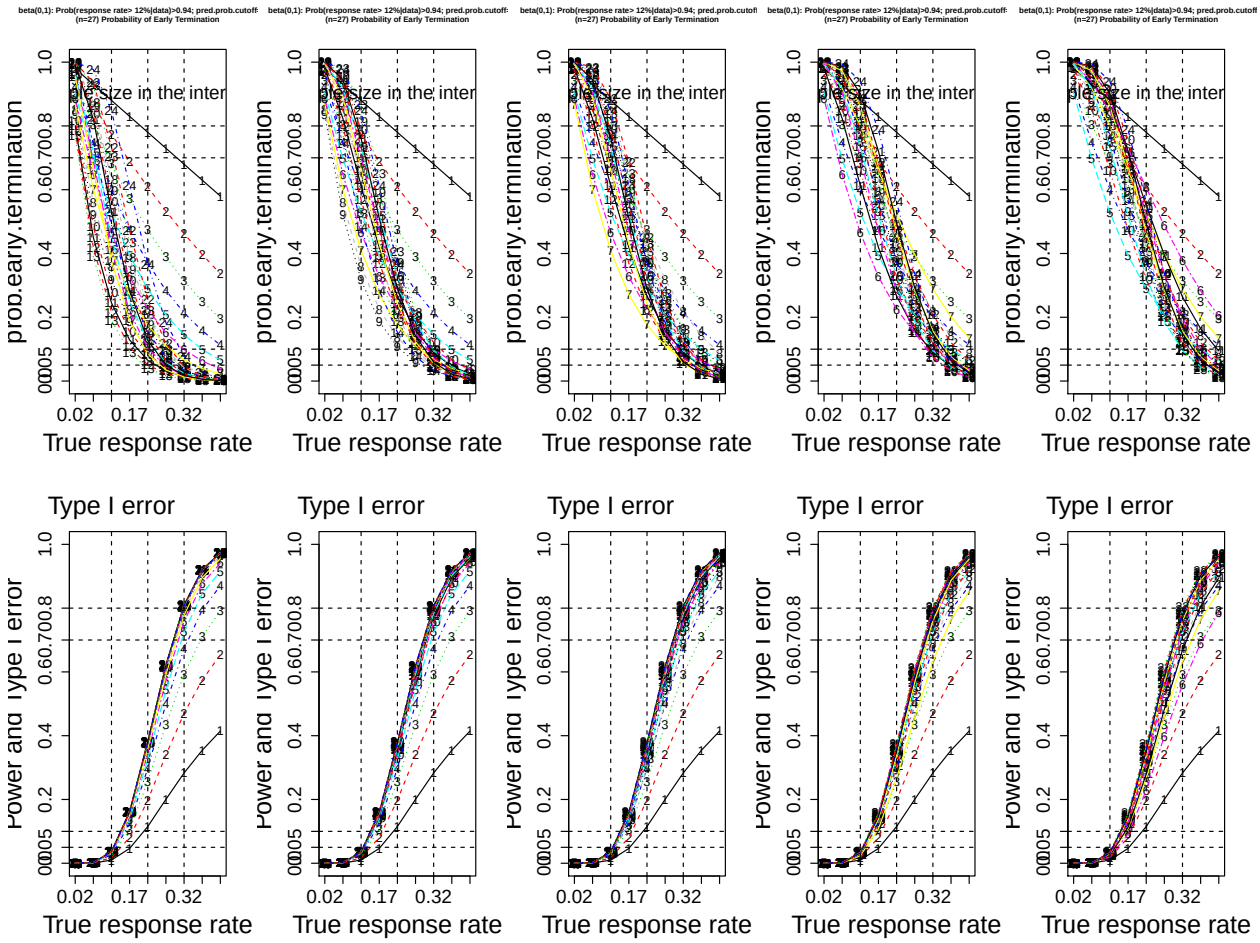
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(n=27) Probability of Early Termination
prob.early.termination
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Power and Type I error
True response rate
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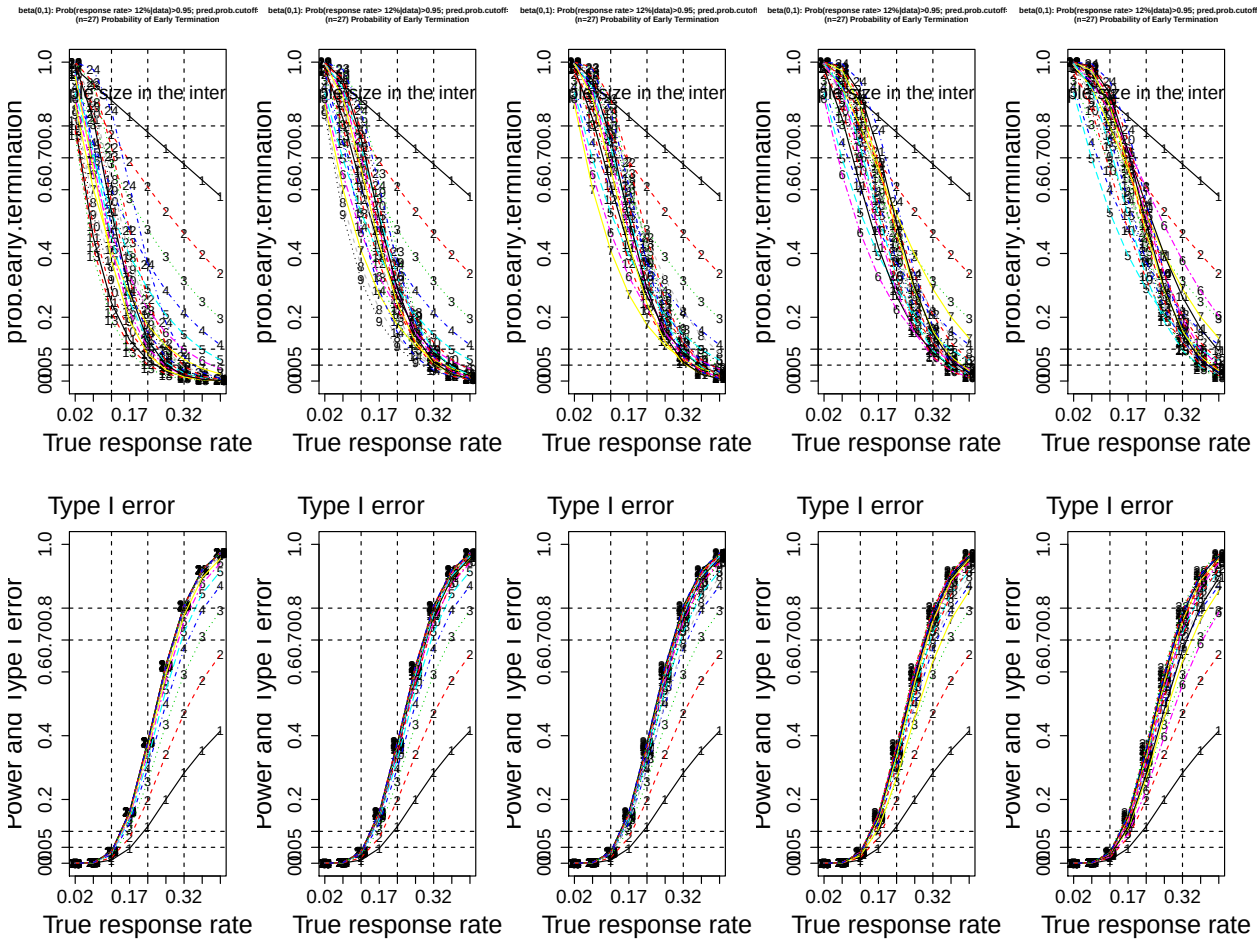
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Type I error
Power and Type I error
True response rate
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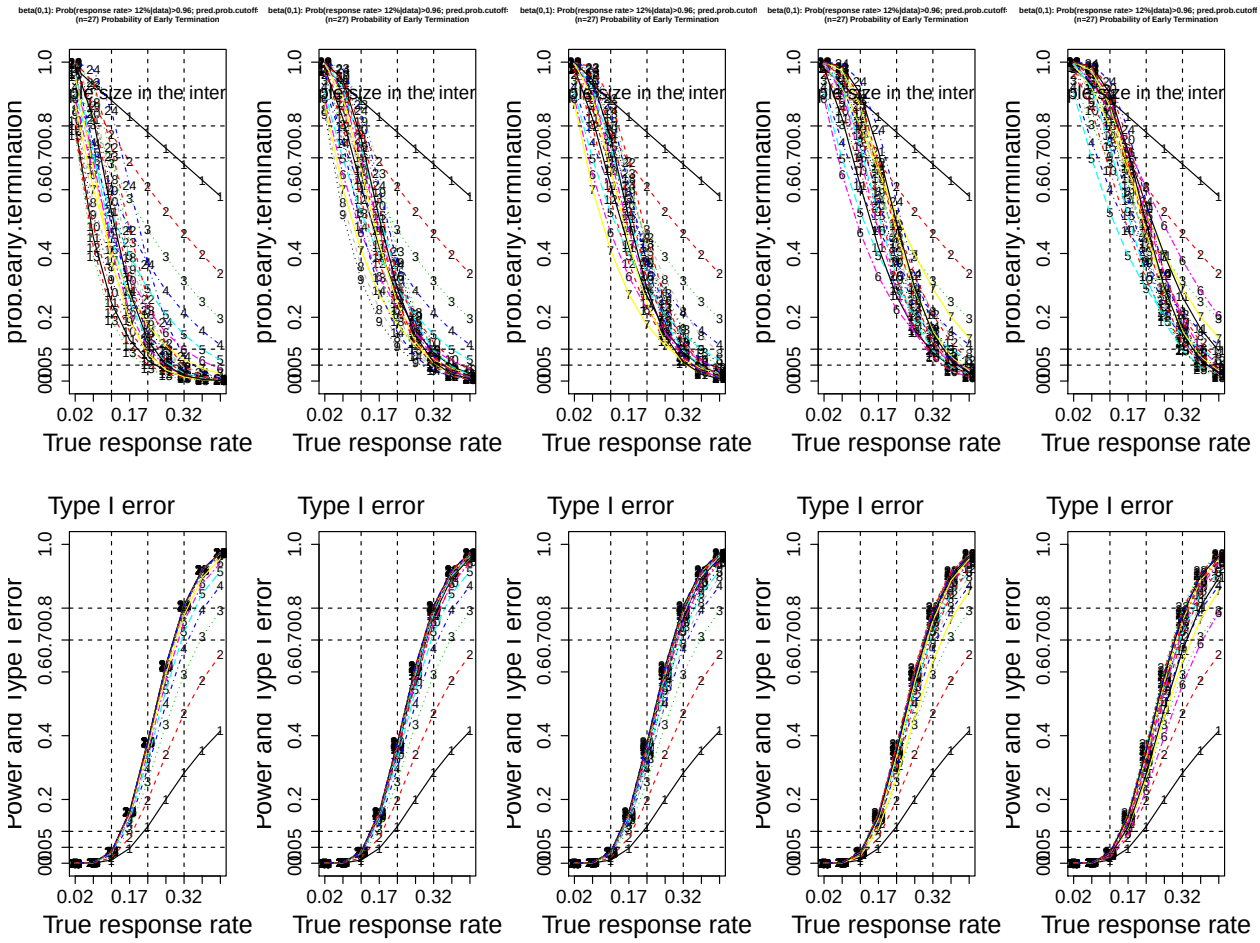
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prob.early.termination
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Power and Type I error
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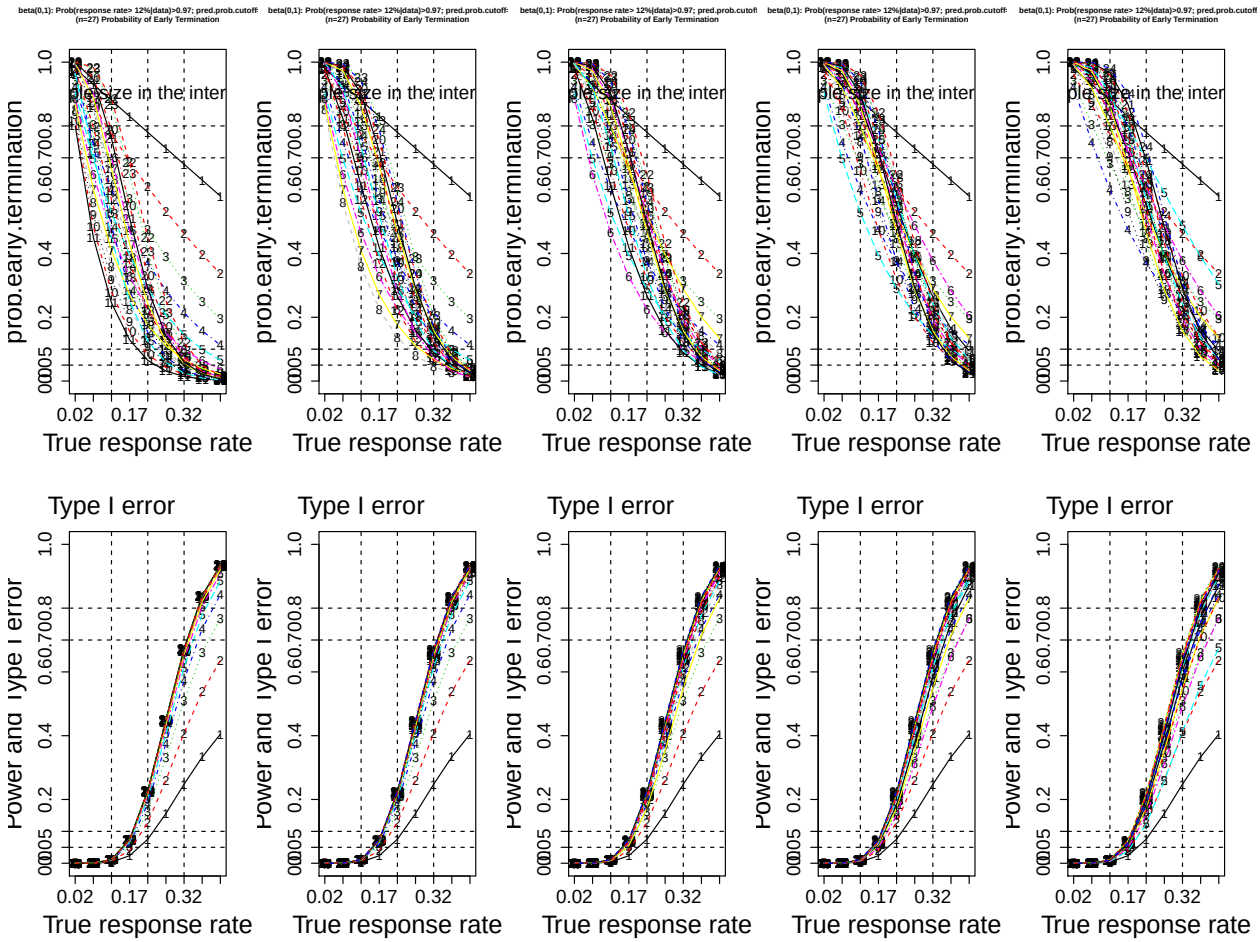
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prob.early.termination
Type I error
Power and Type I error
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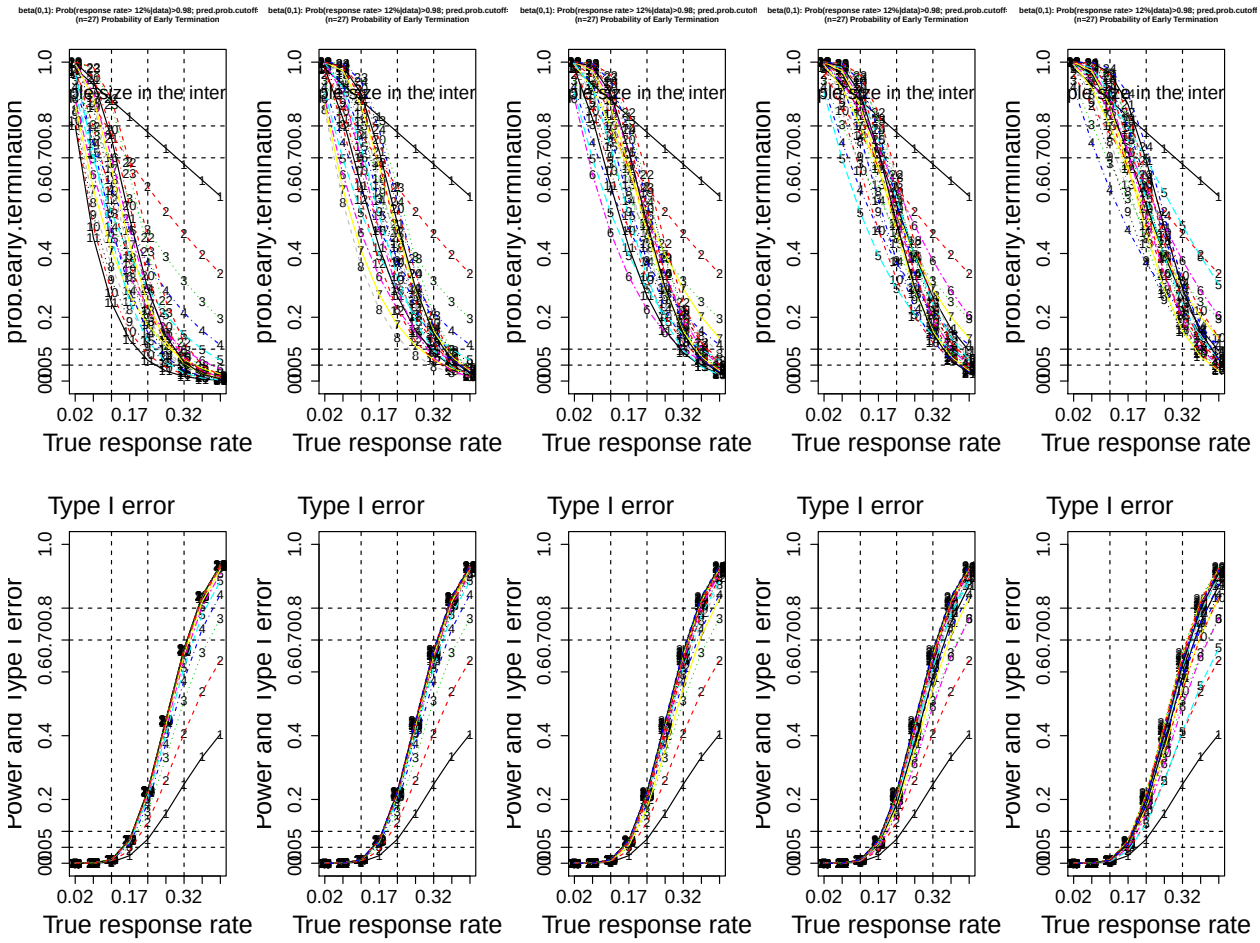
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(n=27) Probability of Early Termination
prob.early.termination
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True response rate
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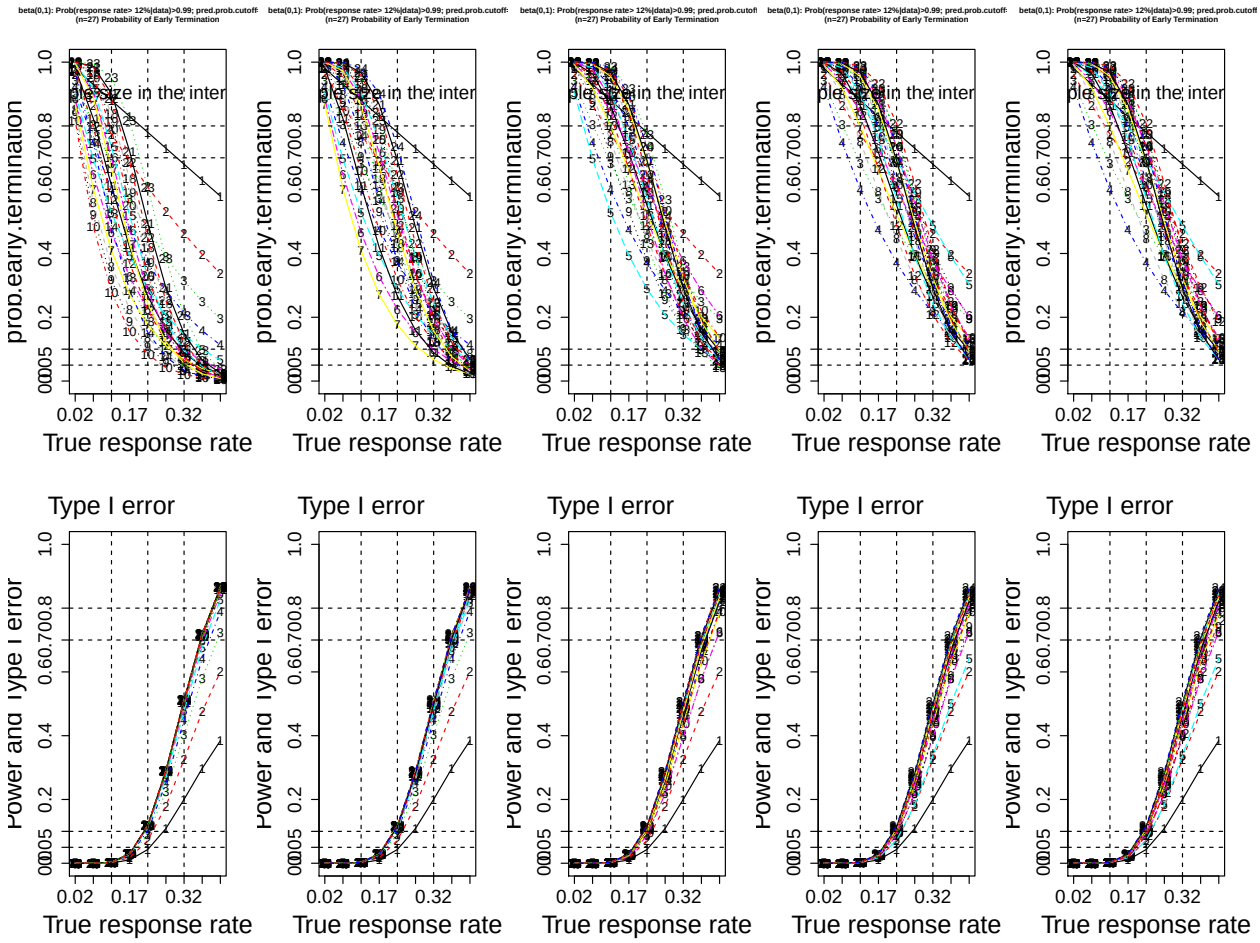
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prob.early.termination
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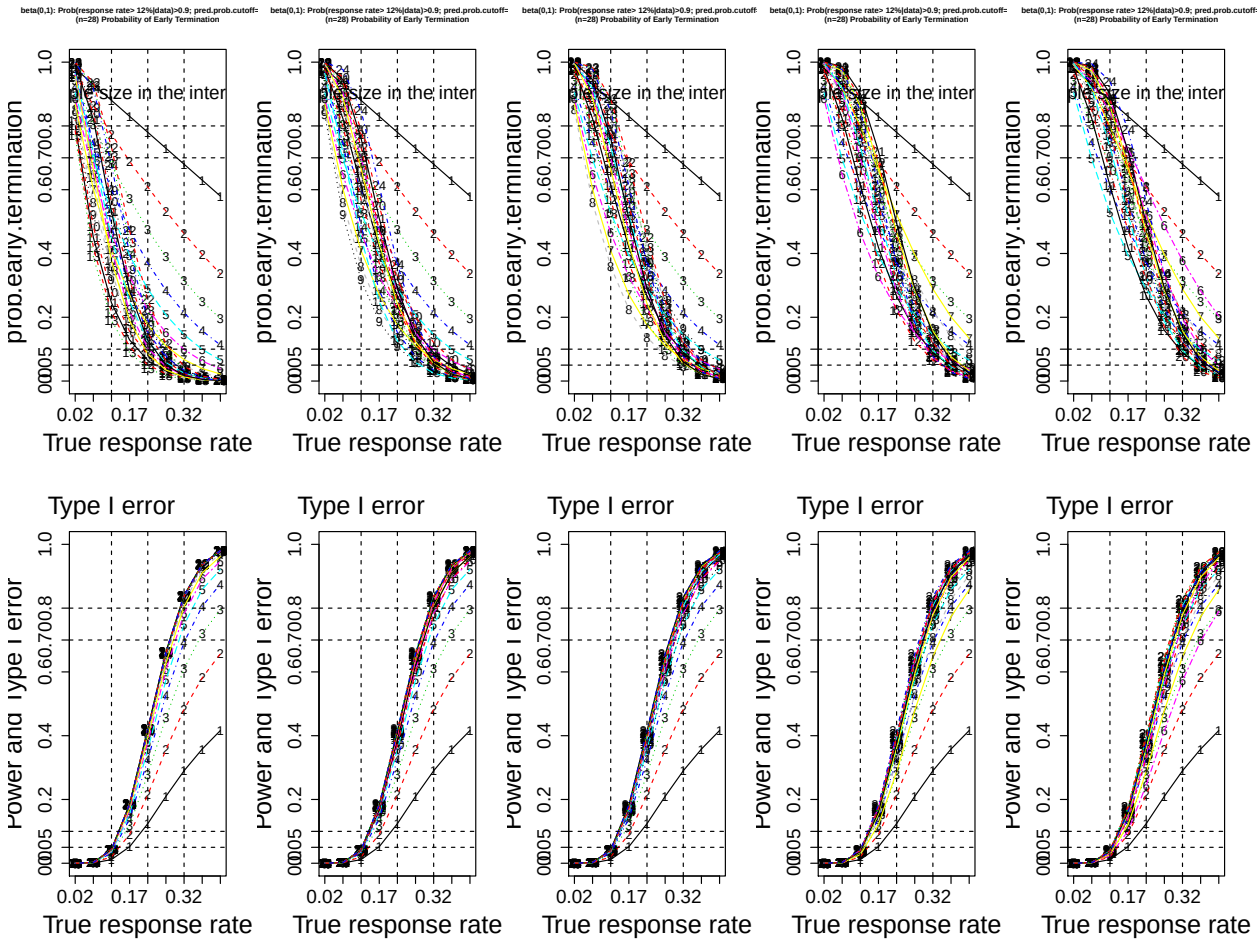
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(n=28) Probability of Early Termination
prob.early.termination
Power and Type I error
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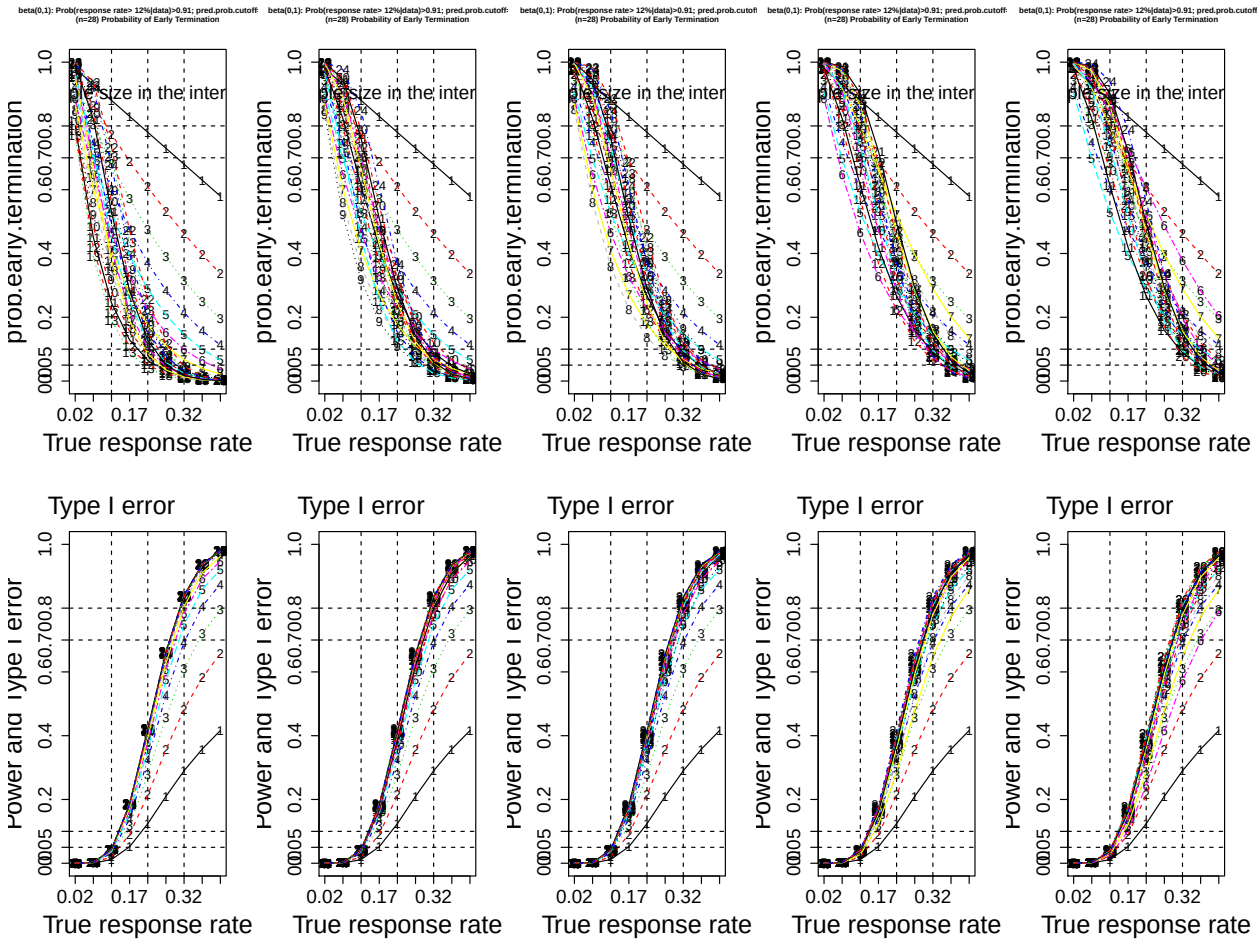
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(n=28) Probability of Early Termination
prob.early.termination
Type I error
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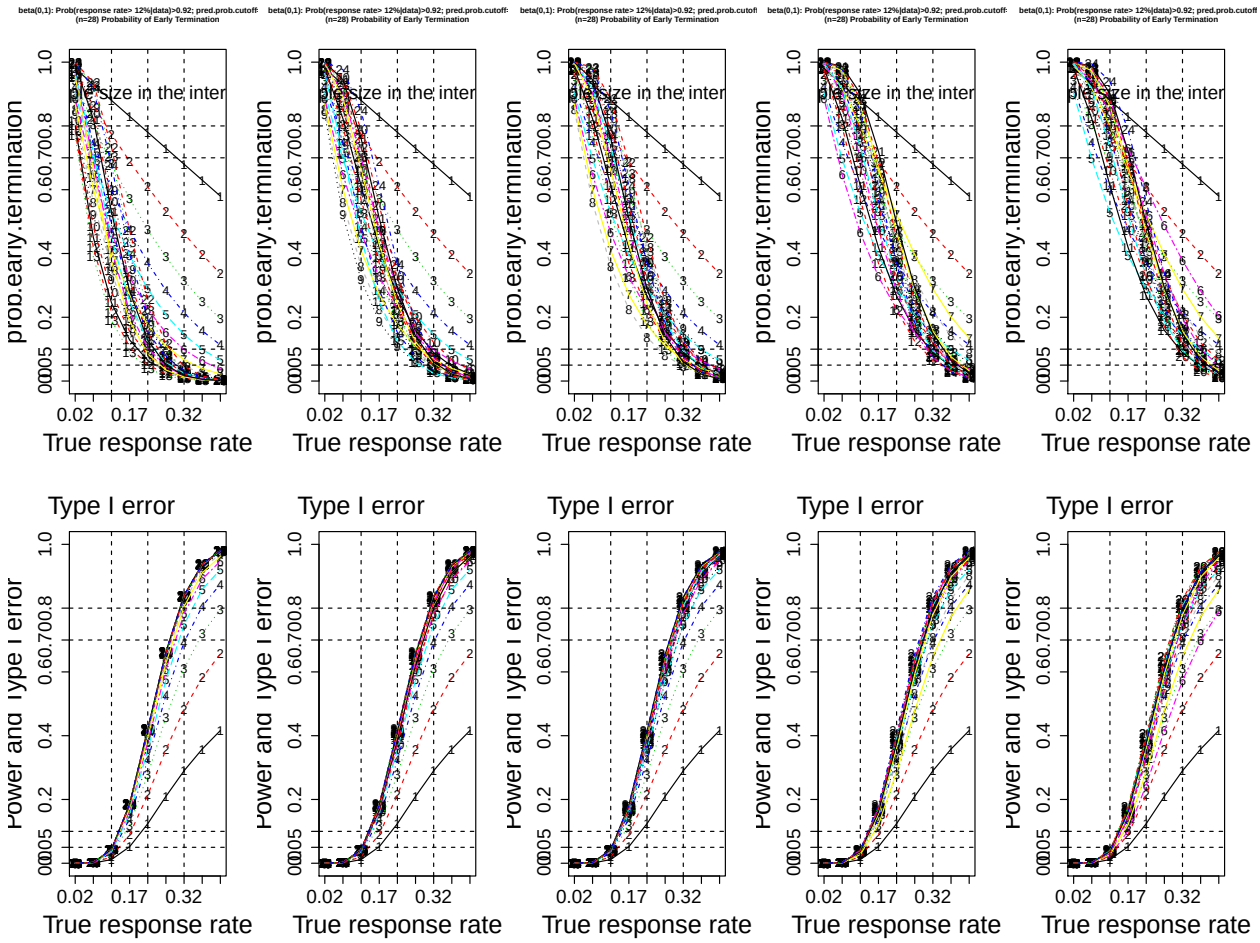
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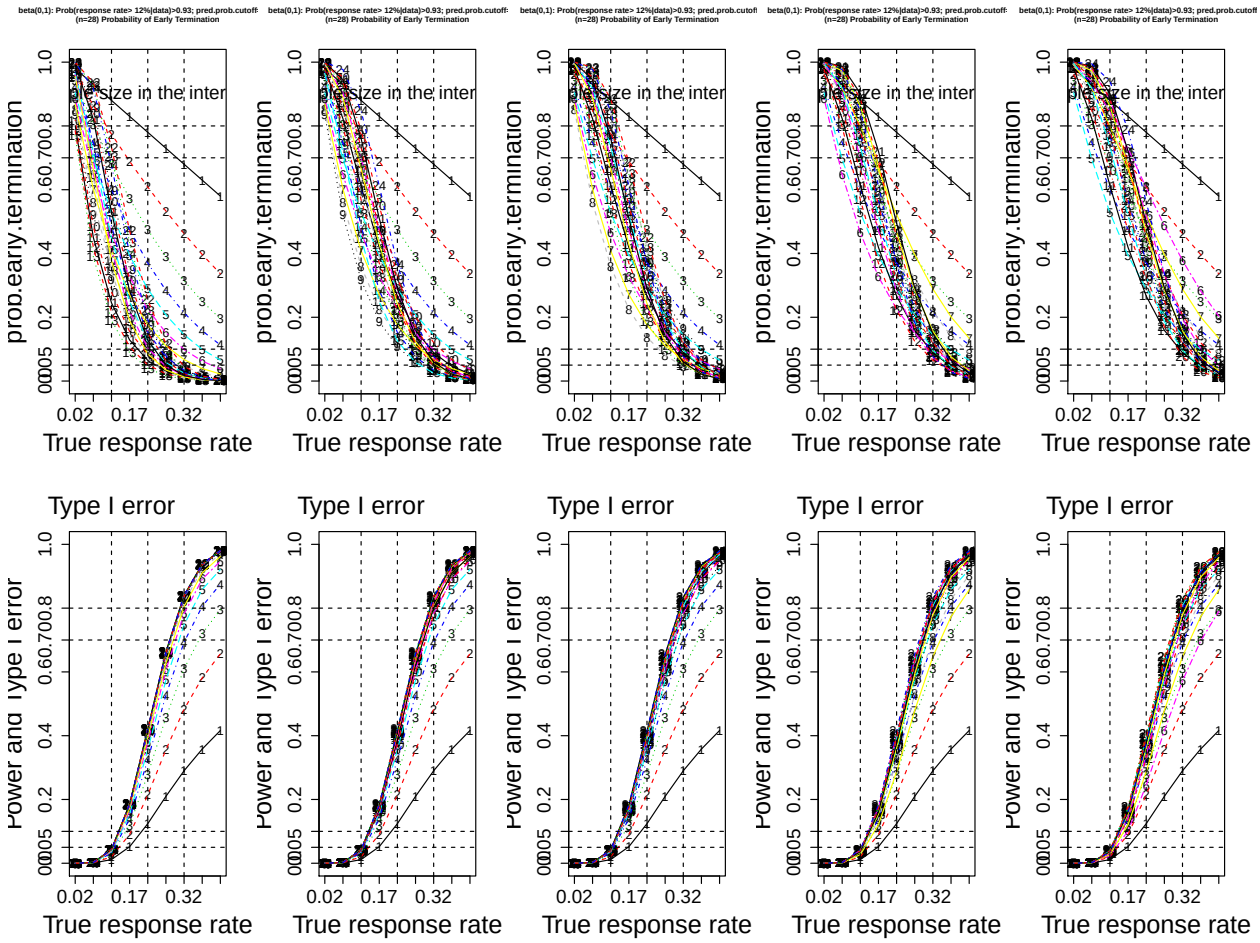
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Power and Type I error
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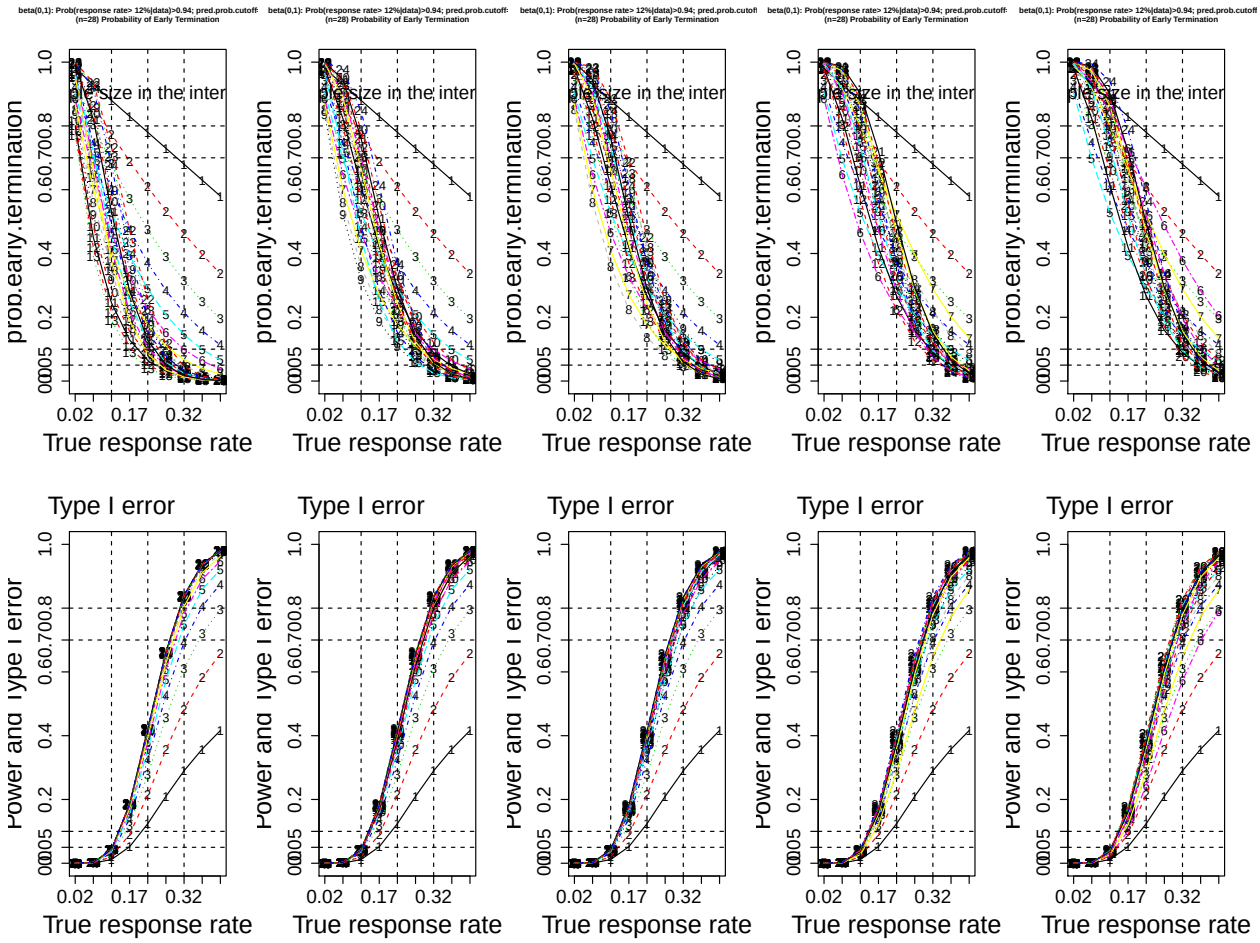
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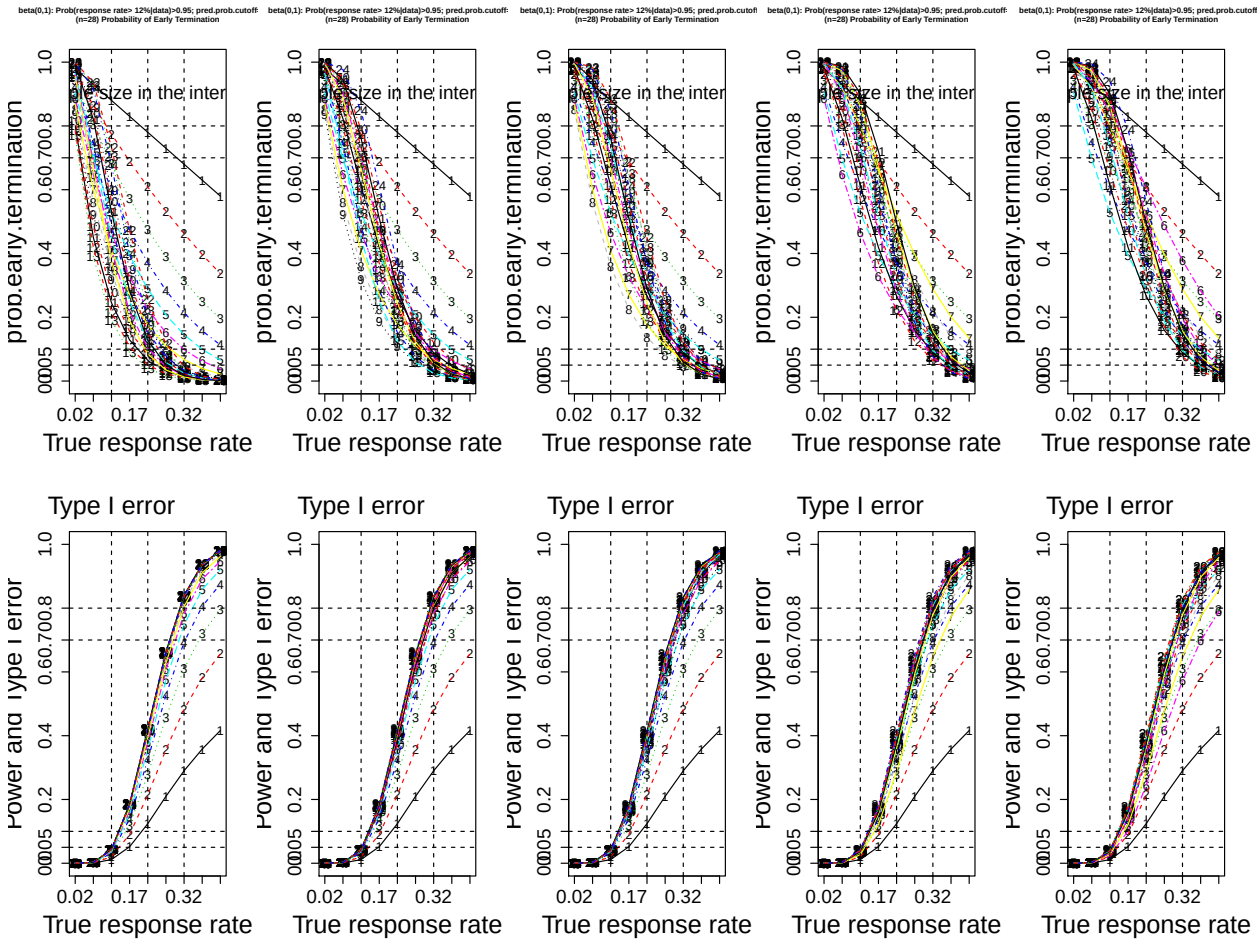
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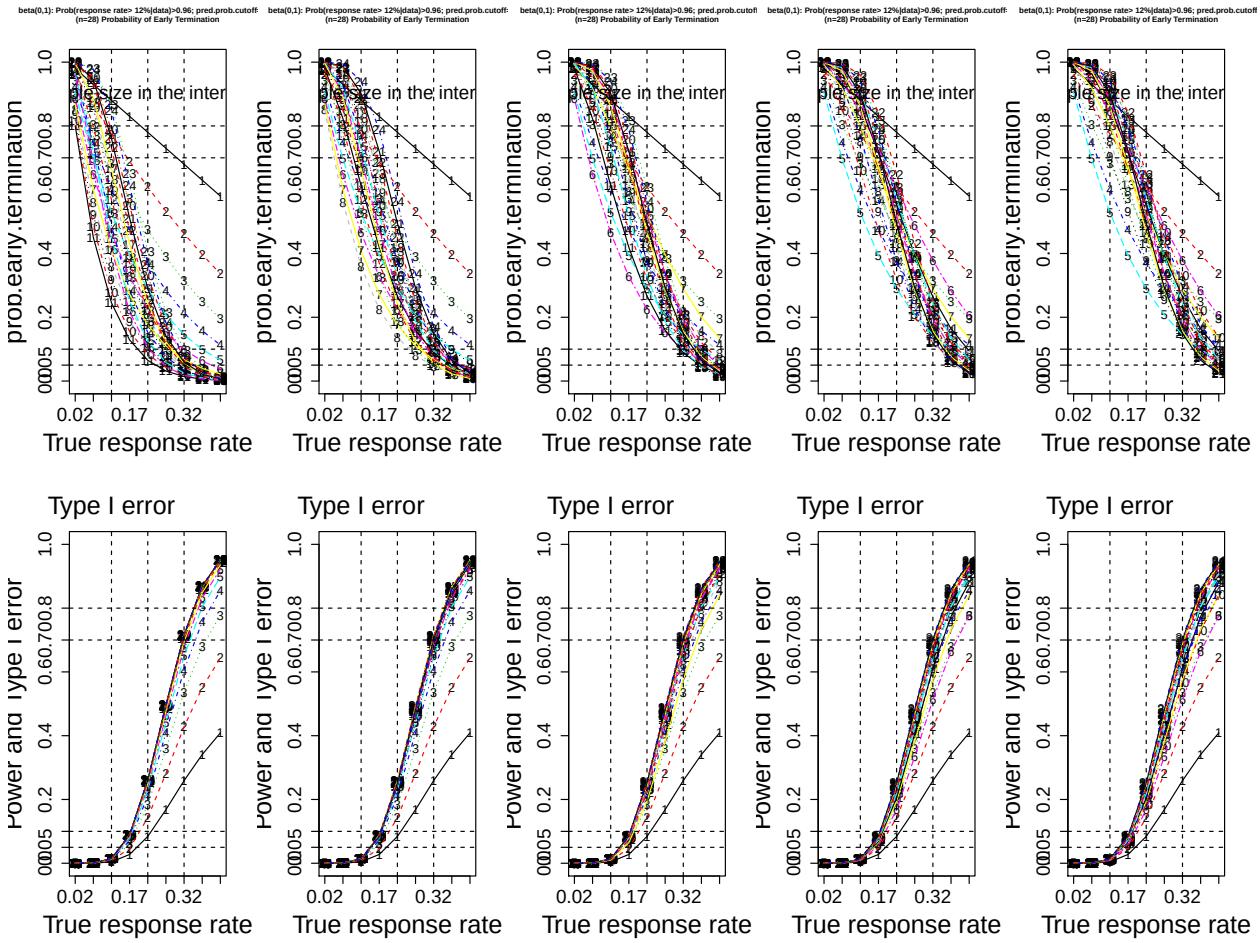
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Power and Type I error
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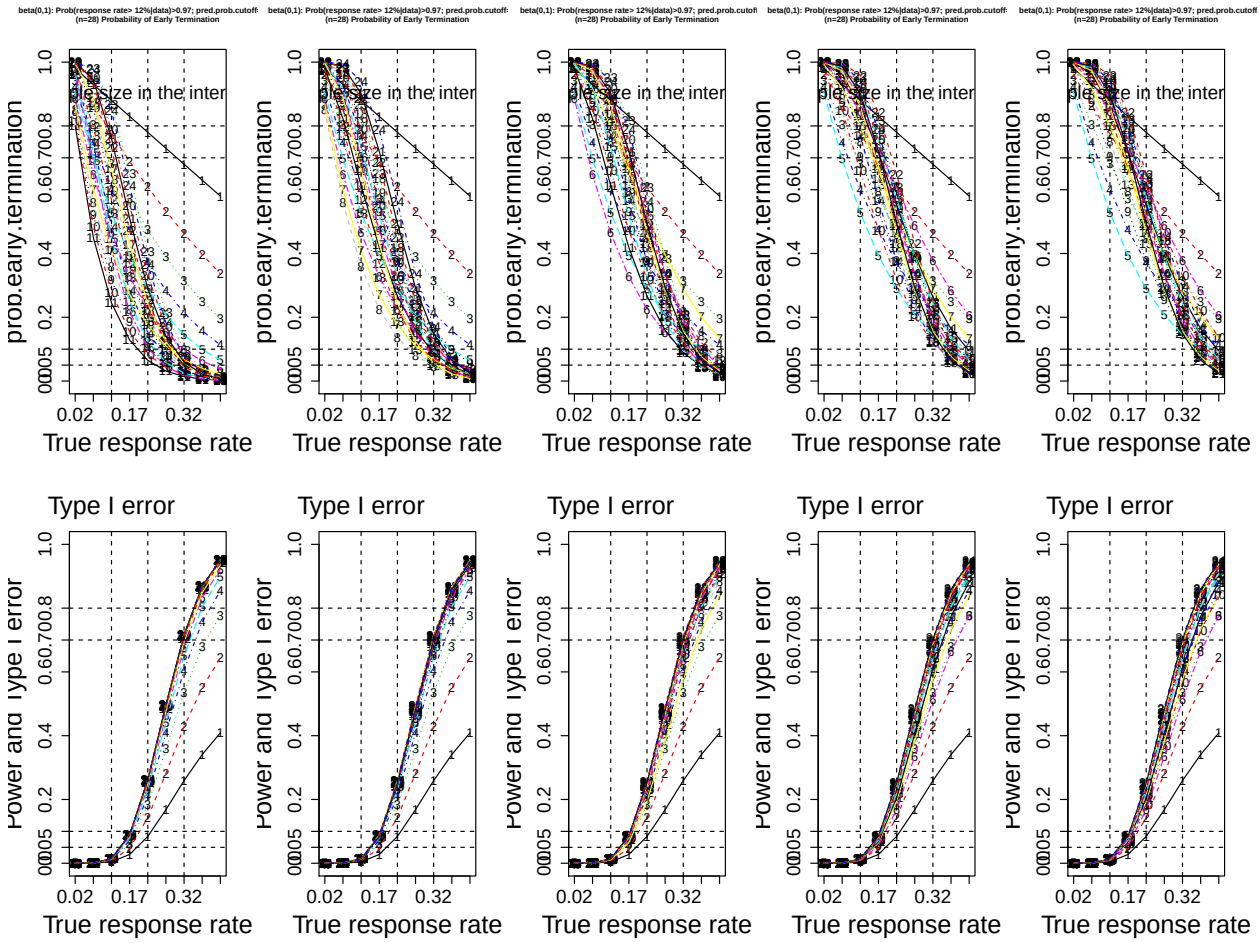
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Type I error
Power and Type I error
True response rate
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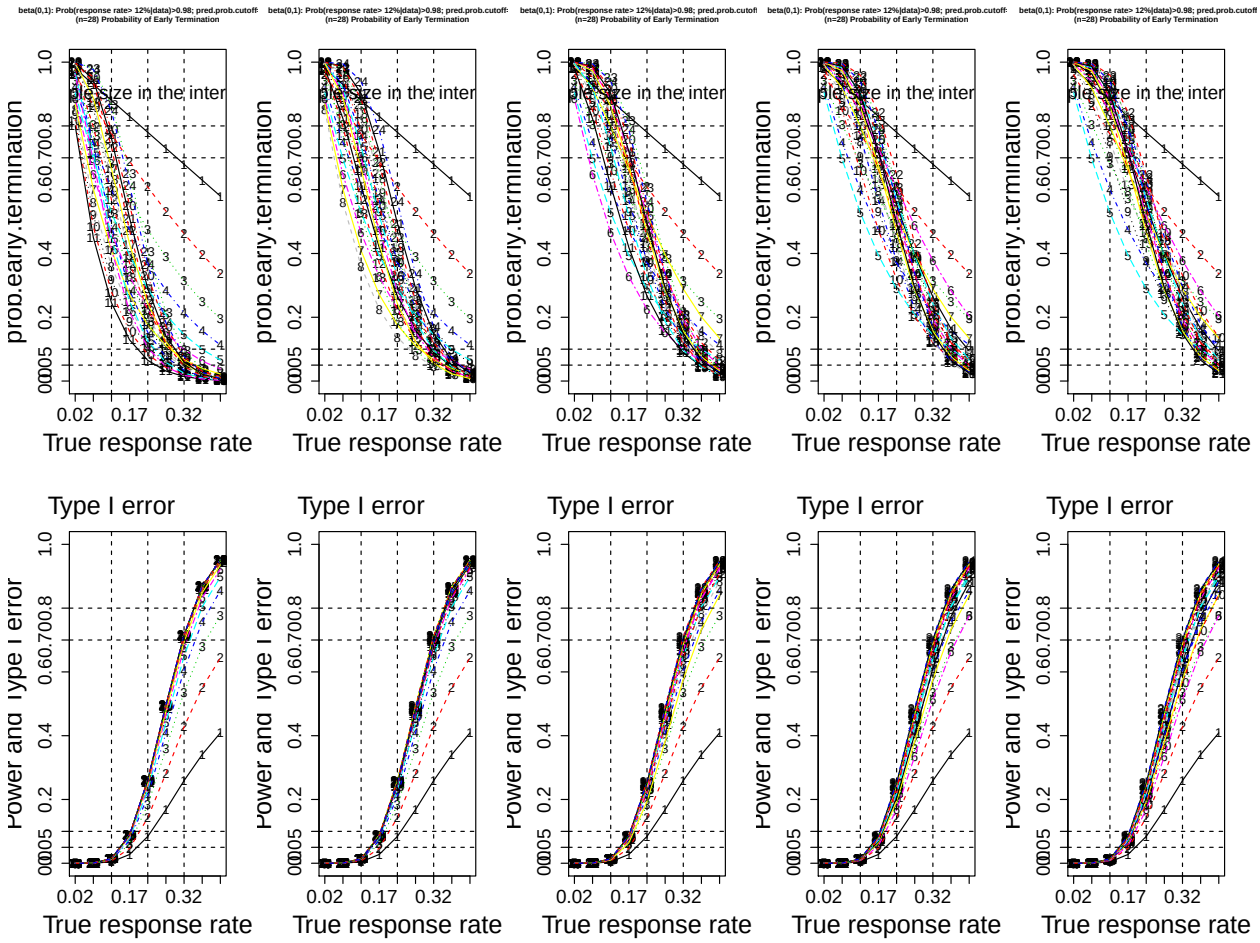
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prob.early.termination
Power and Type I error
Type I error
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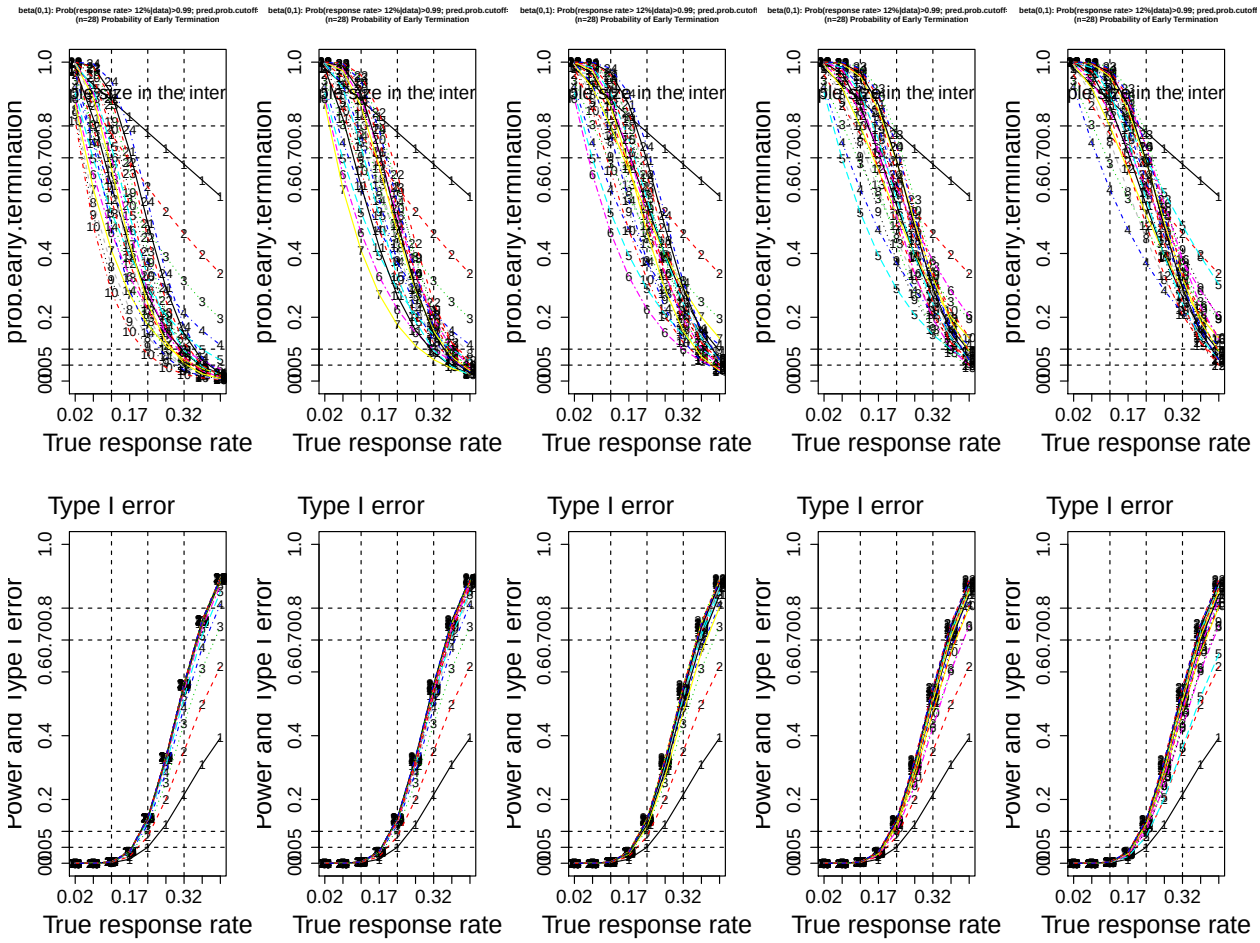
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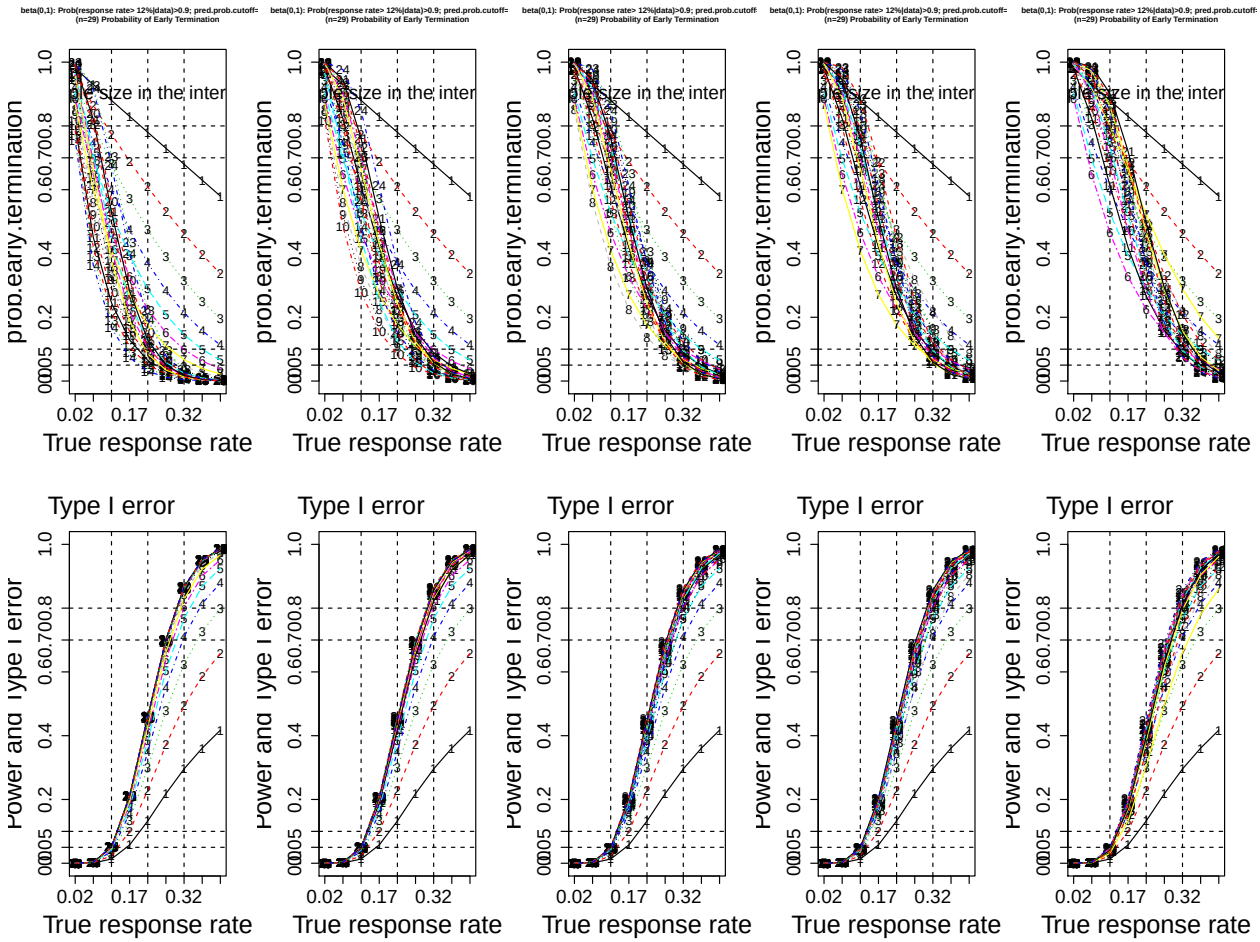
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Power and Type I error
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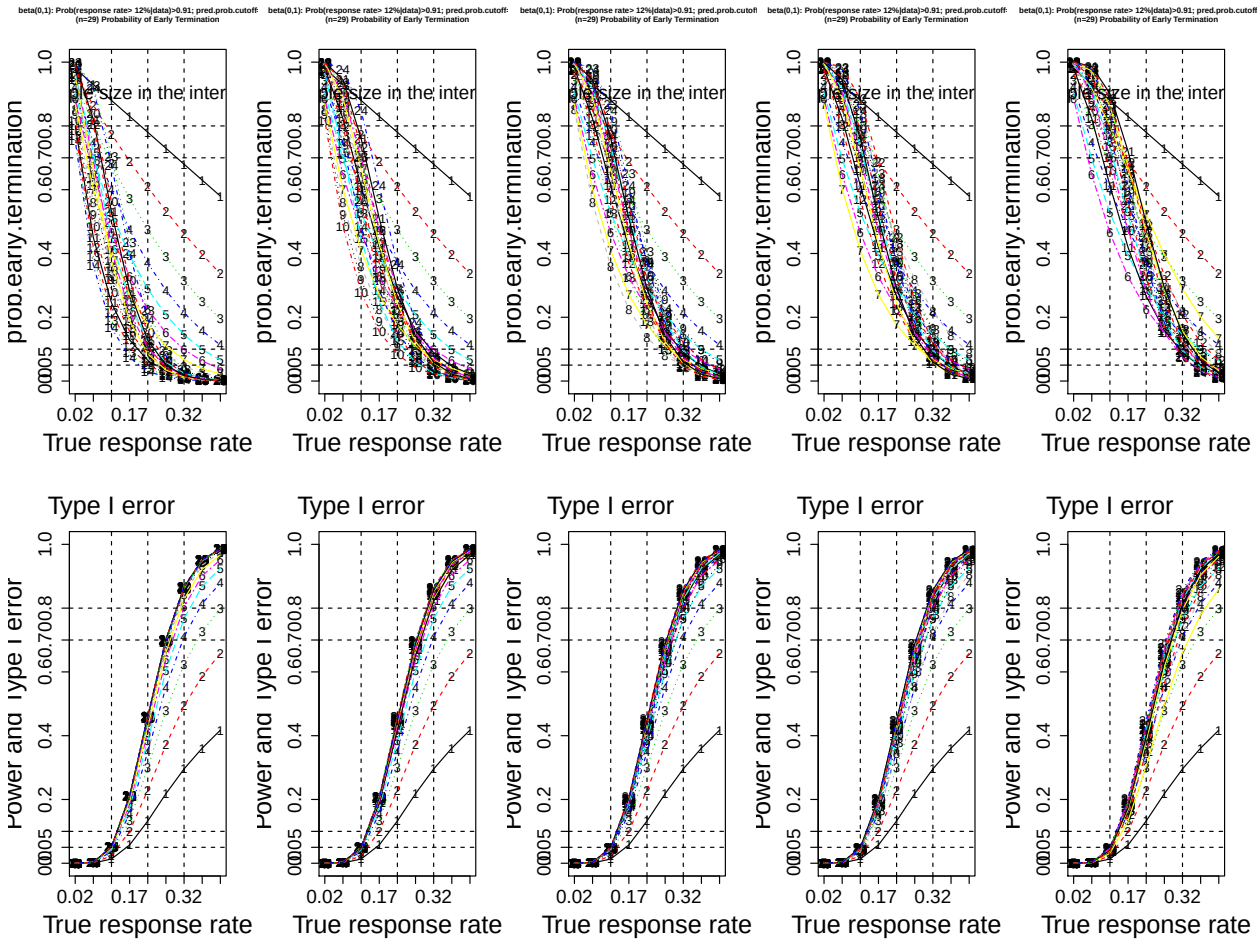
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Power and Type I error
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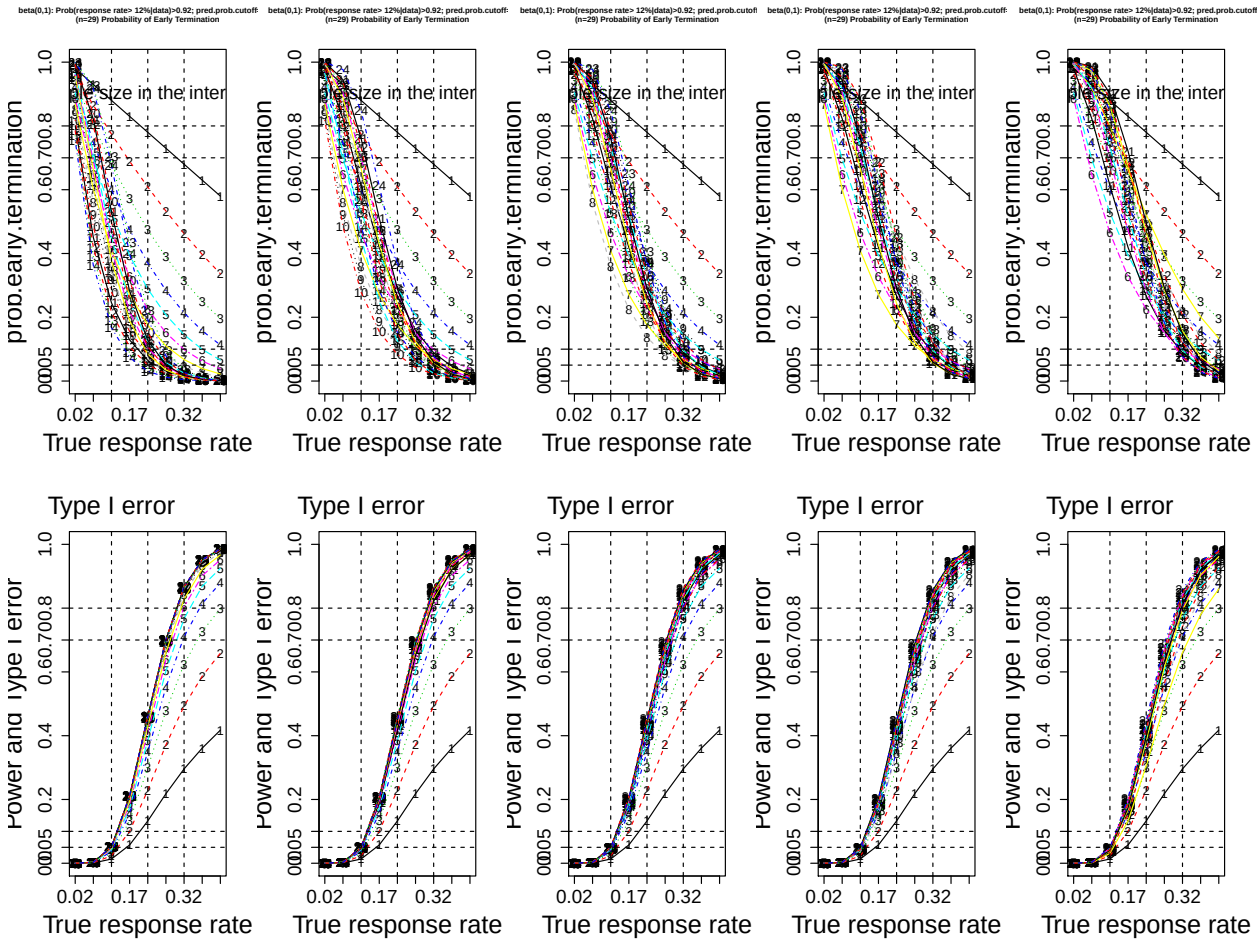
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Power and Type I error
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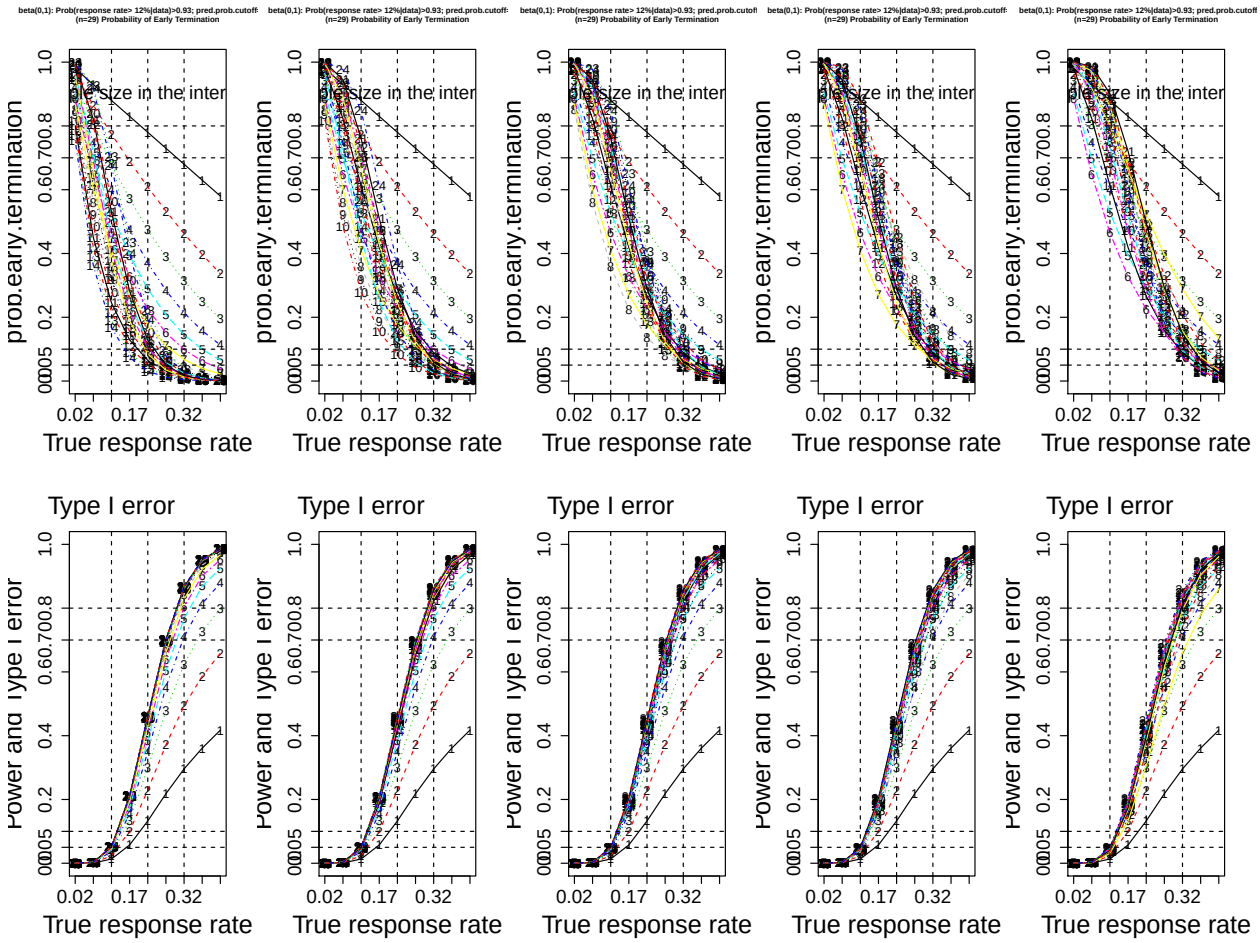
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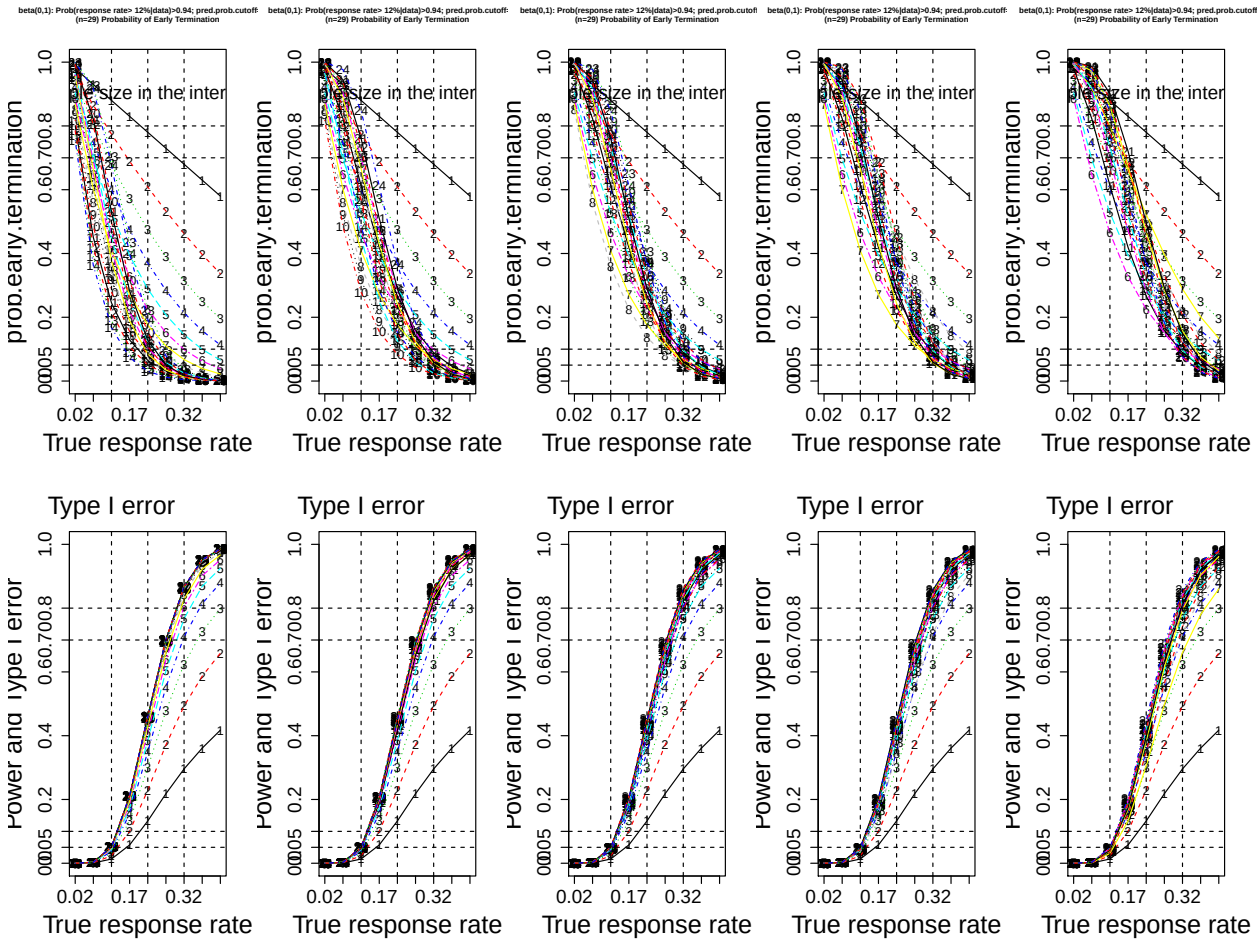
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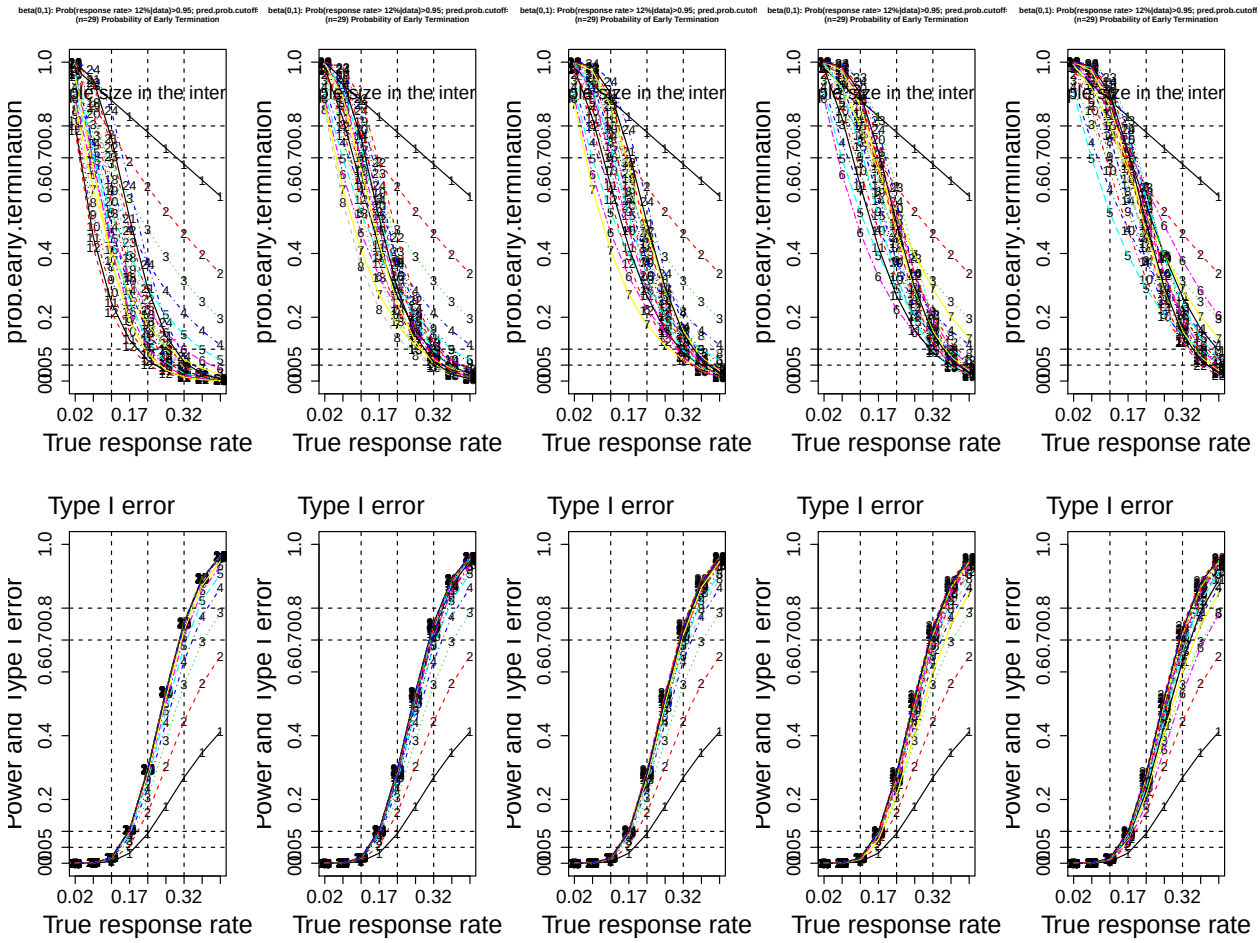
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Power and Type I error
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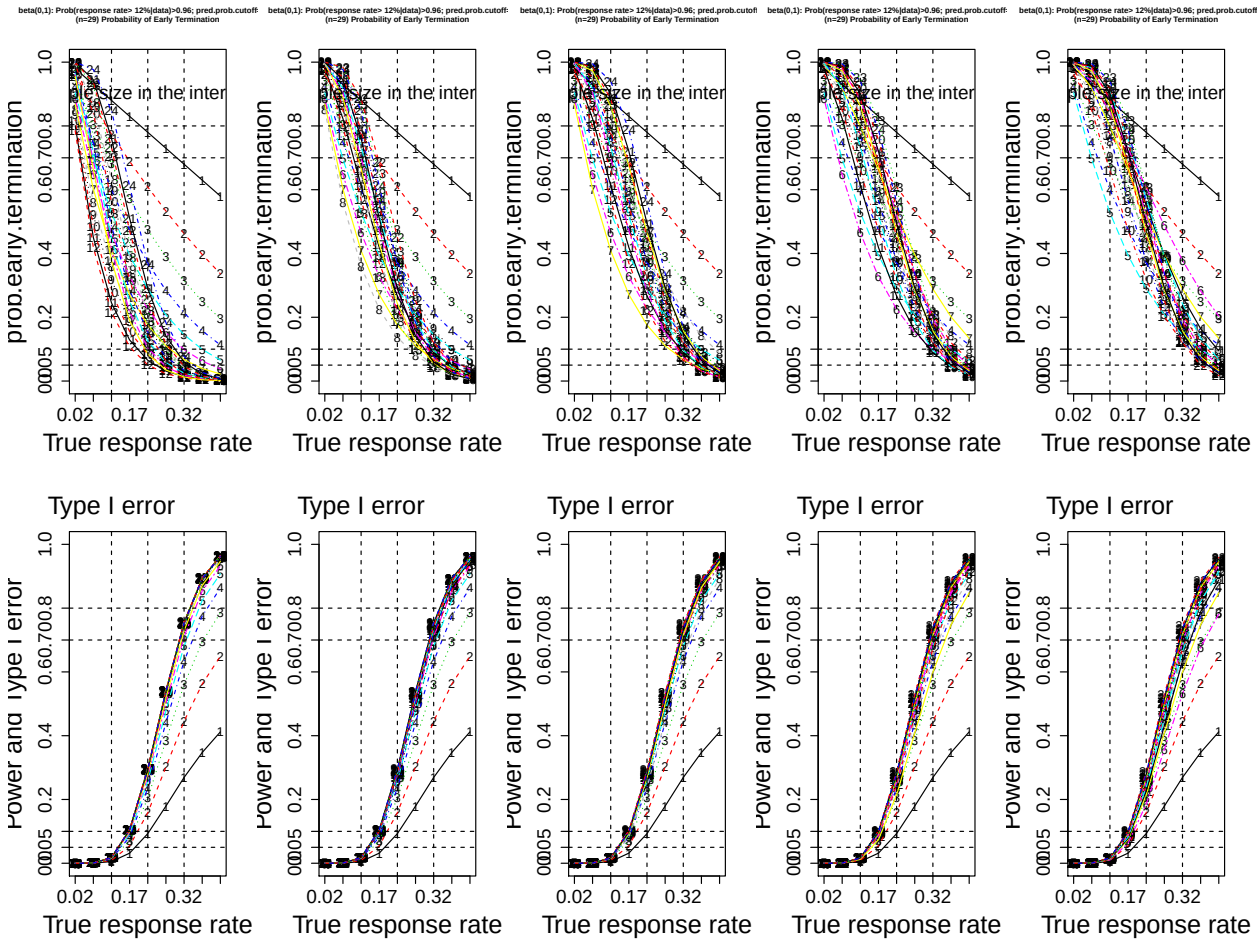
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Power and Type I error
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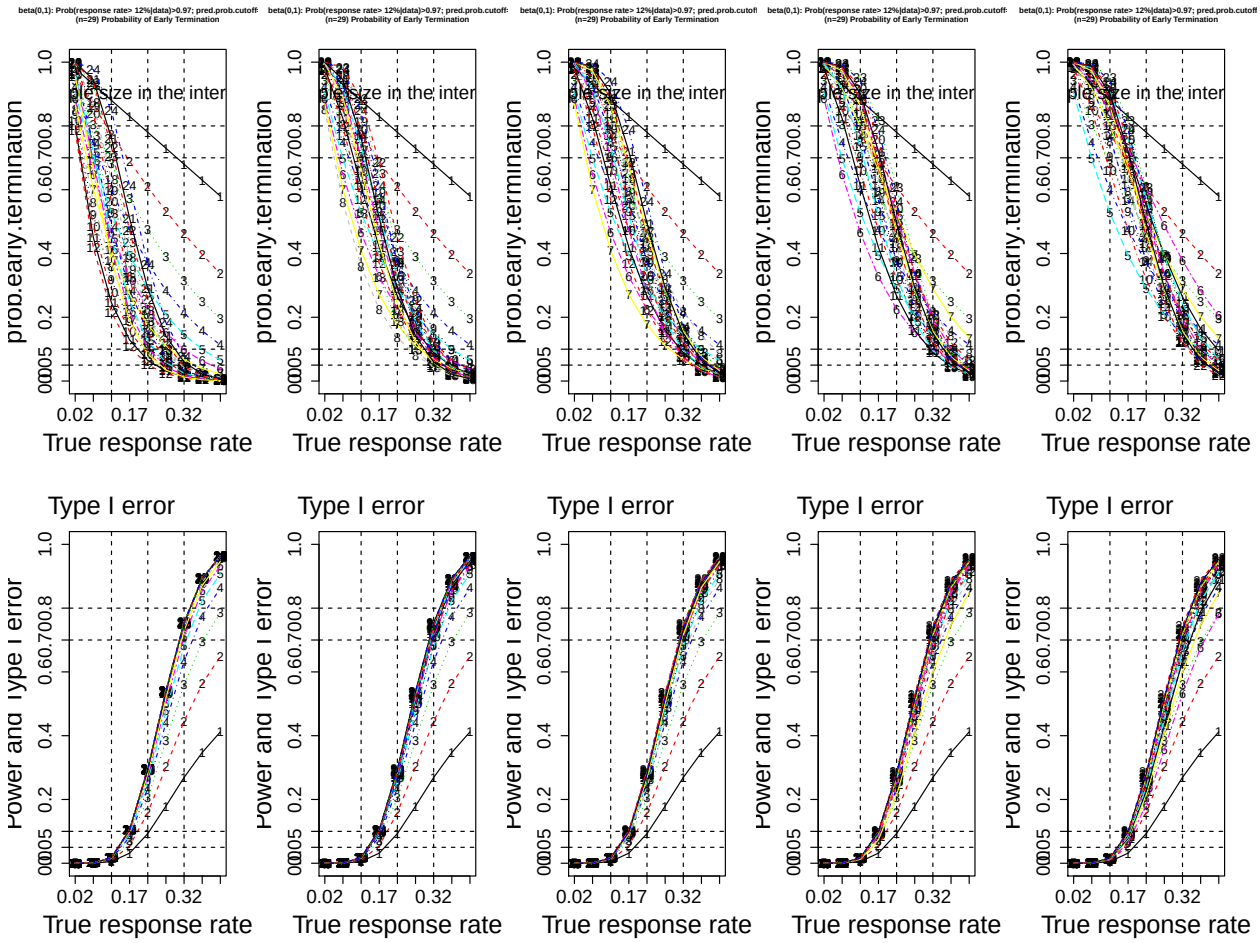
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Type I error
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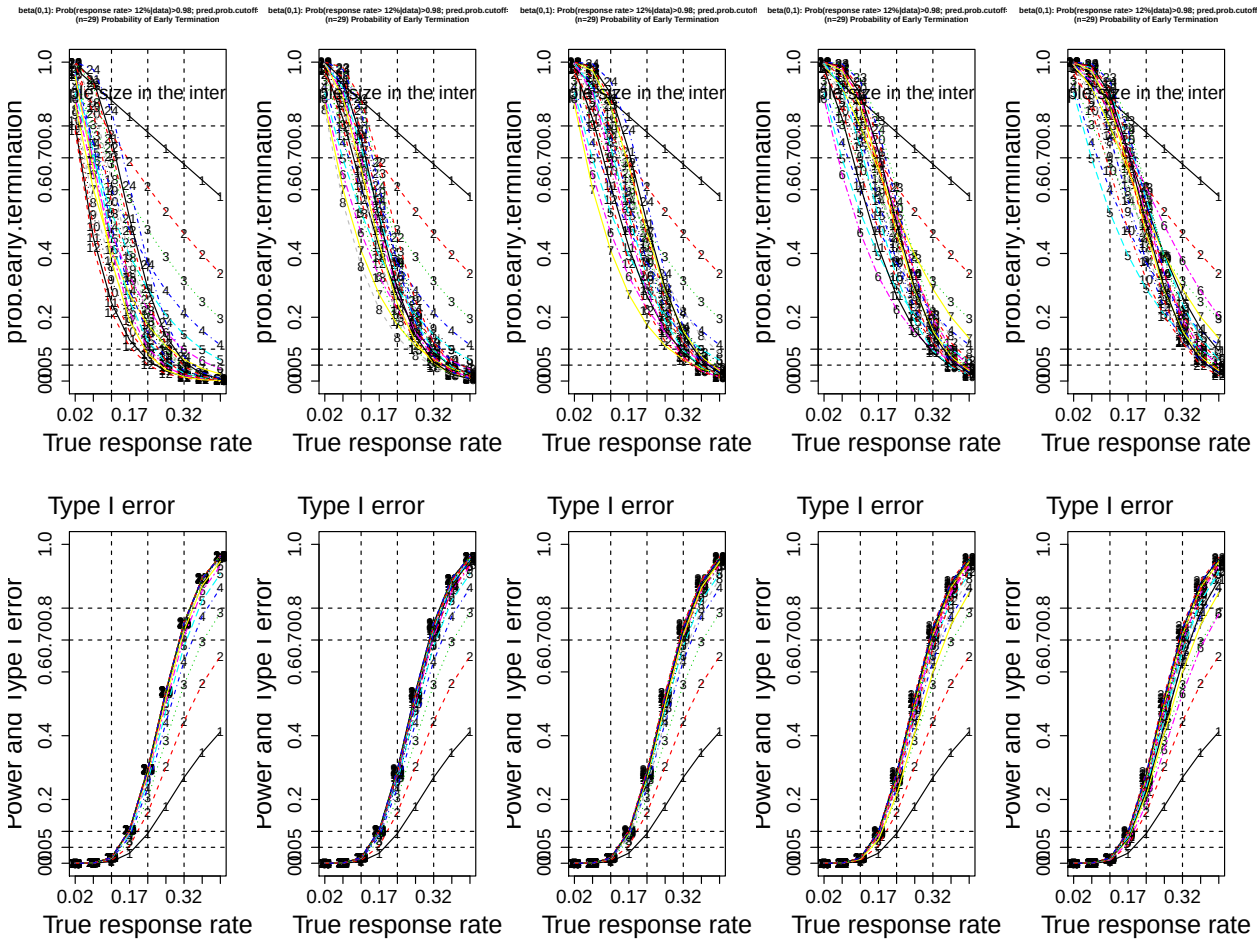
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prob.early.termination
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Power and Type I error
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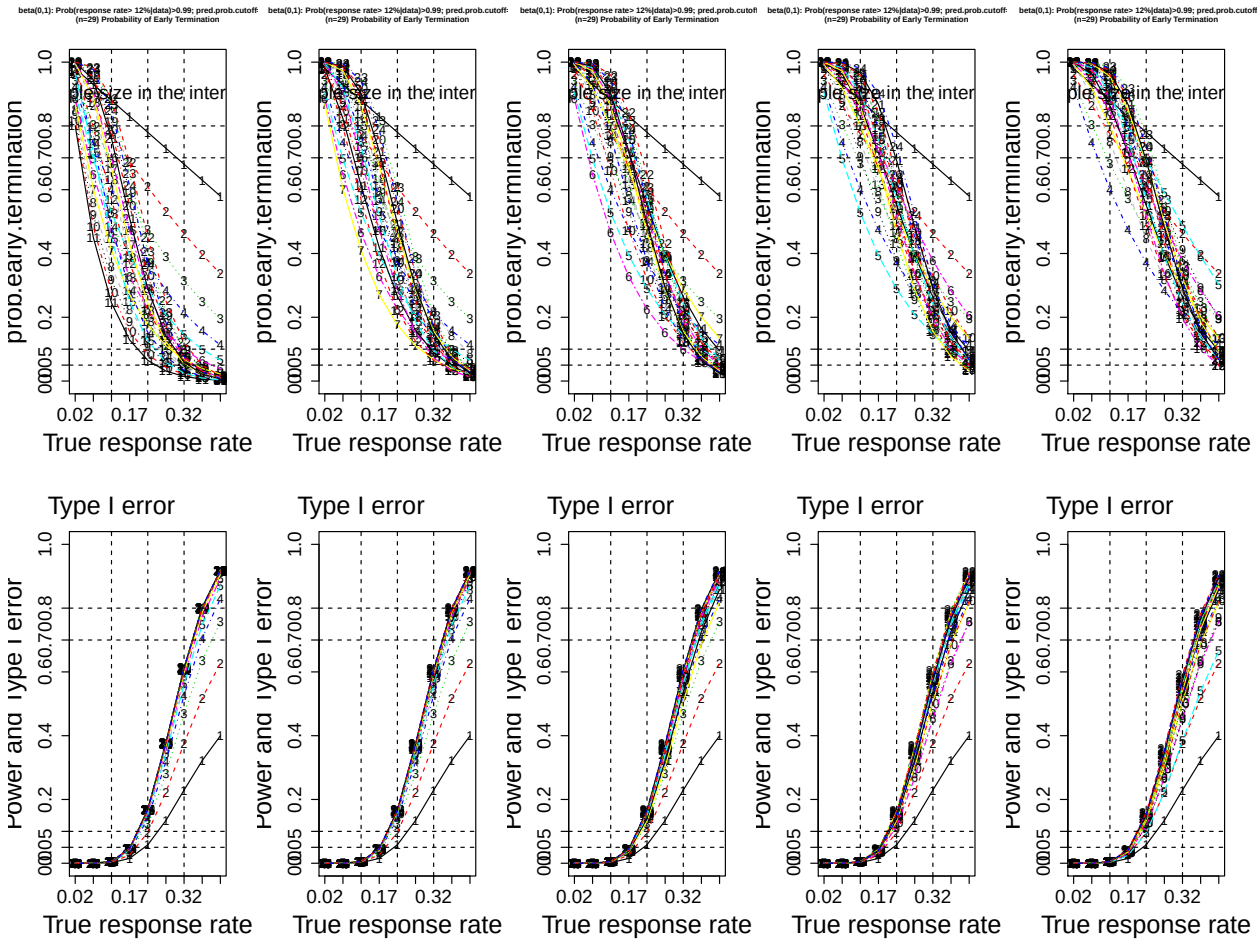
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prob.early.termination
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Power and Type I error
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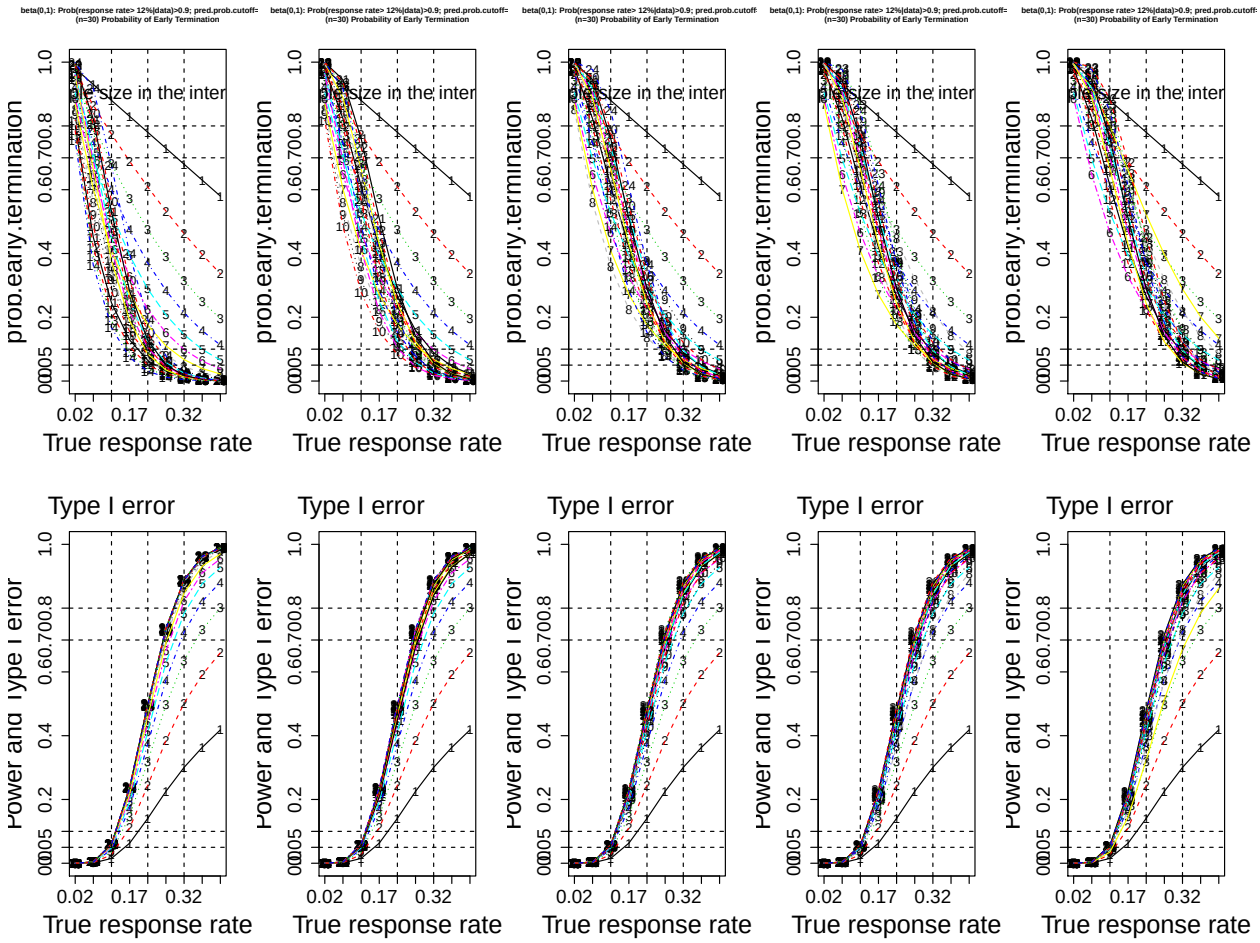
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Power and Type I error
True response rate
Type I error
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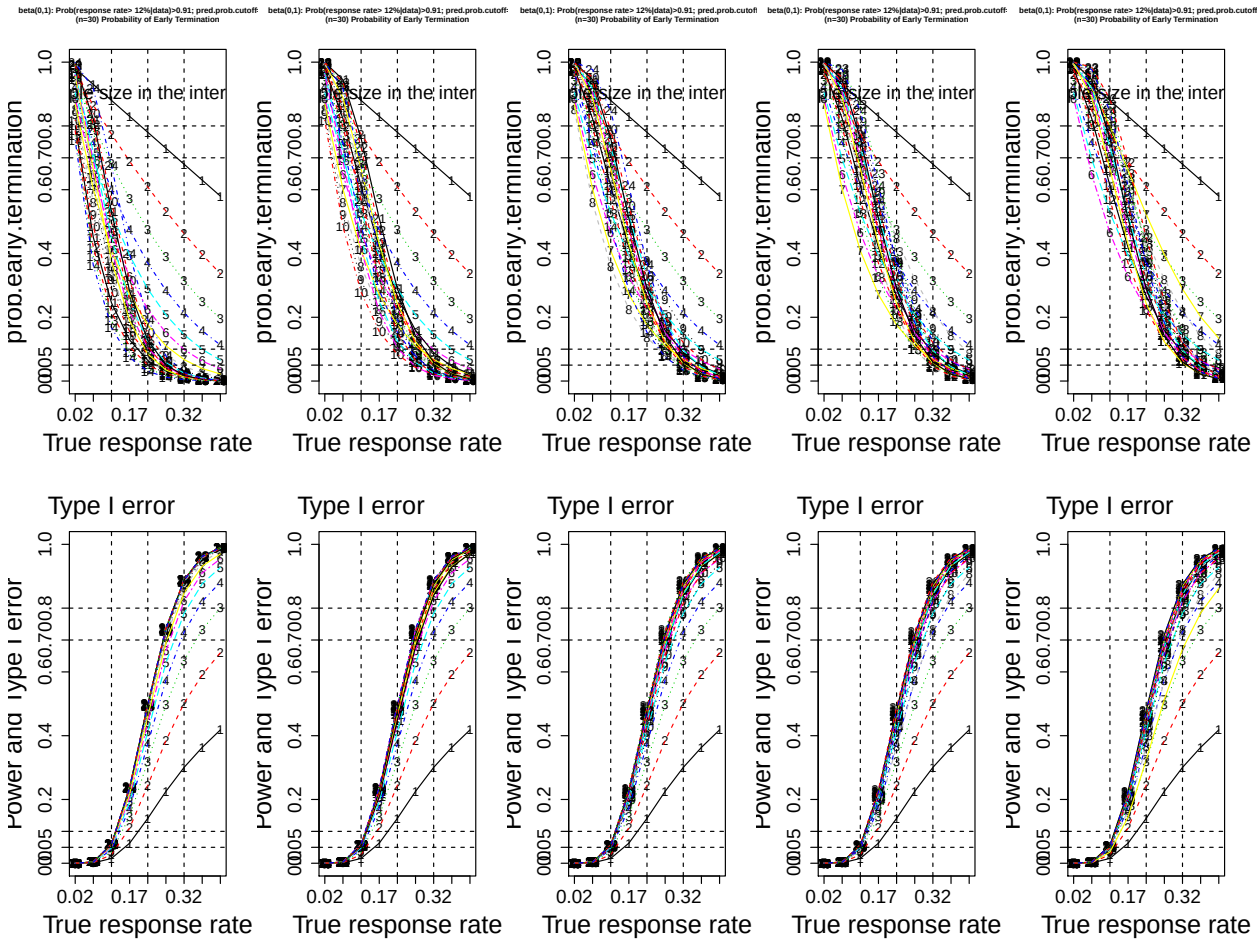
beta(0,1): Prob(response rate> 12%|data)>0.91; pred.prob.cutoff
(n=30) Probability of Early Termination
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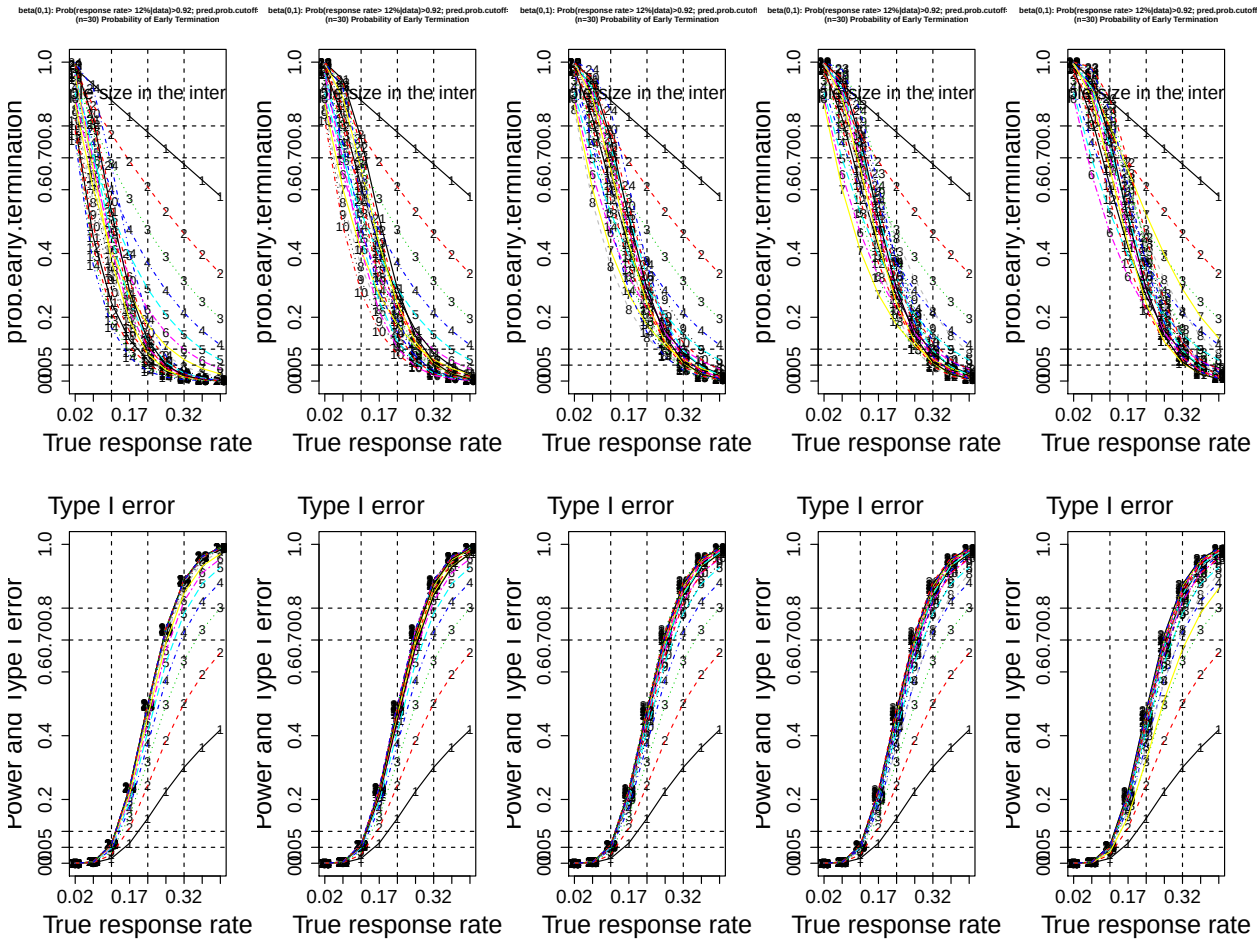
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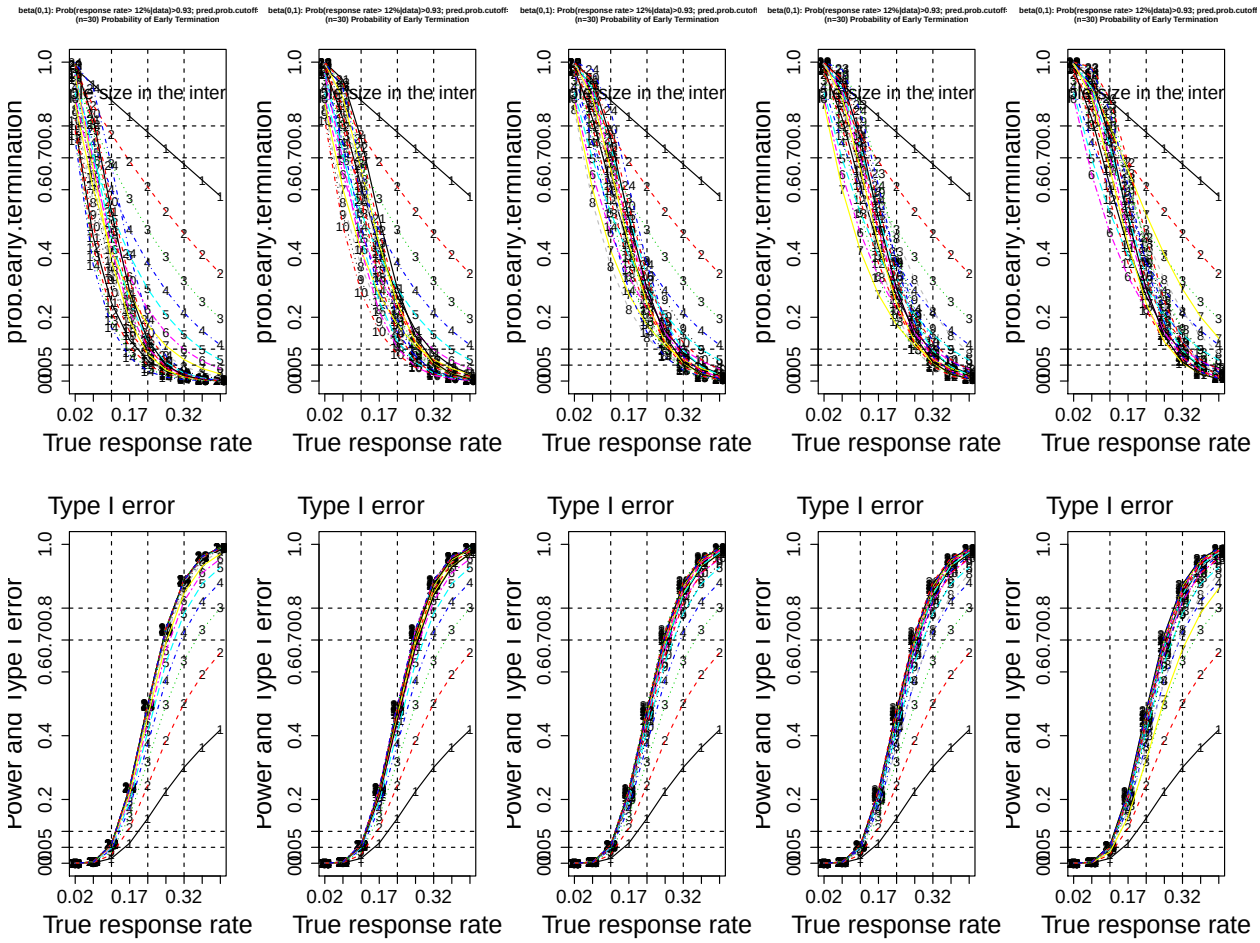
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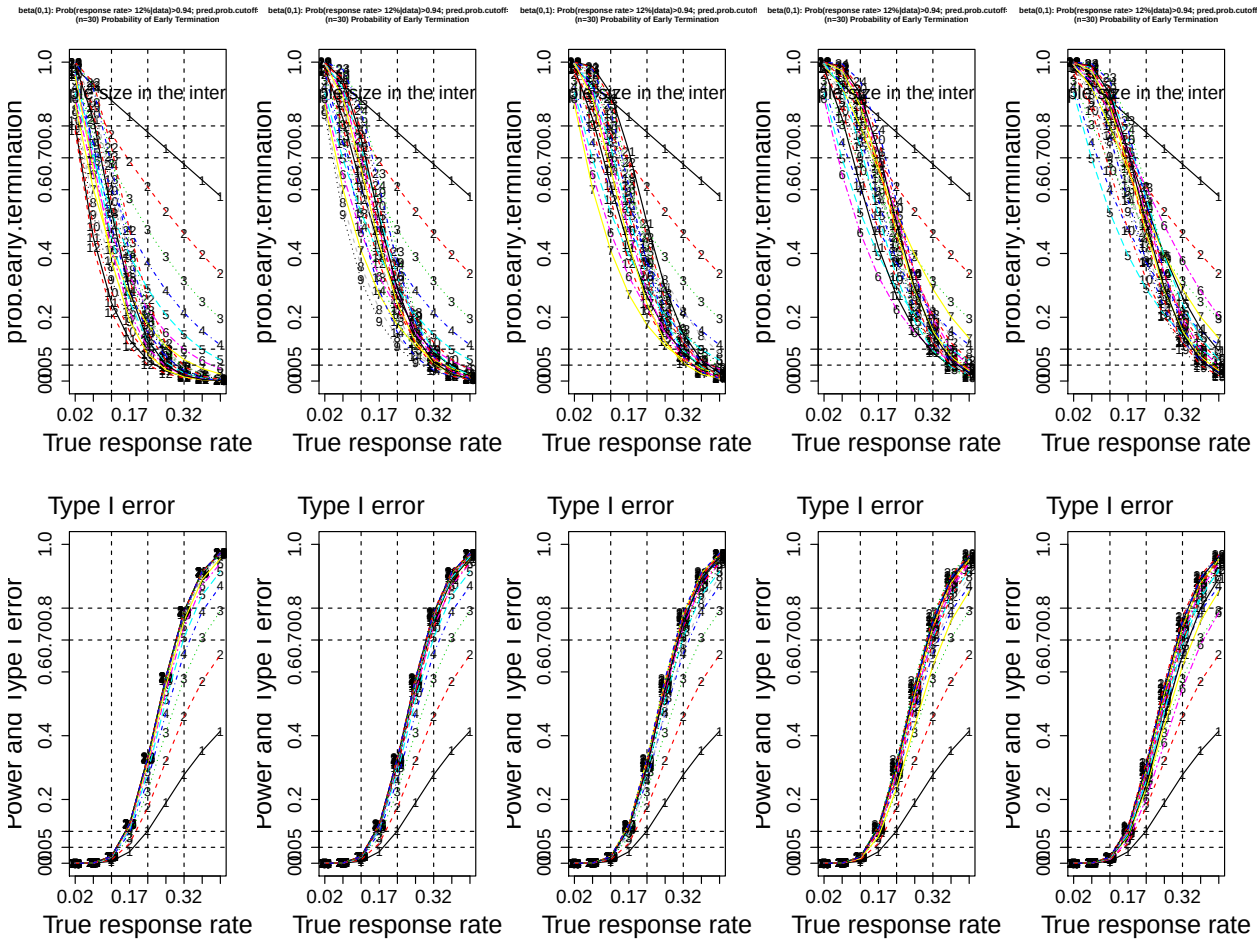
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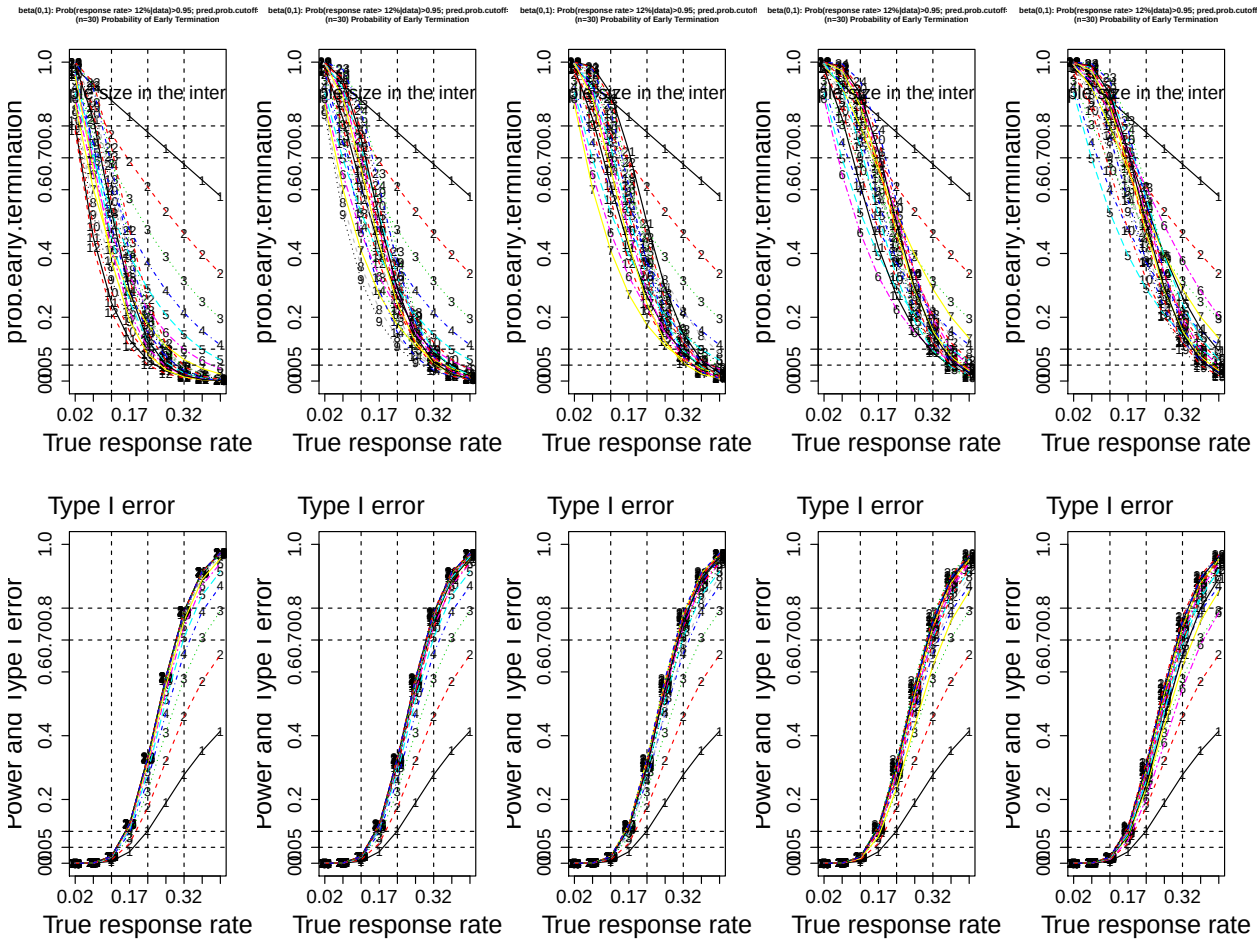
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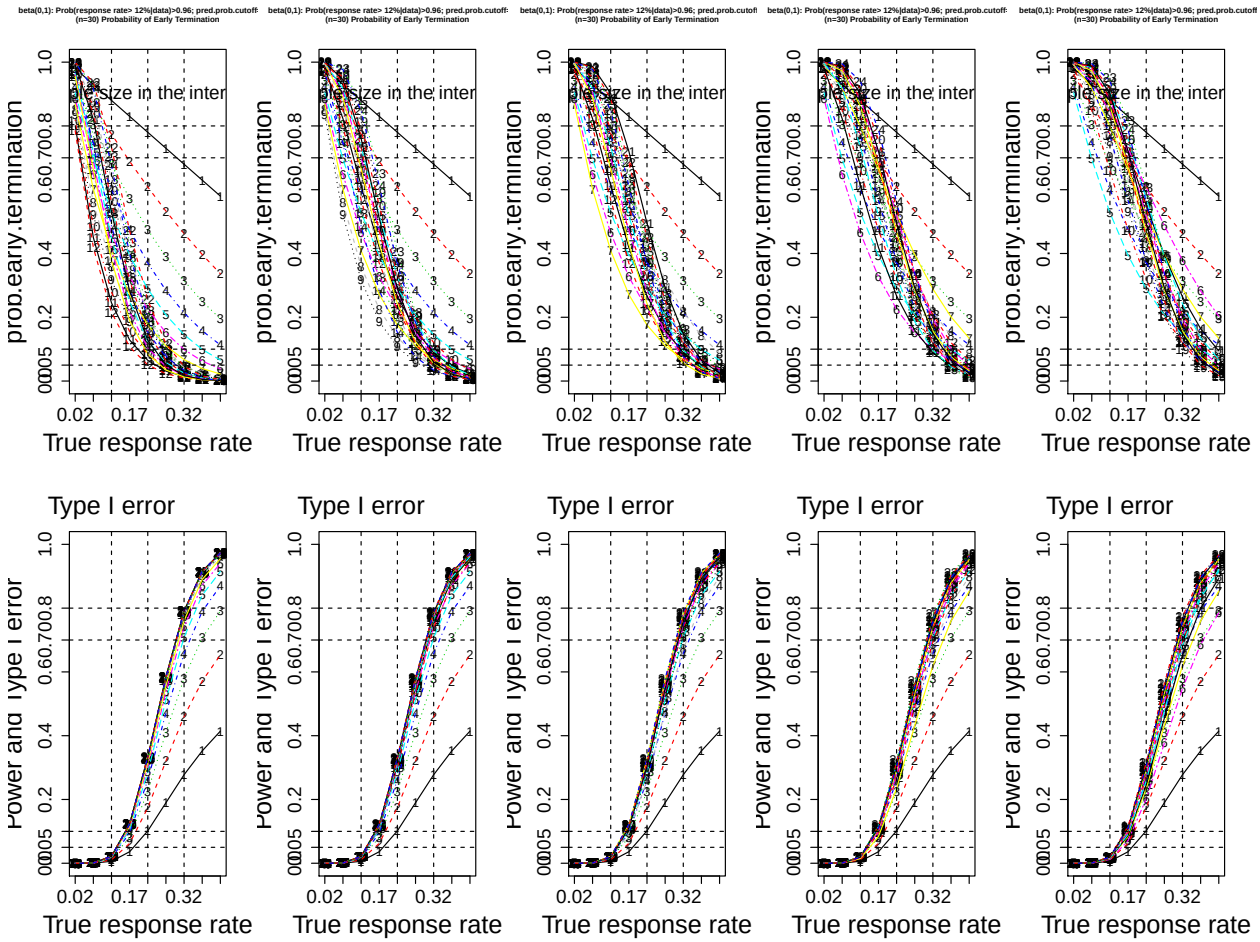
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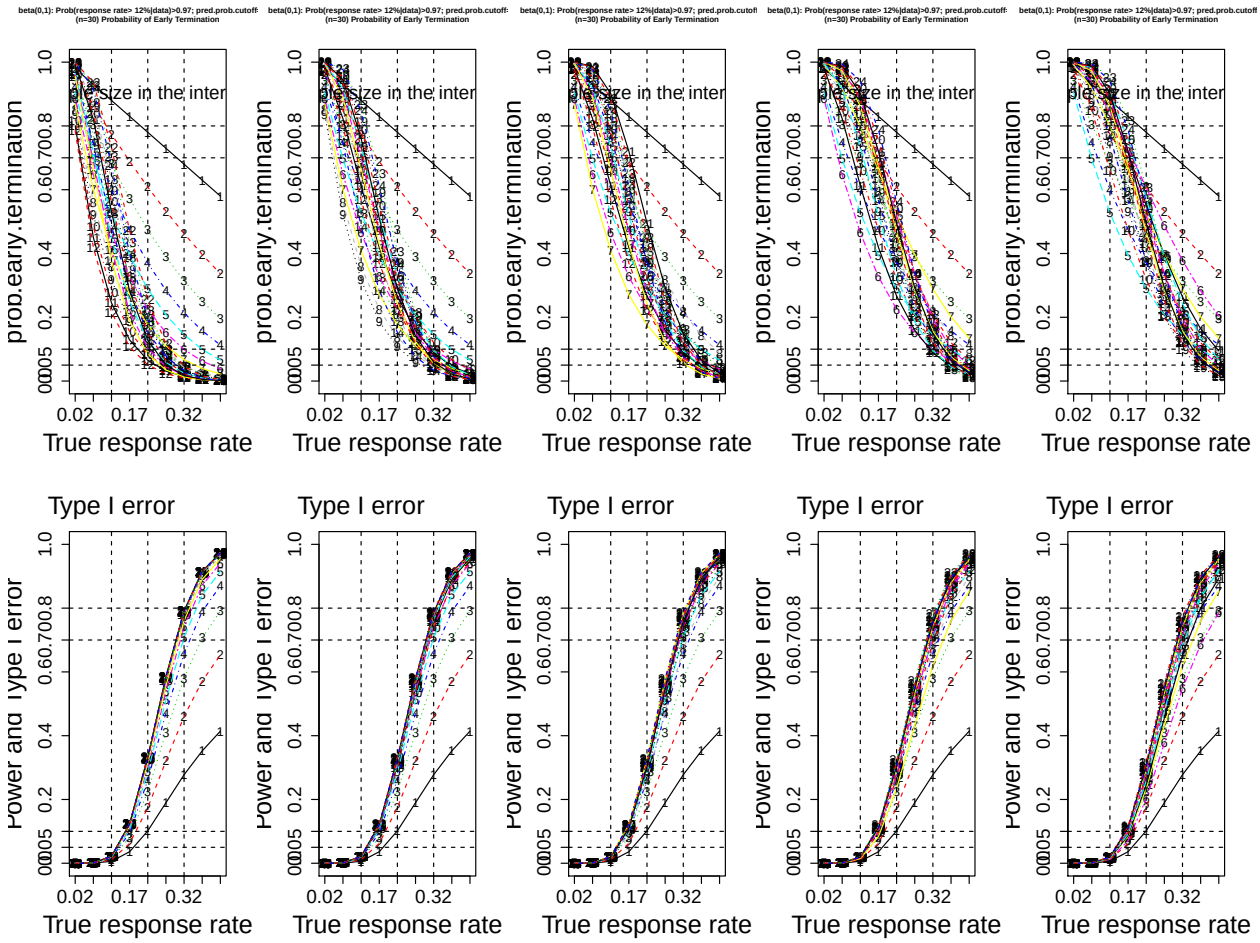
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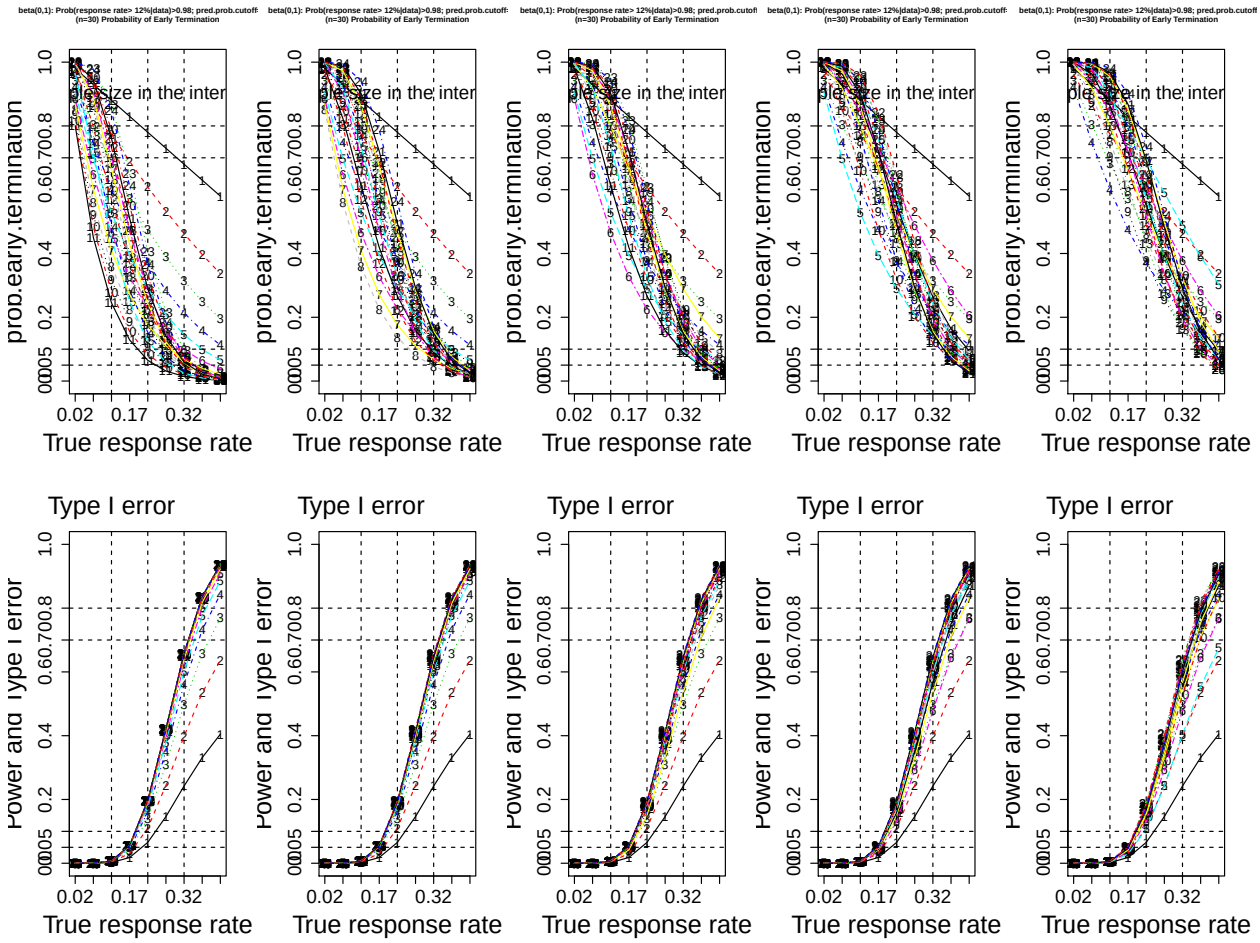
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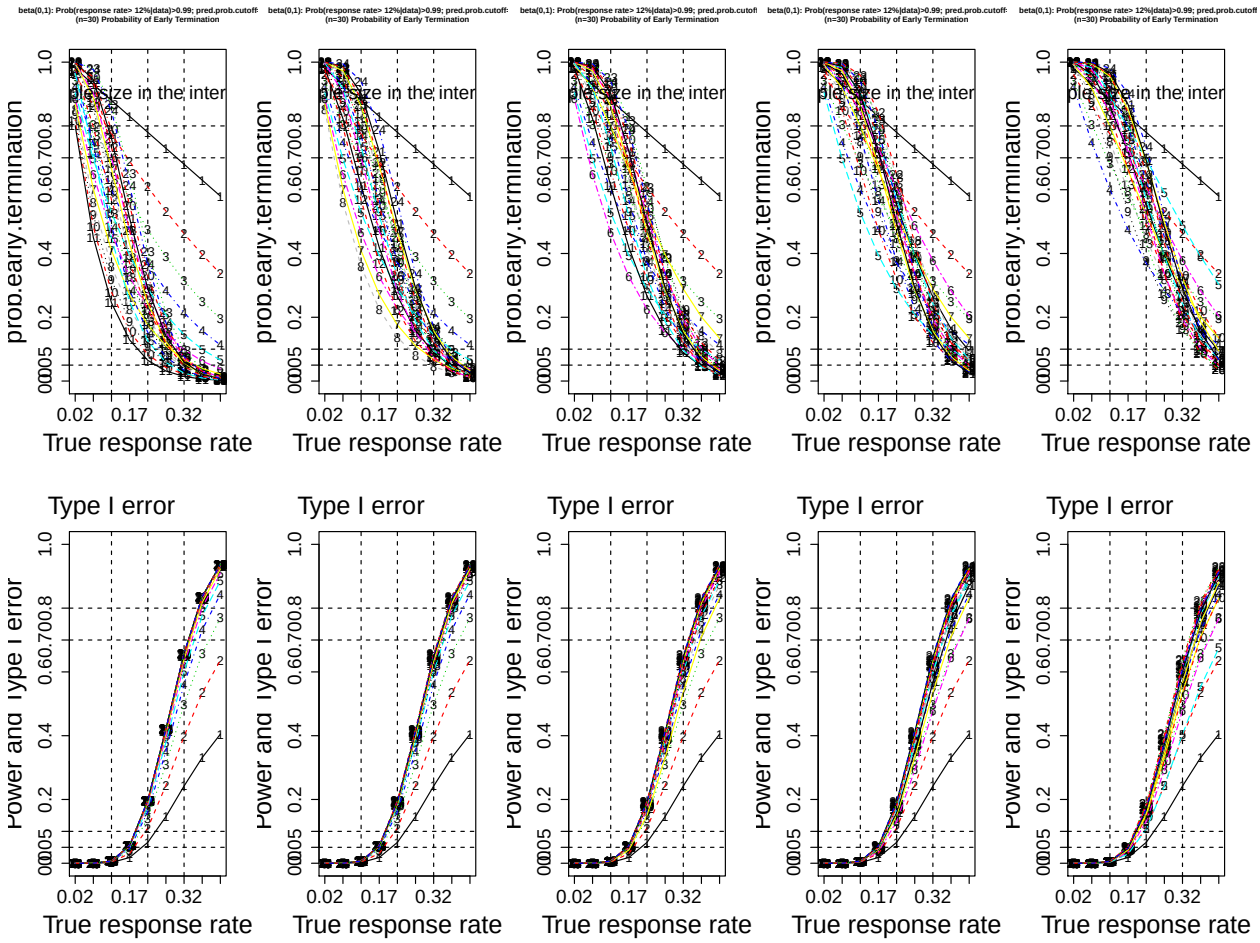
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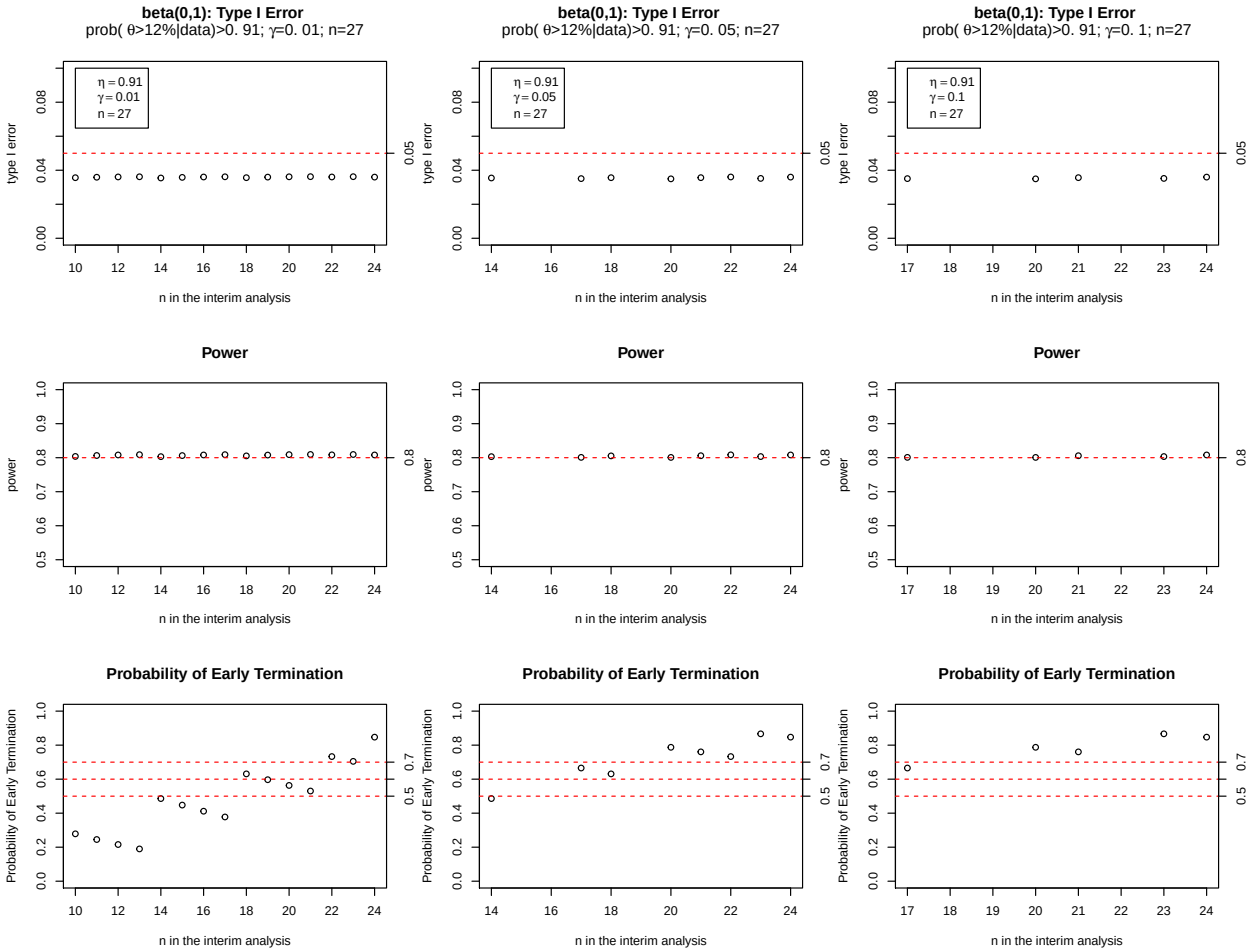
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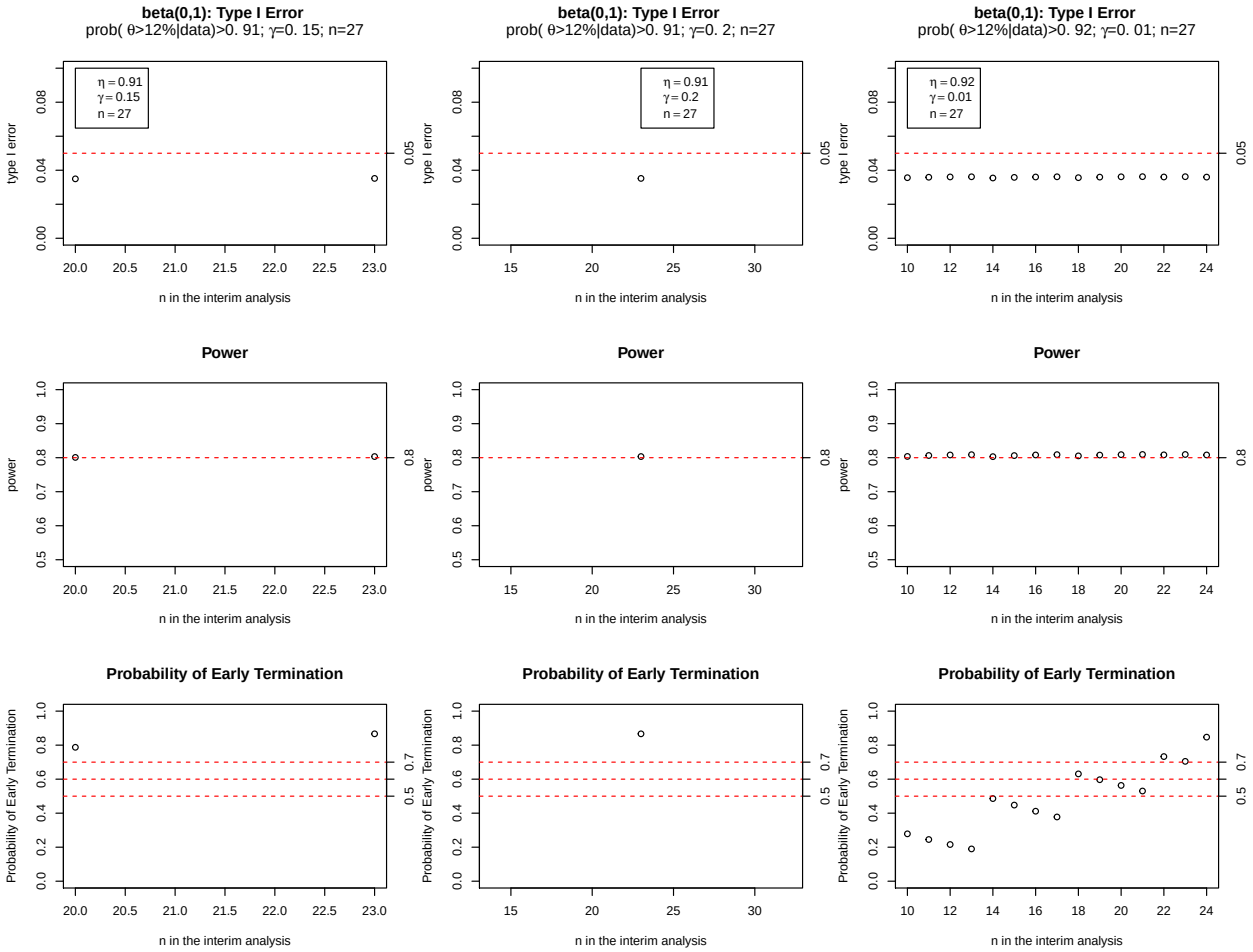
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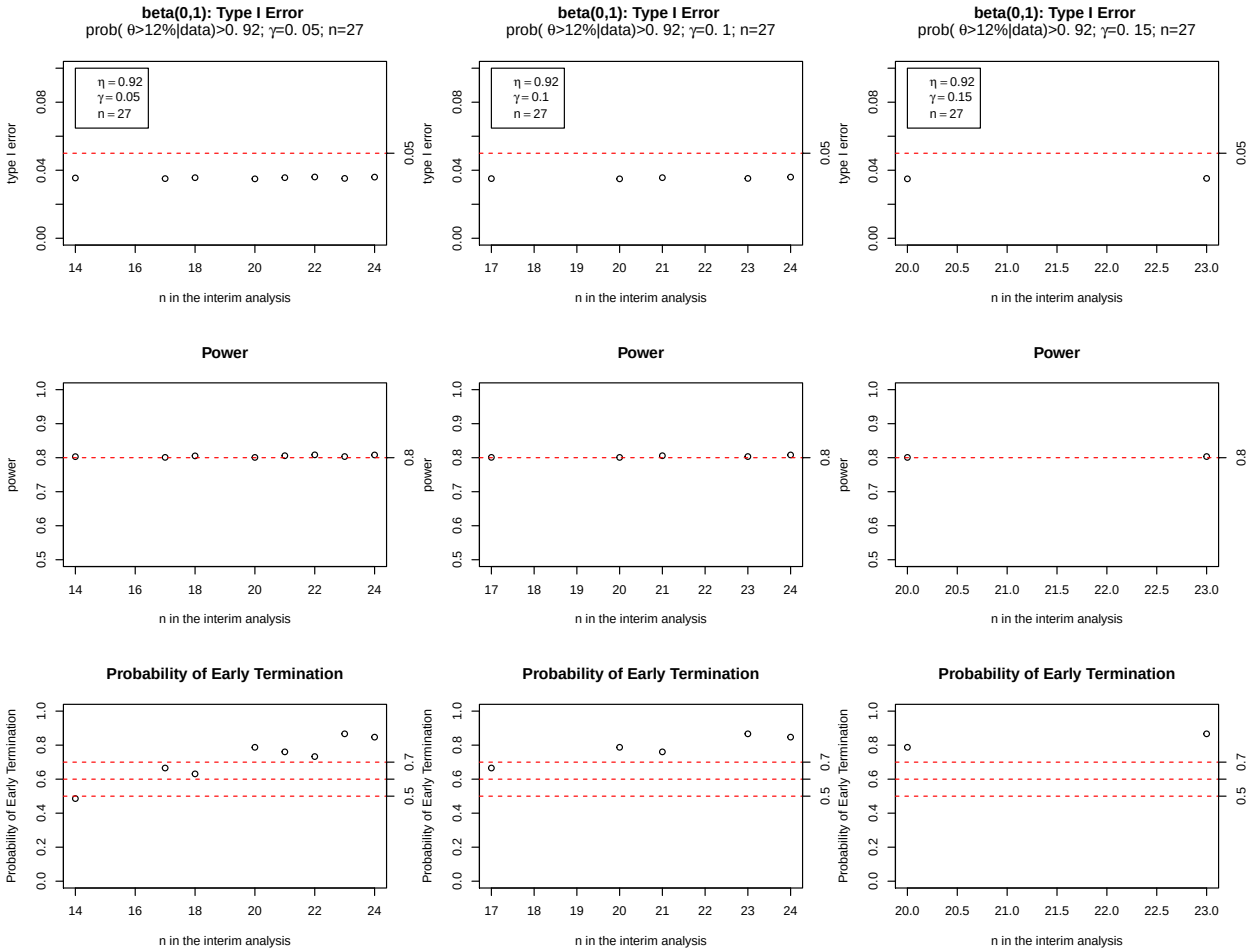
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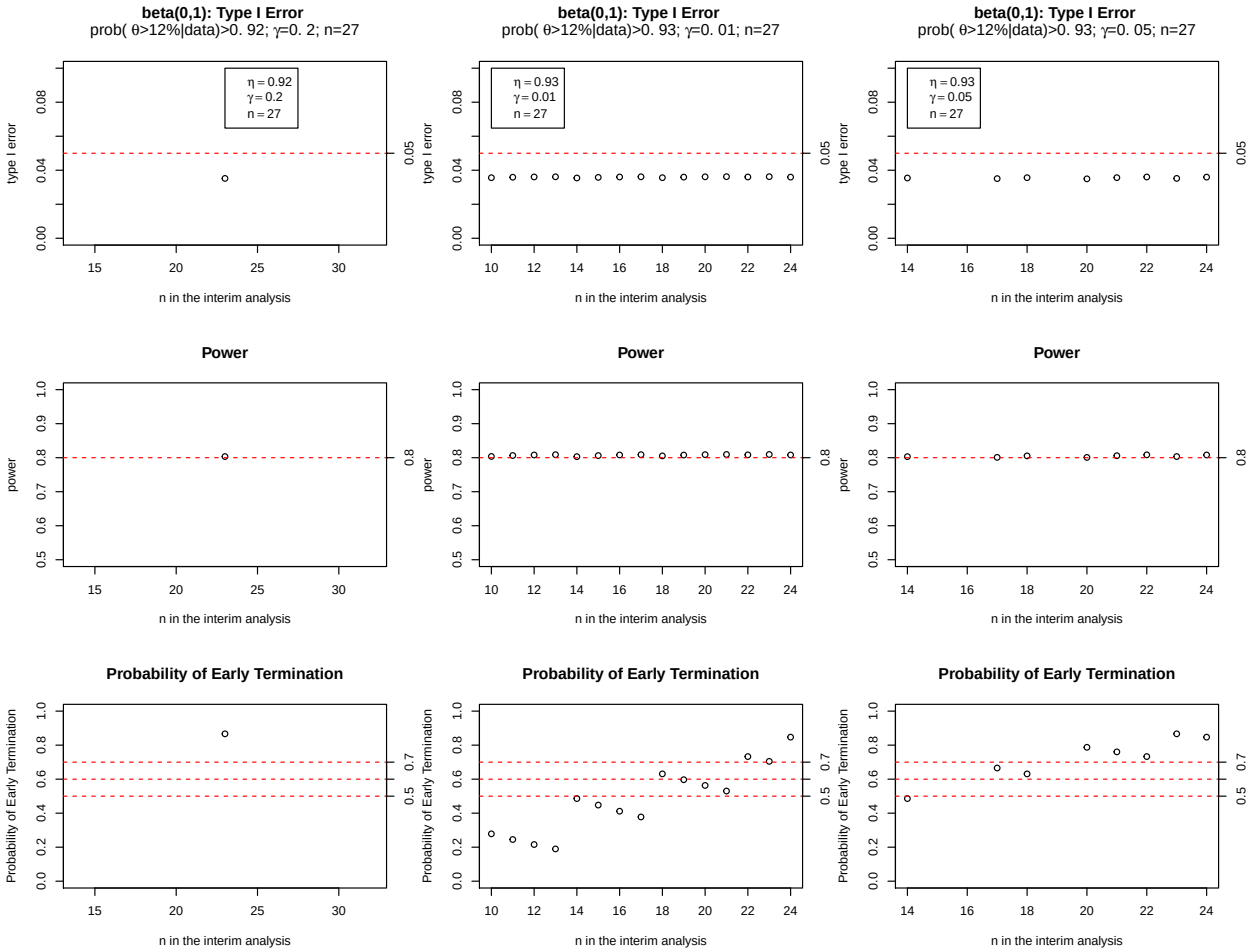
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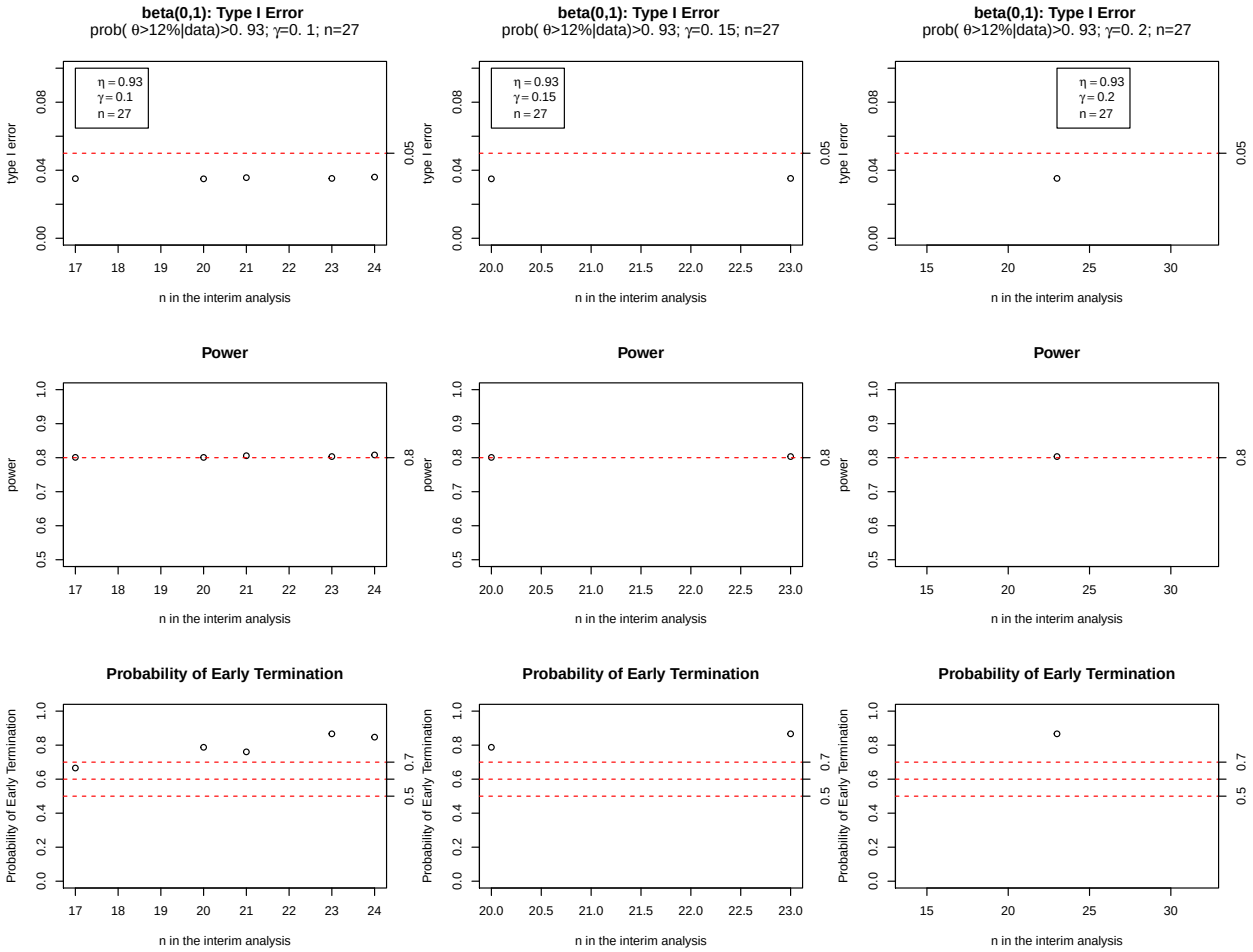
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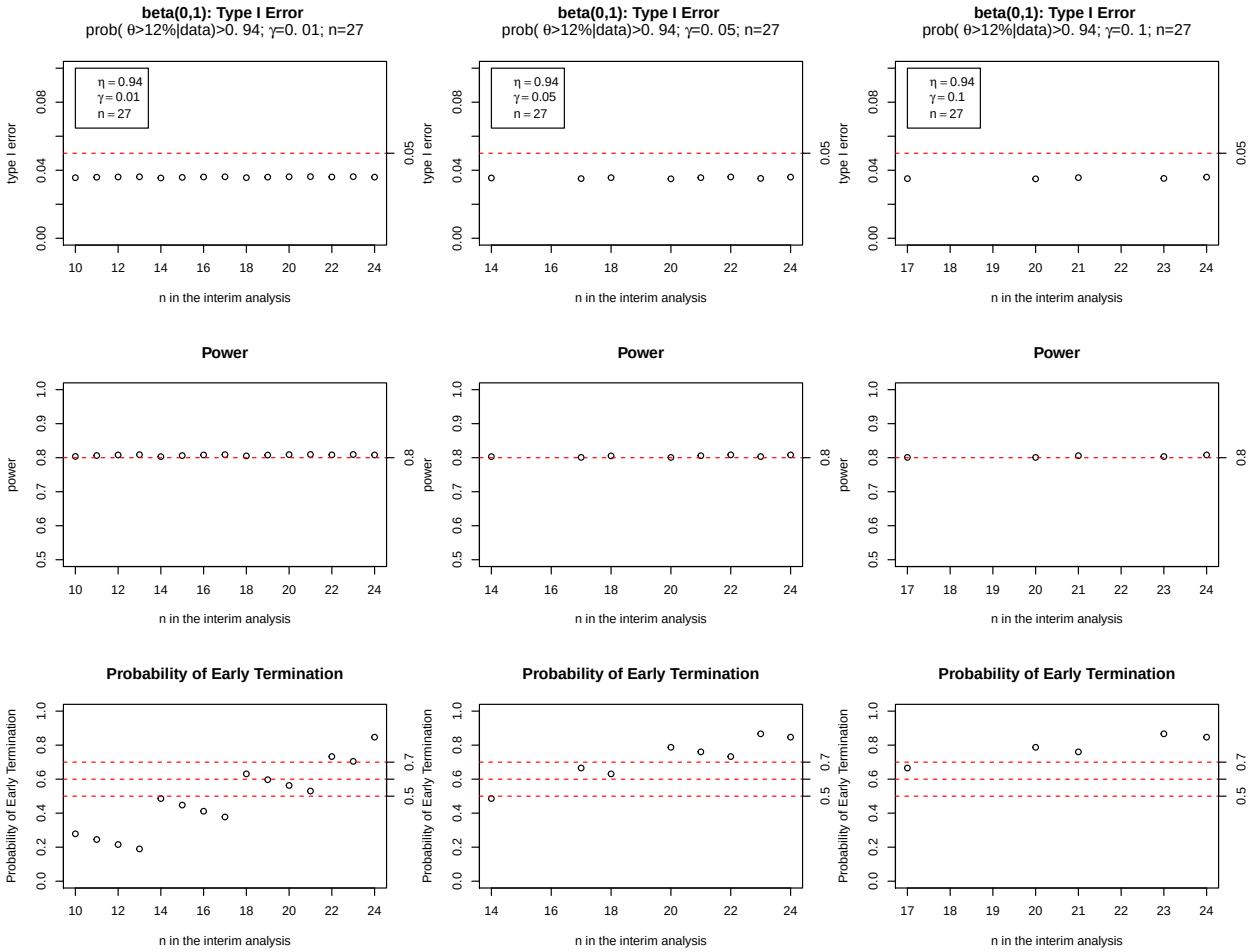
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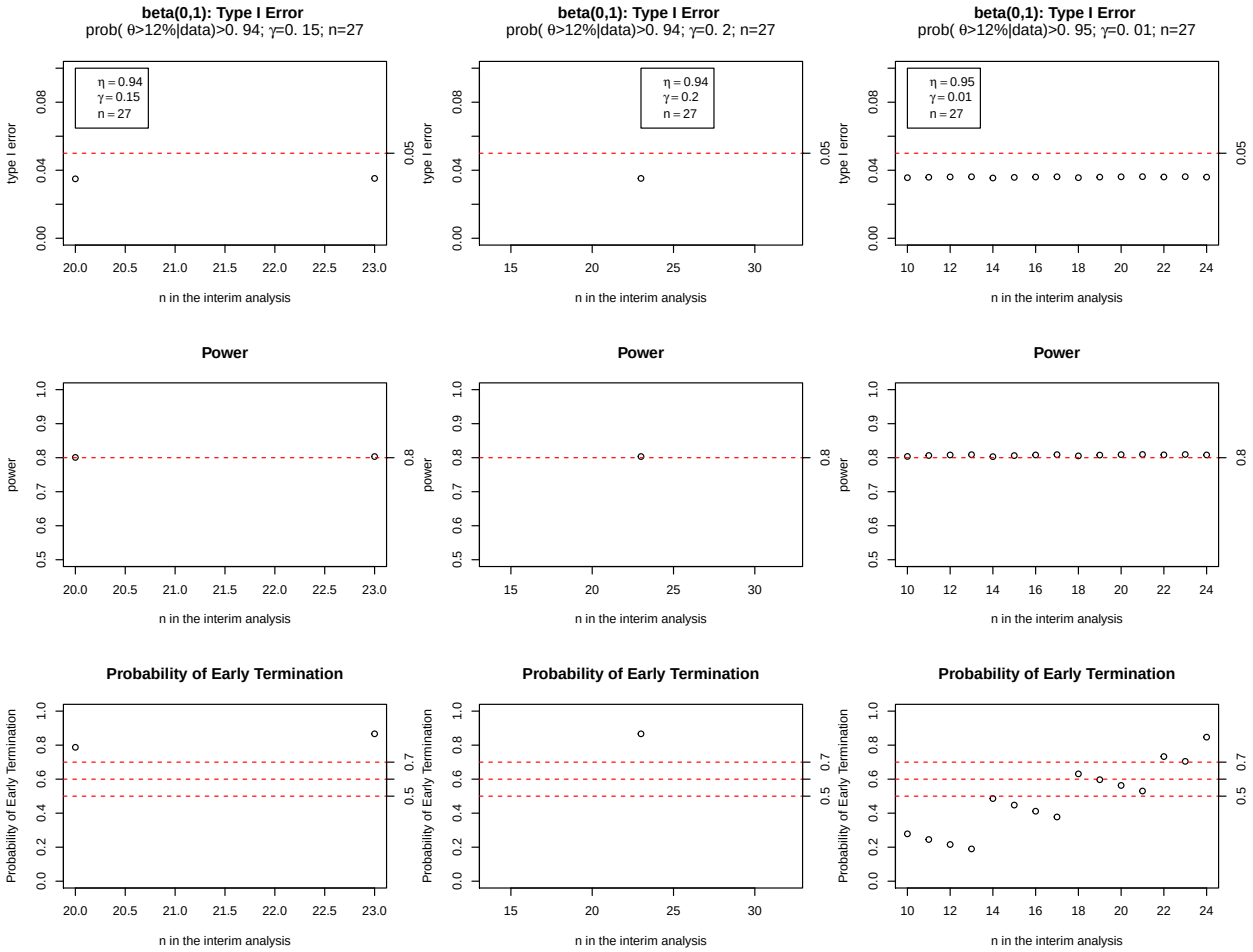
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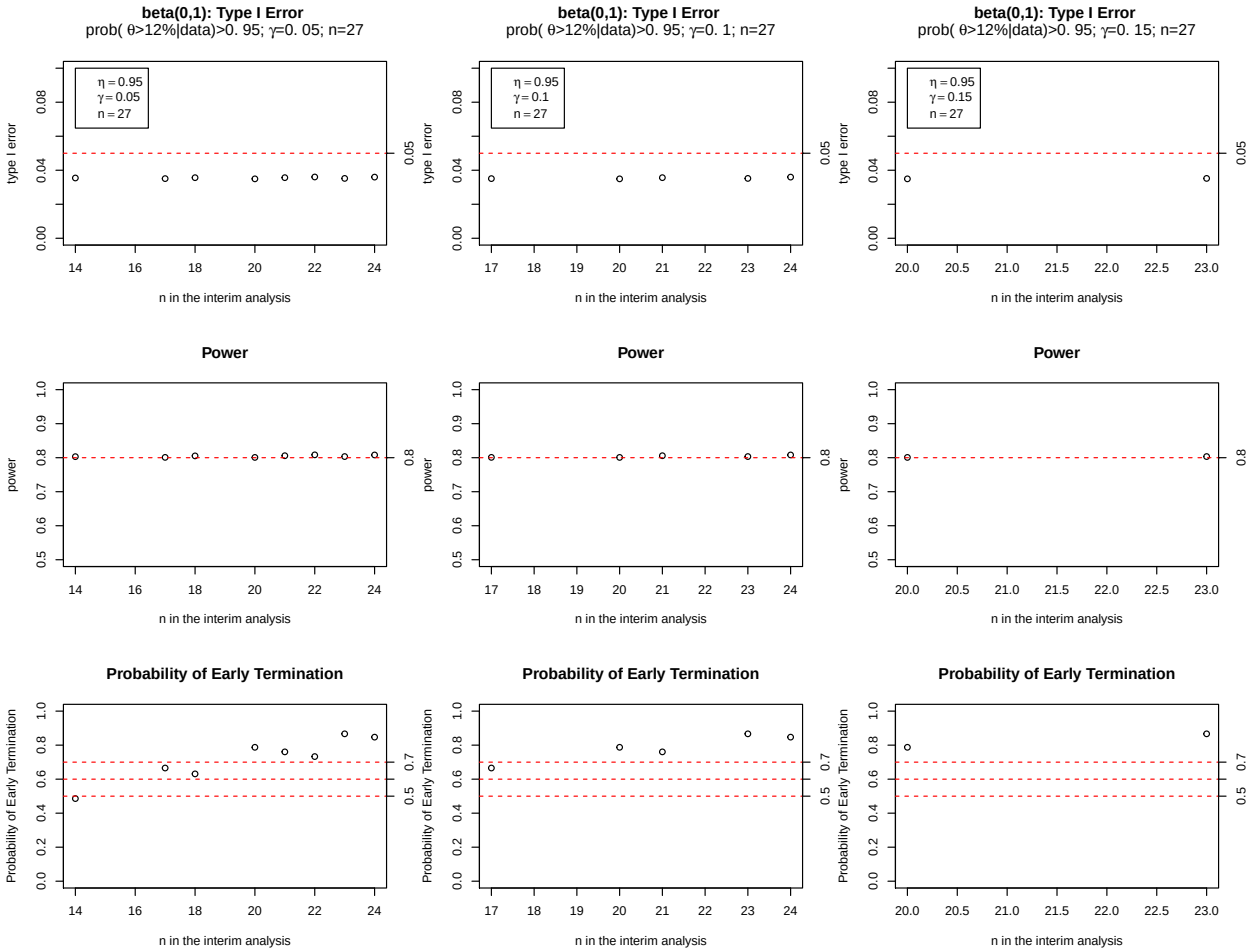
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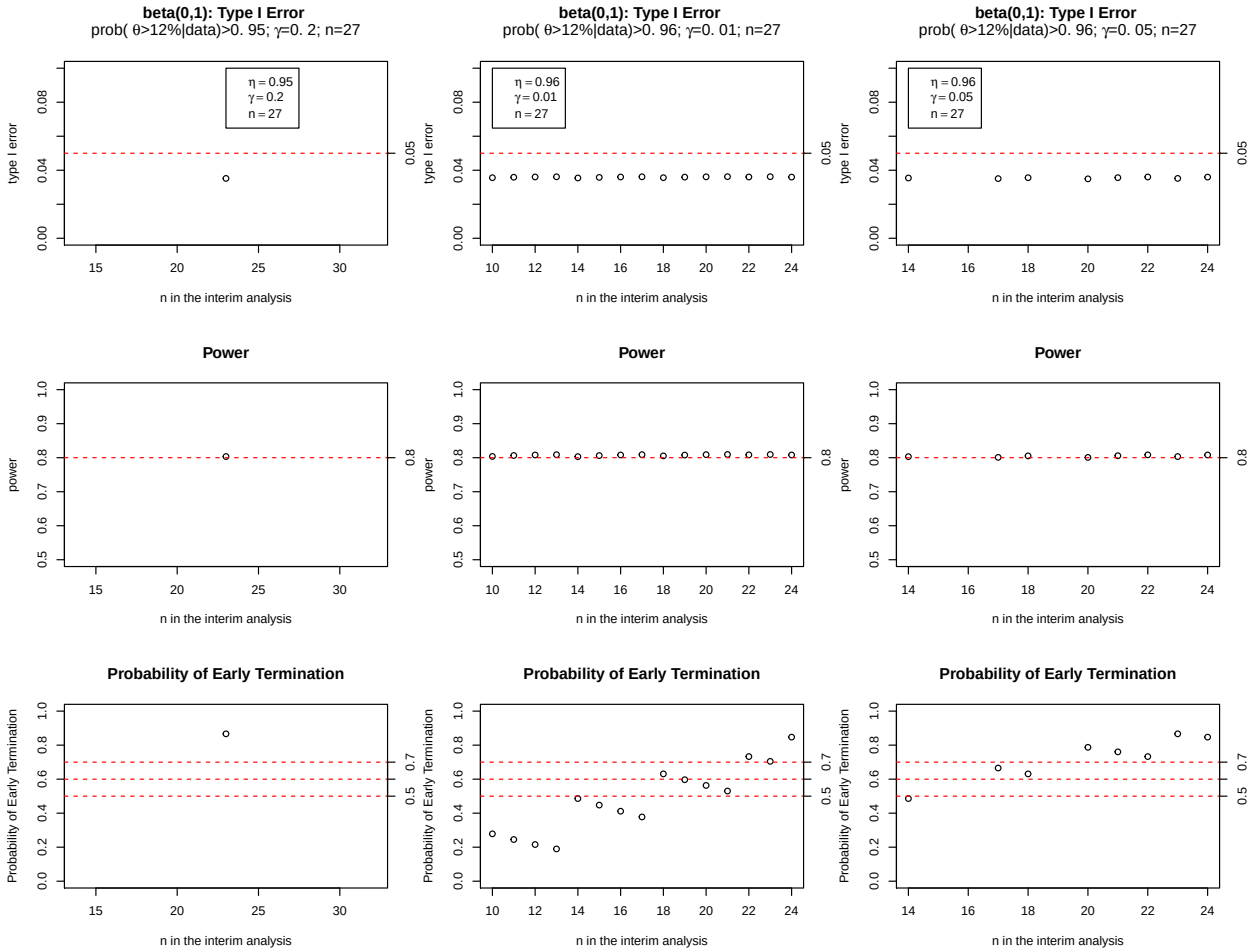
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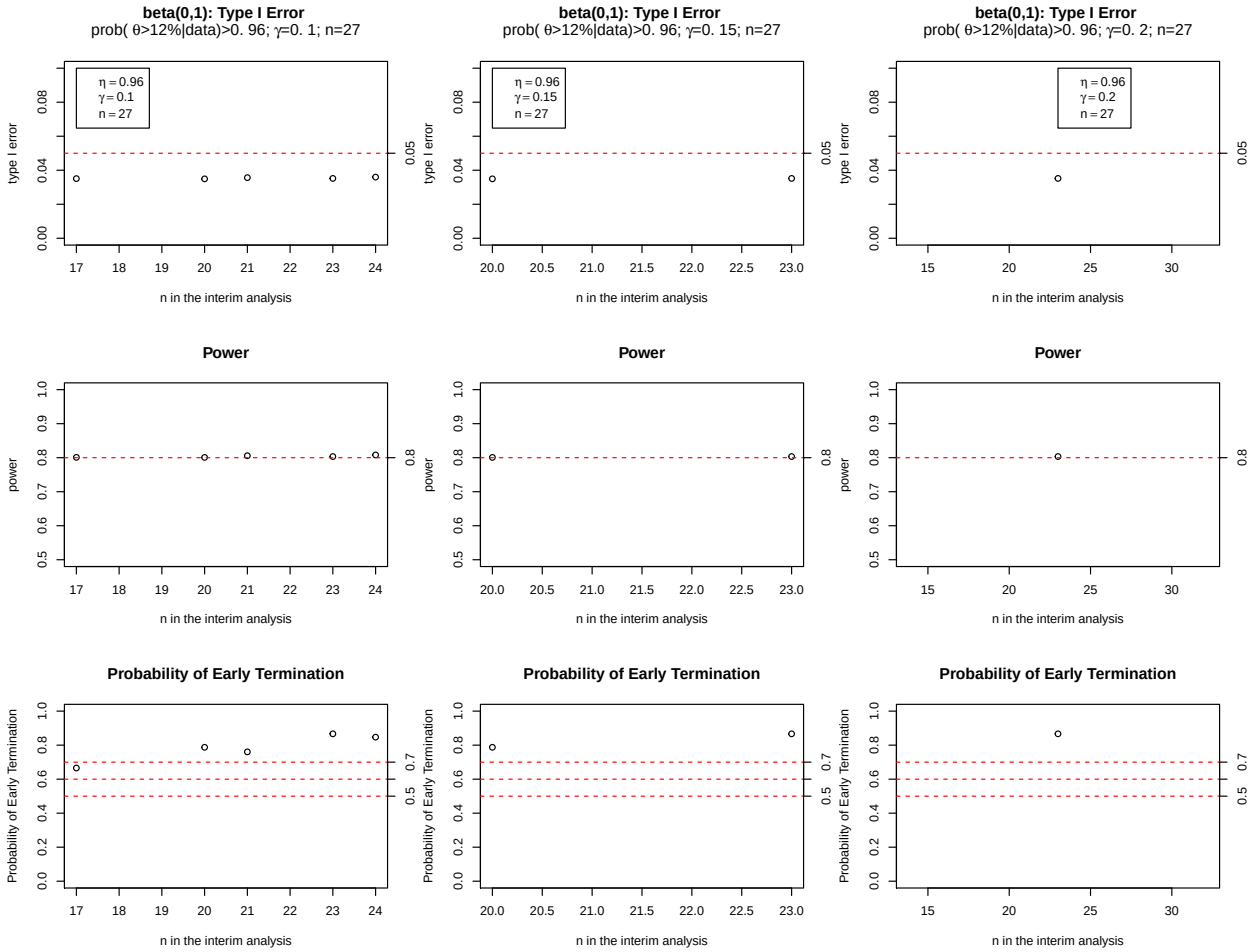
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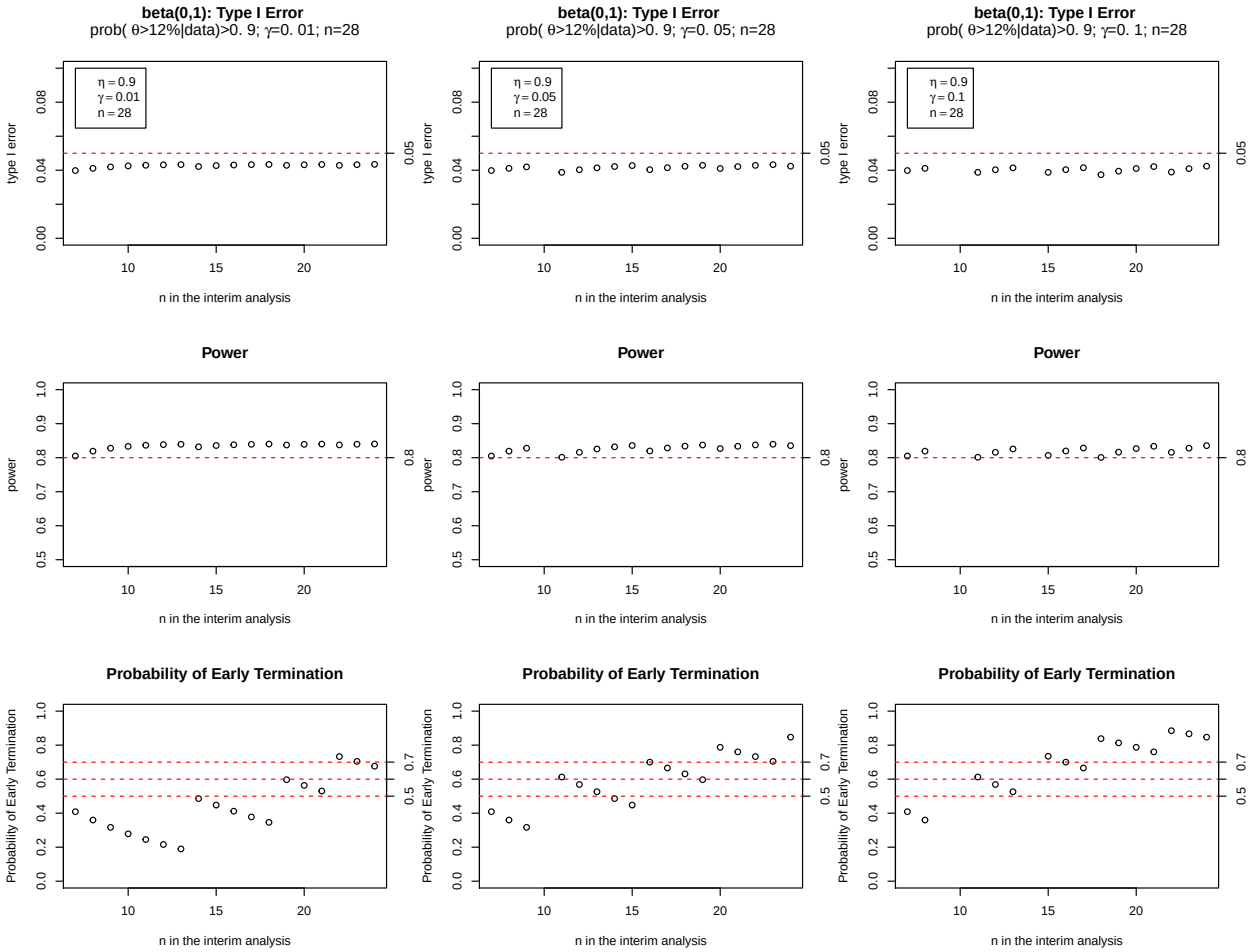
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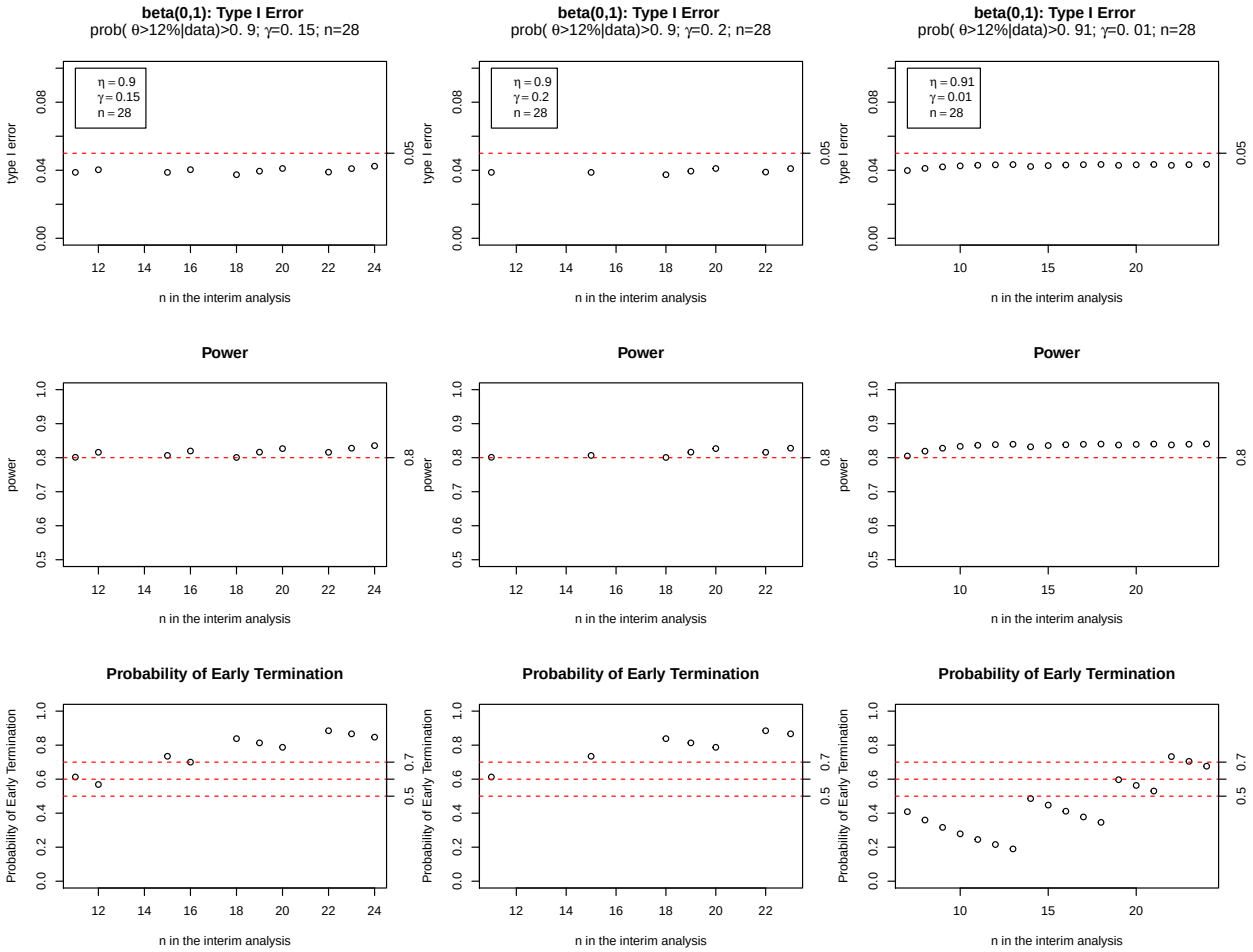
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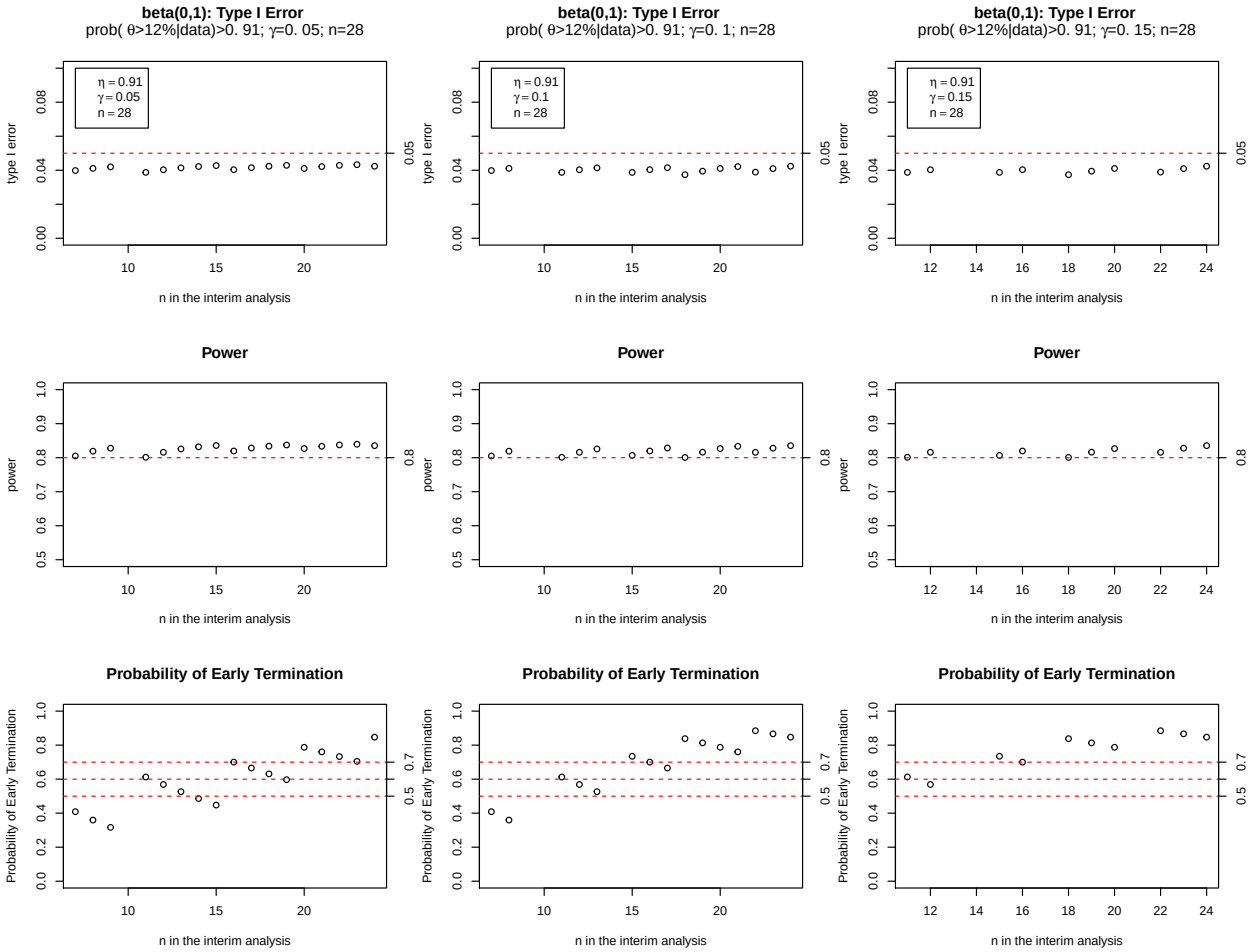
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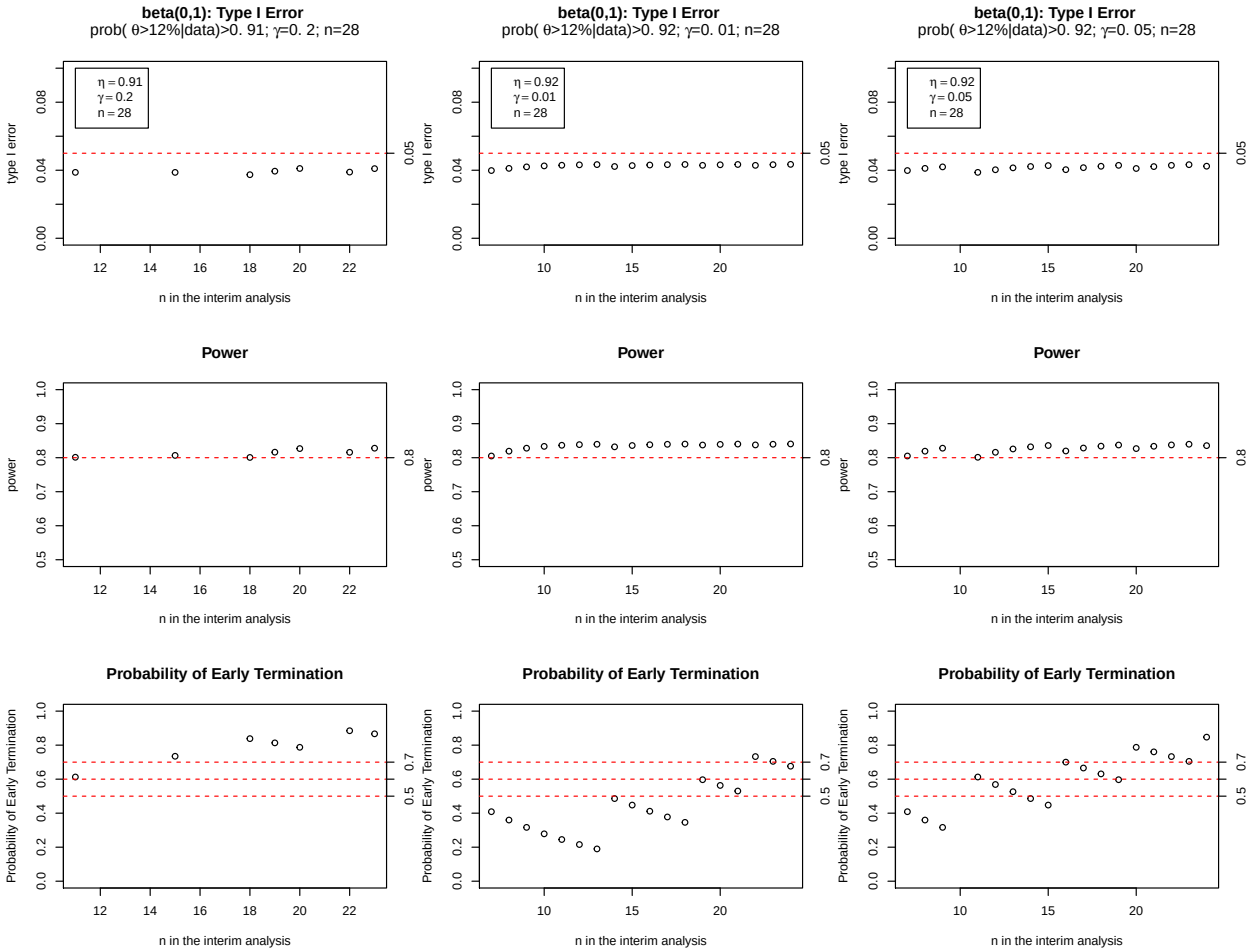
beta(0,1): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 2; n=28
η = 0.91
γ = 0.2
n = 28
type I error
n in the interim analysis
beta(0,1): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 01; n=28
η = 0.92
γ = 0.01
n = 28
type I error
n in the interim analysis
beta(0,1): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 05; n=28
η = 0.92
γ = 0.05
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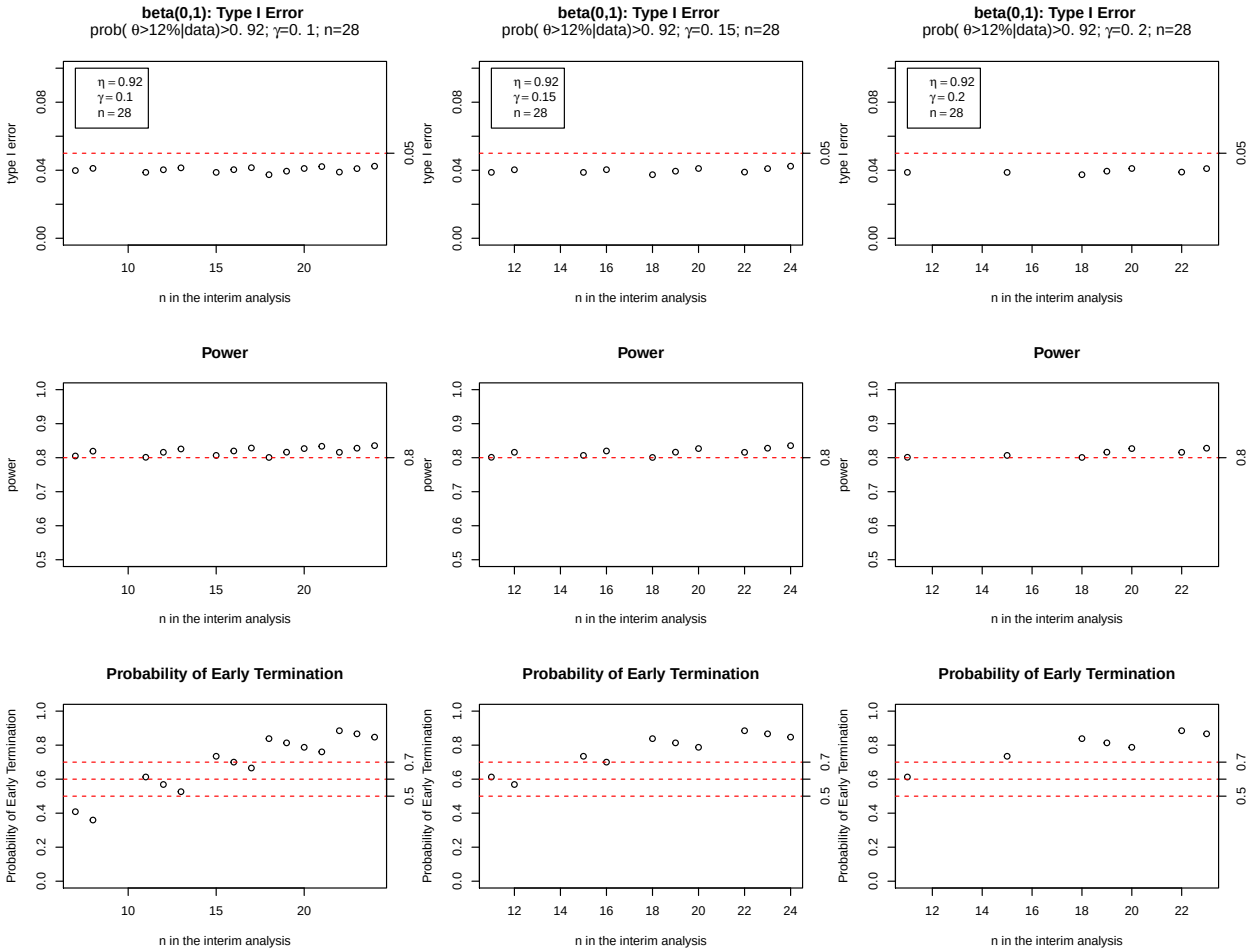
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beta(0,1): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 15; n=28
η = 0.92
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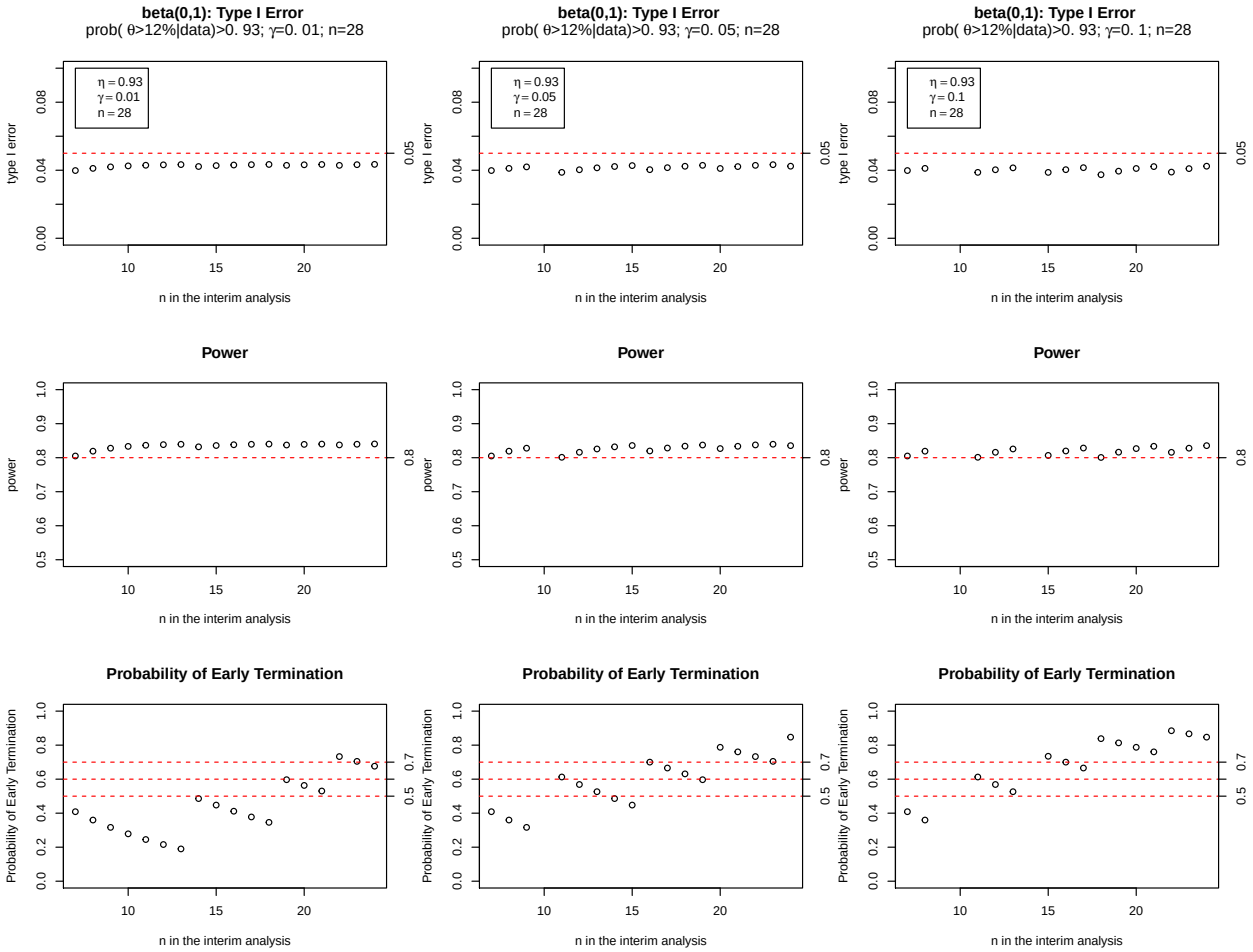
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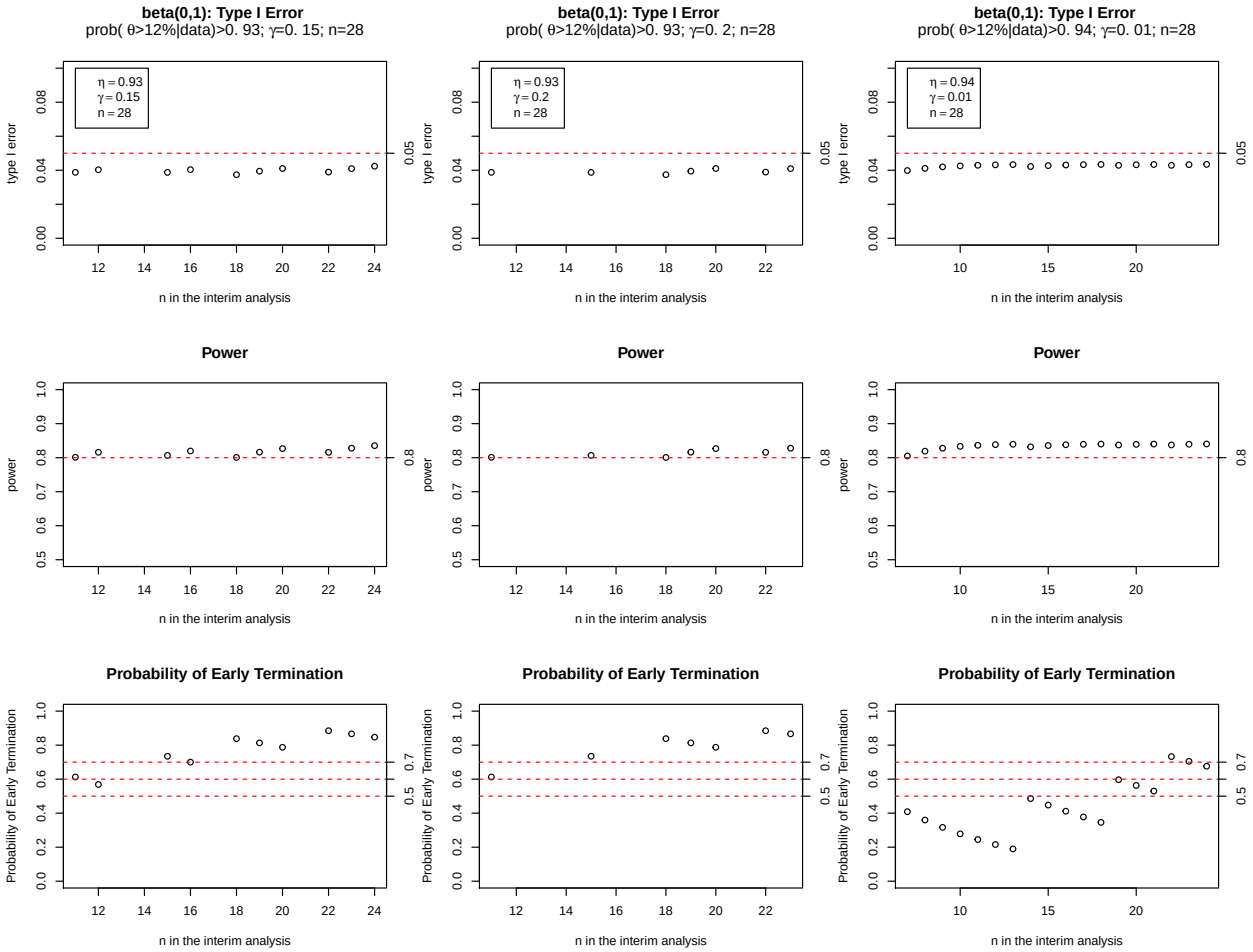
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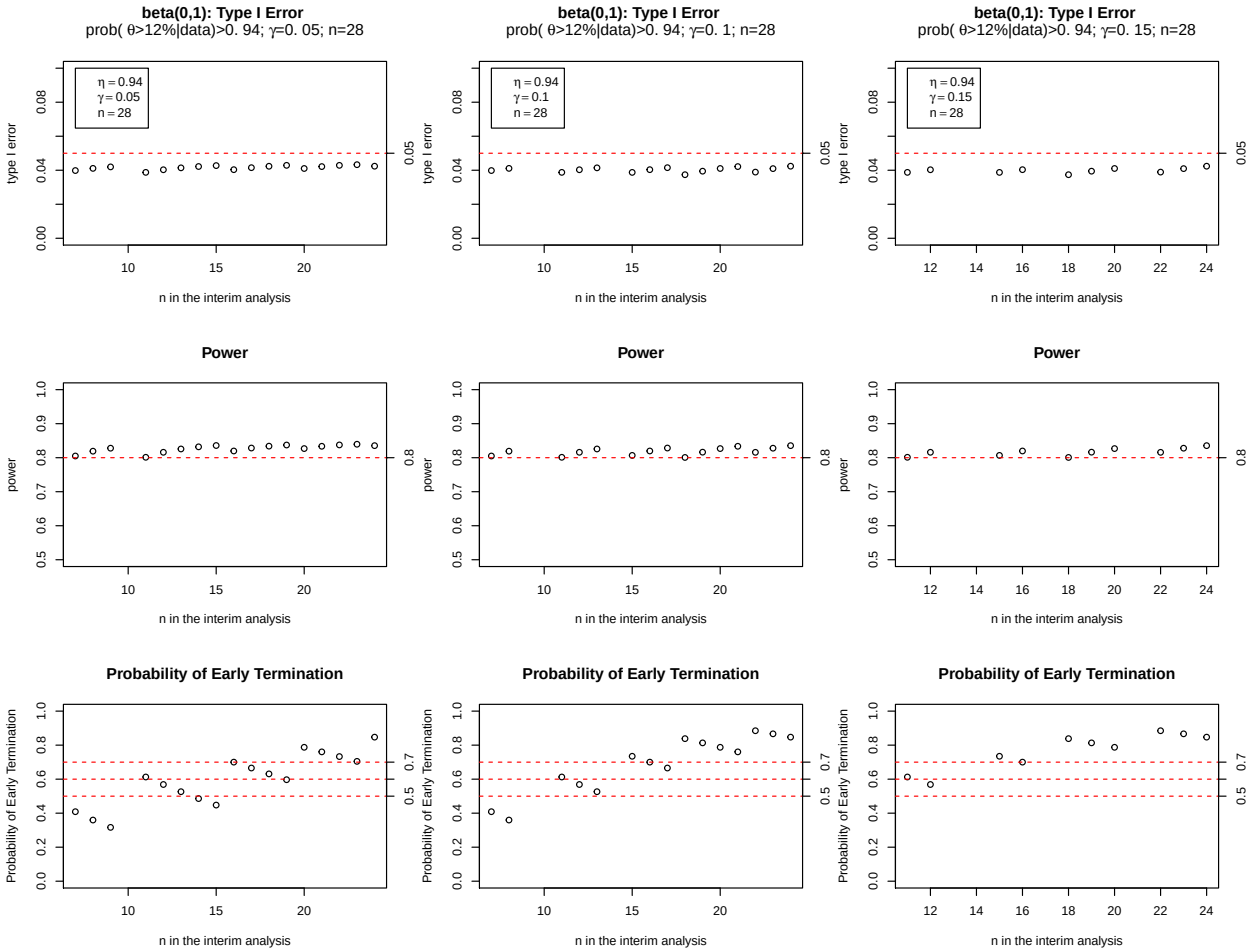
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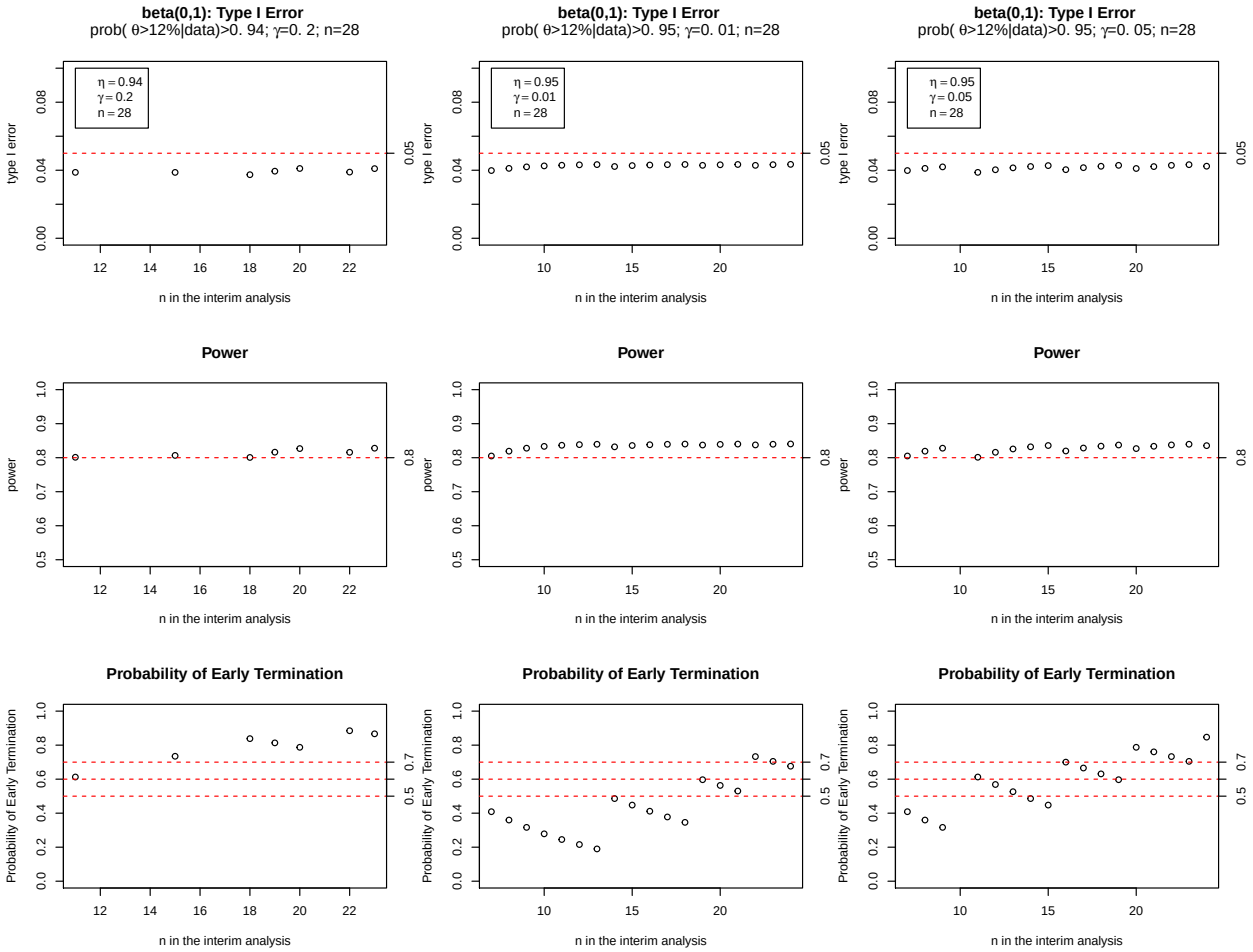
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γ = 0.2
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beta(0,1): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 01; n=28
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beta(0,1): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 05; n=28
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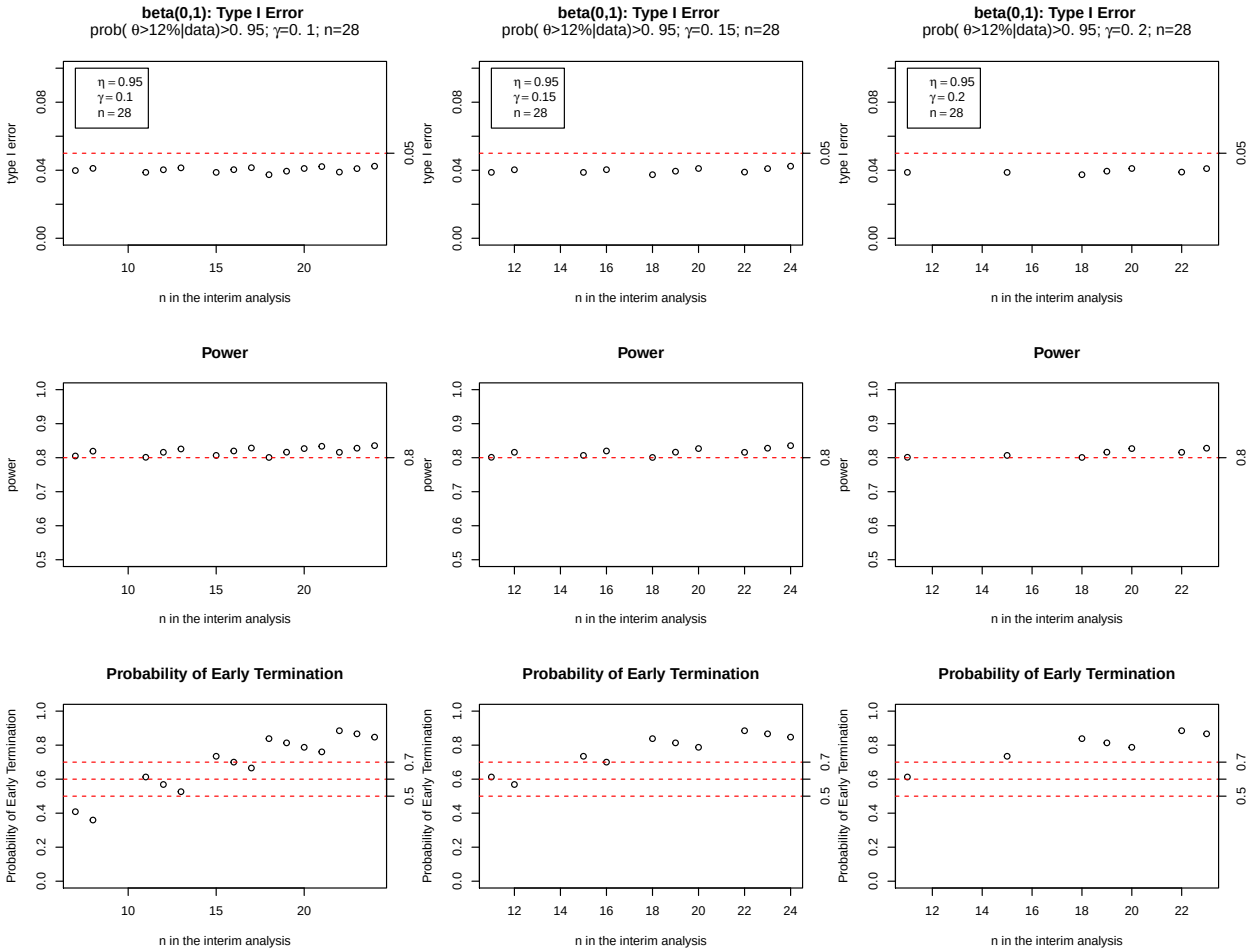
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beta(0,1): Type I Error
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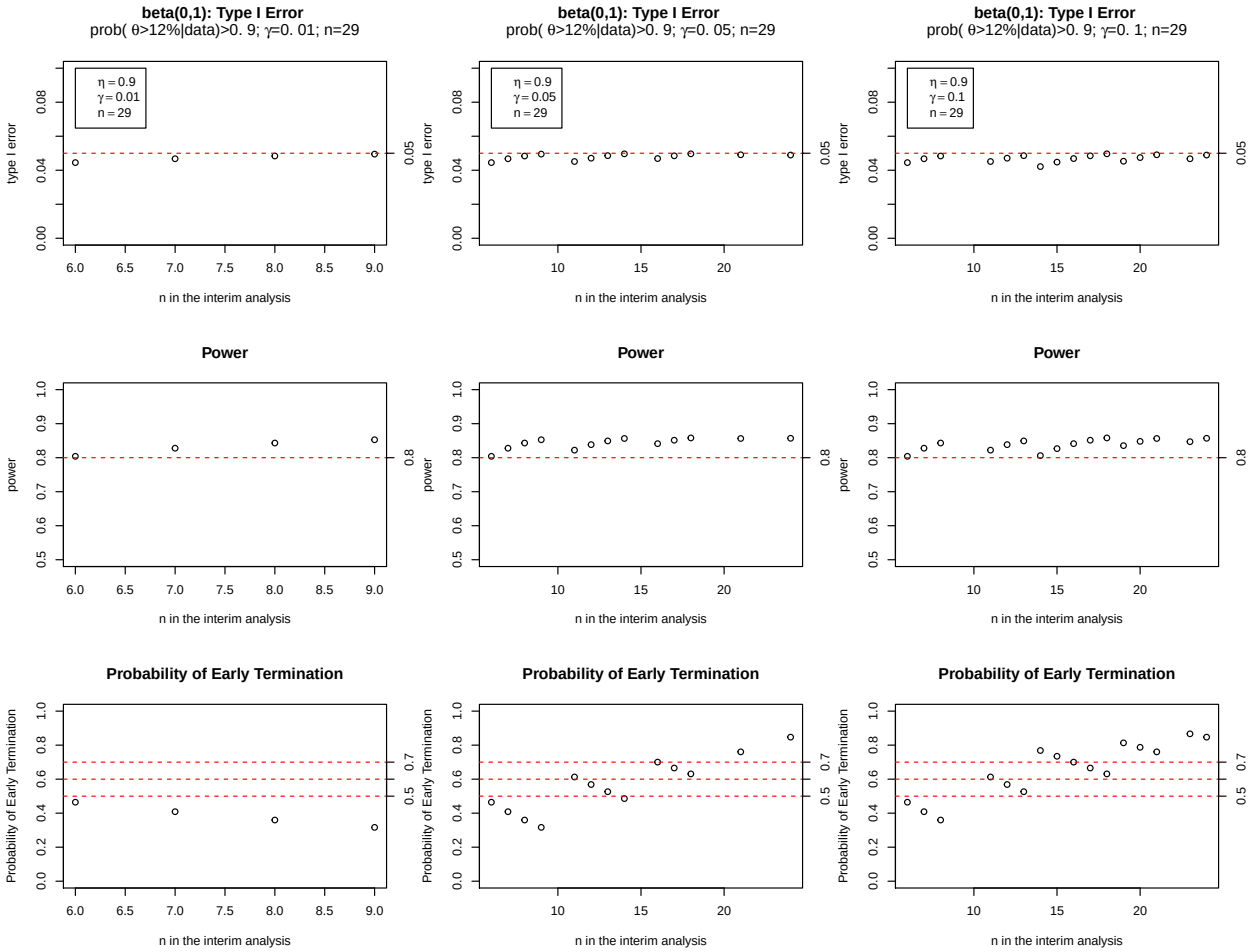
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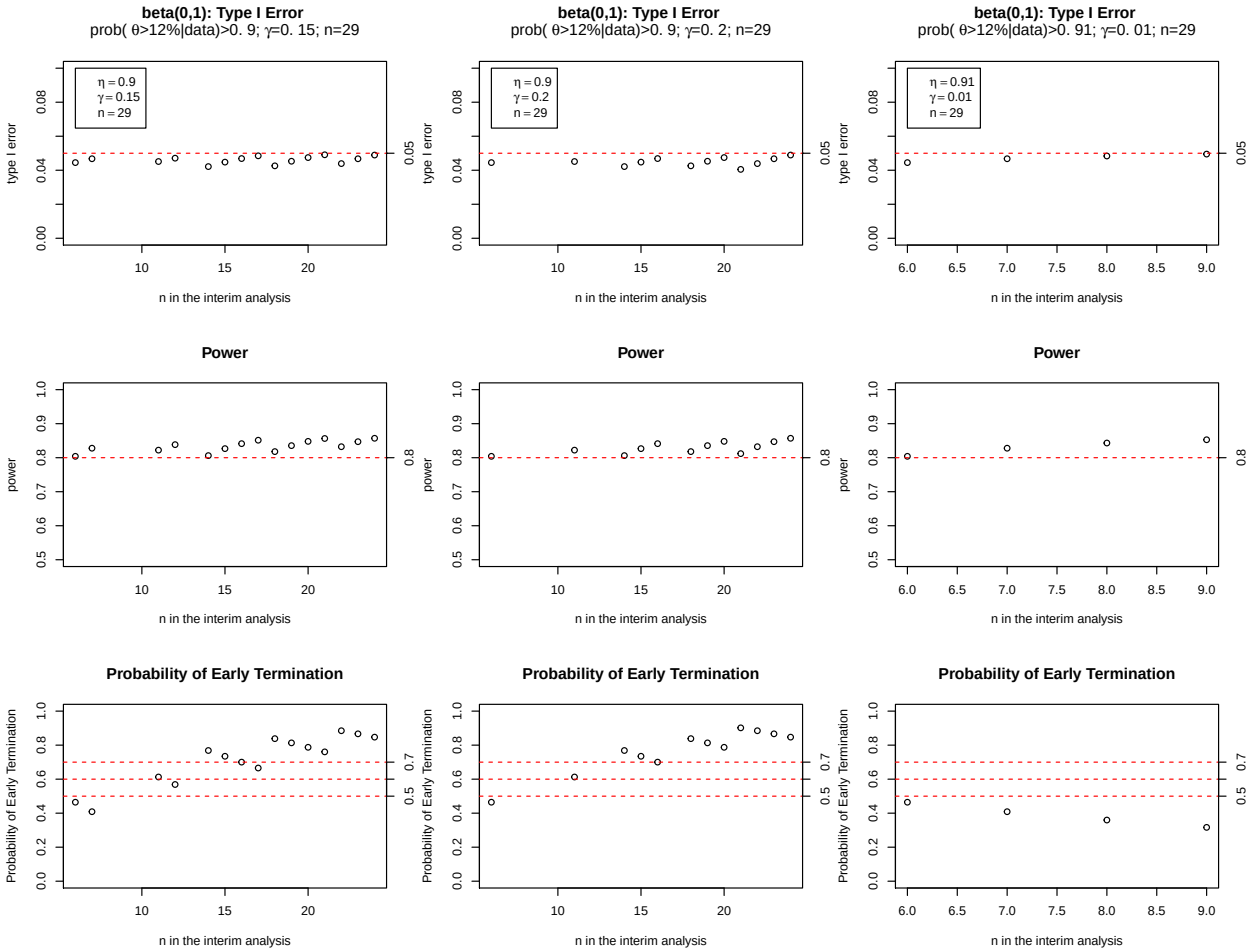
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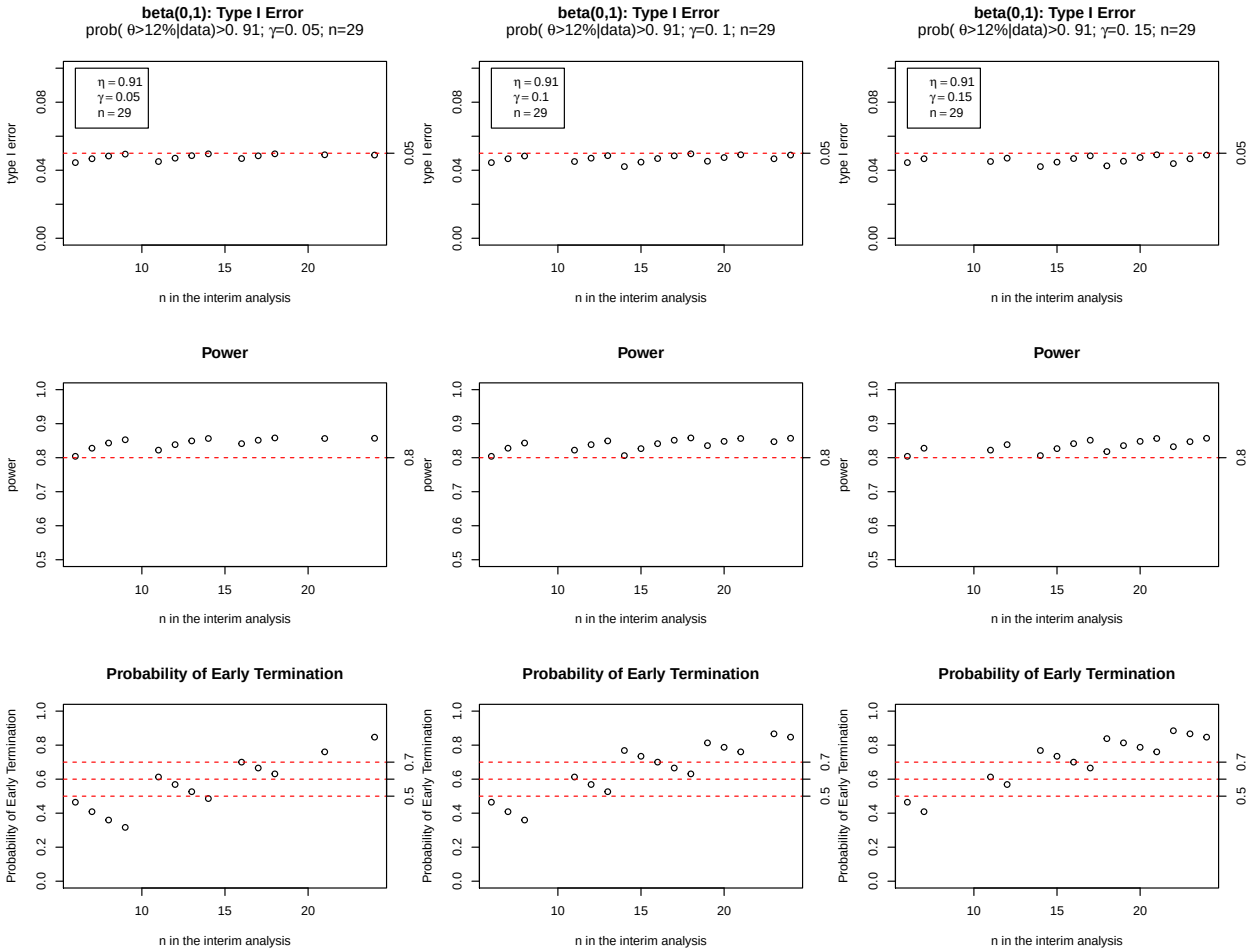
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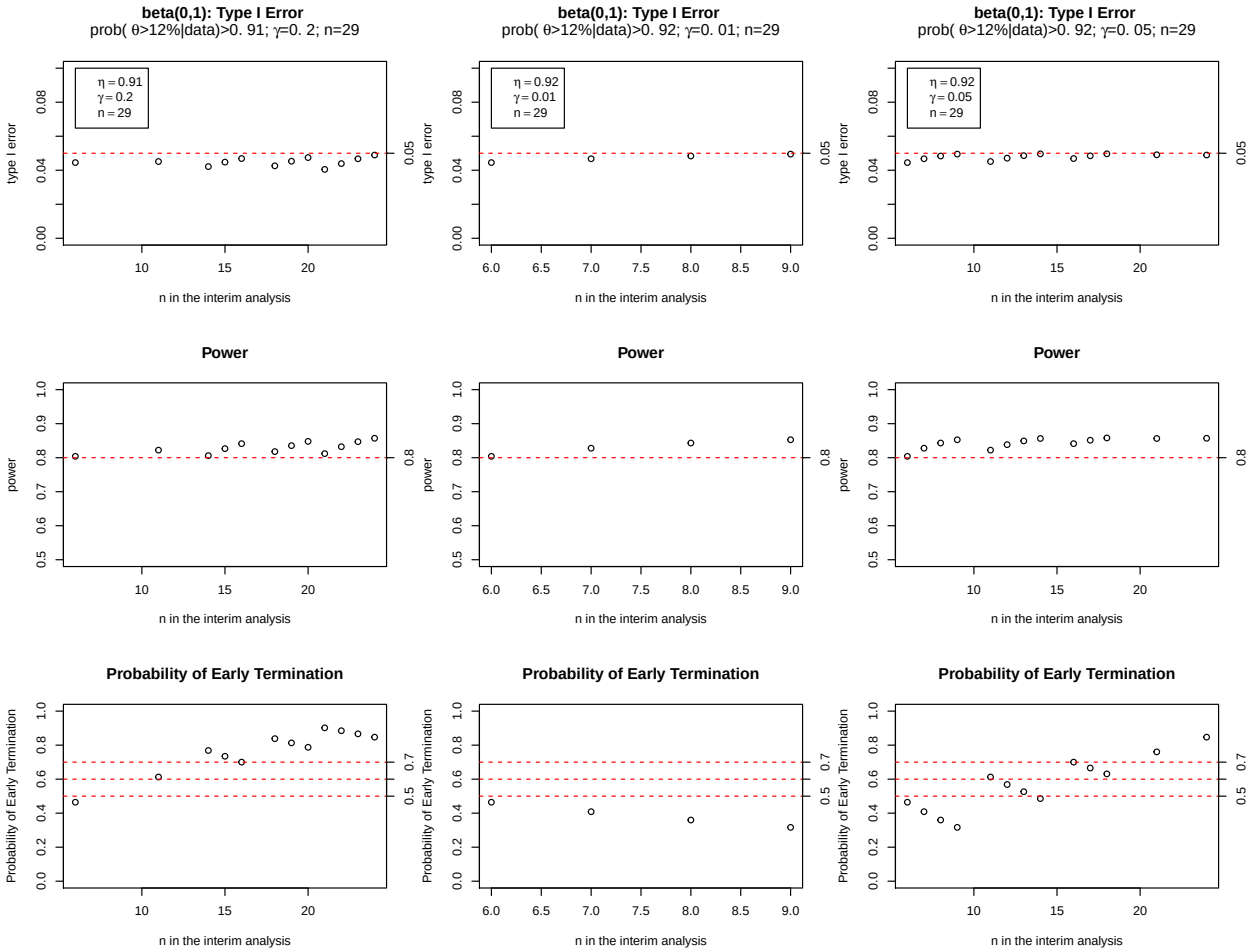
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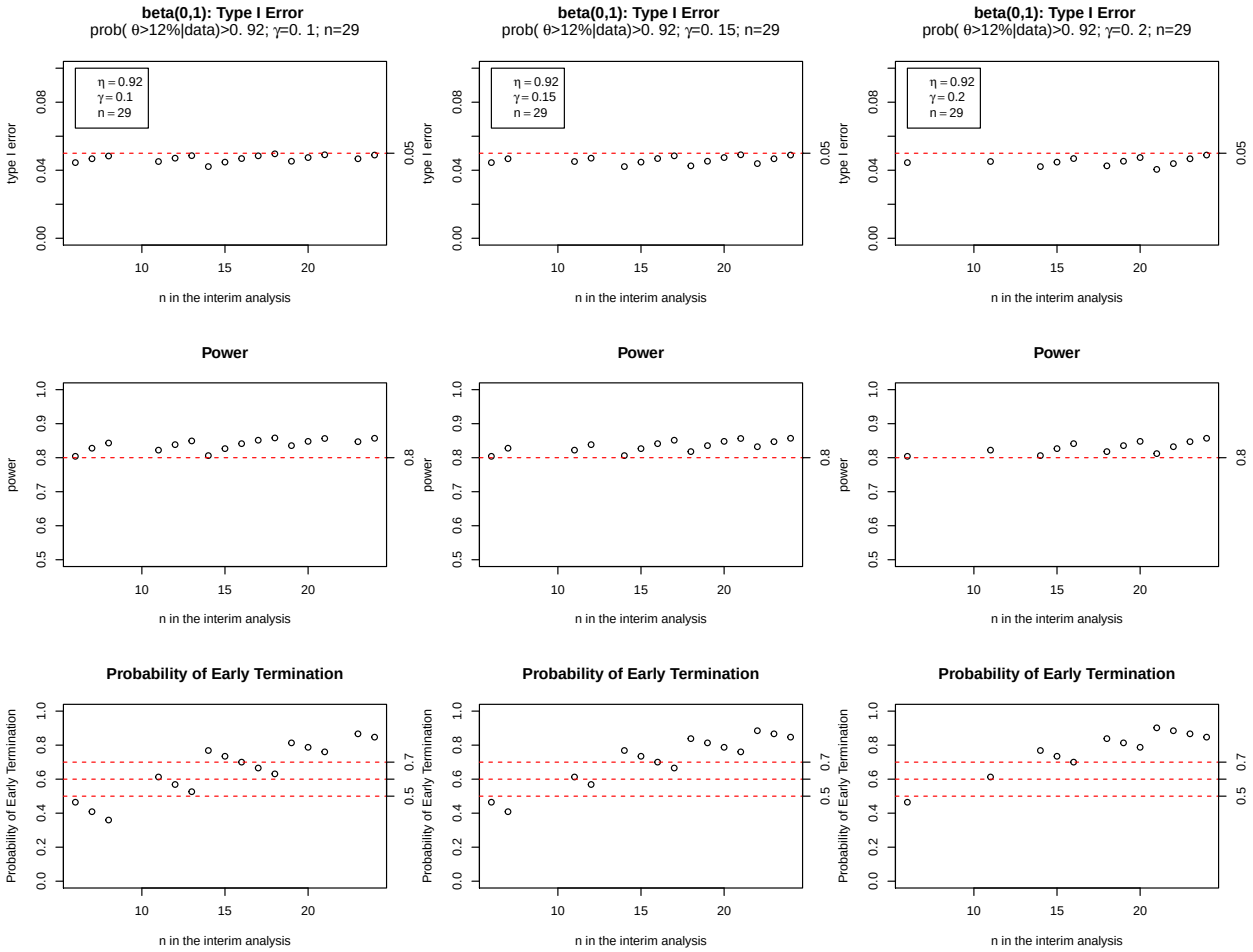
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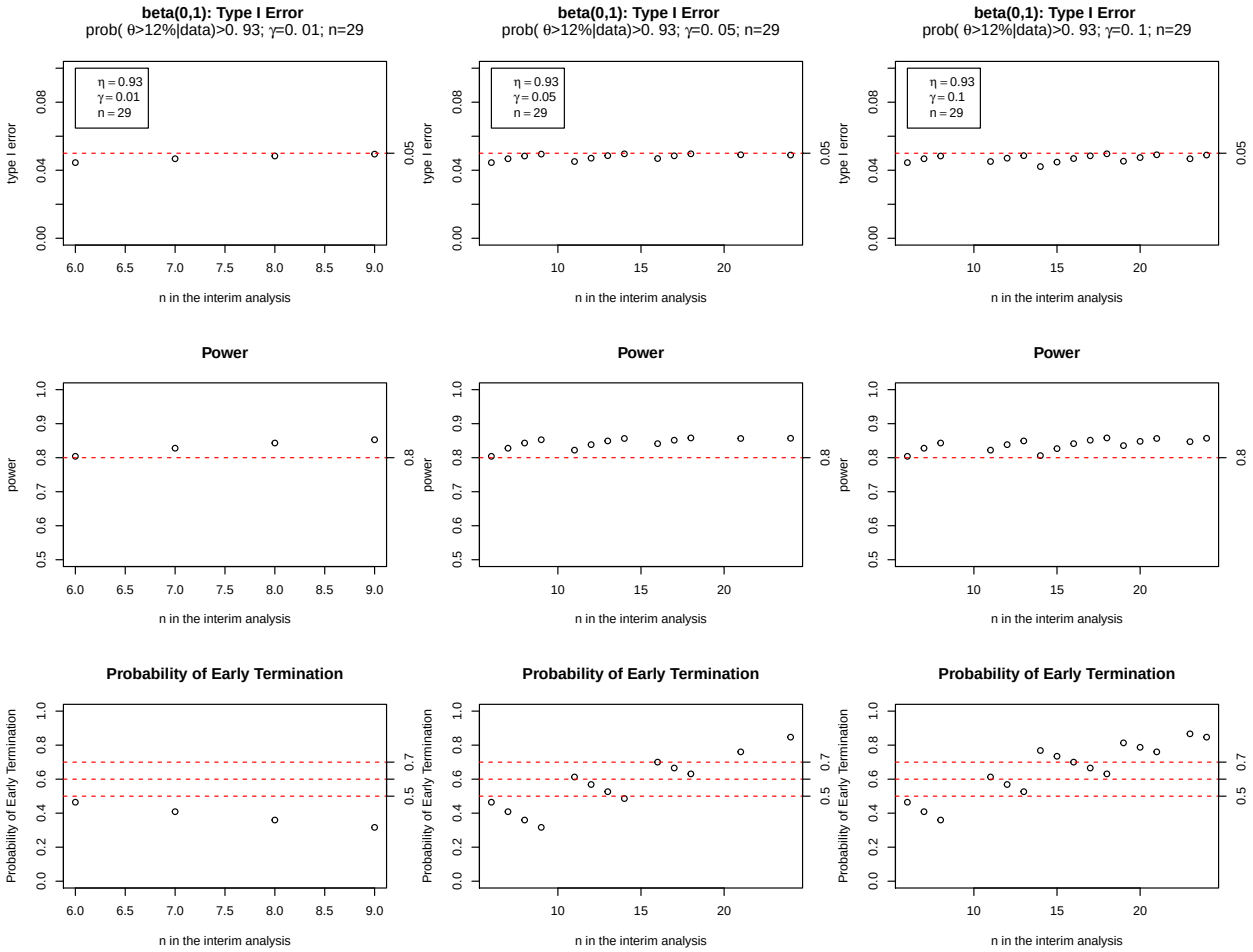
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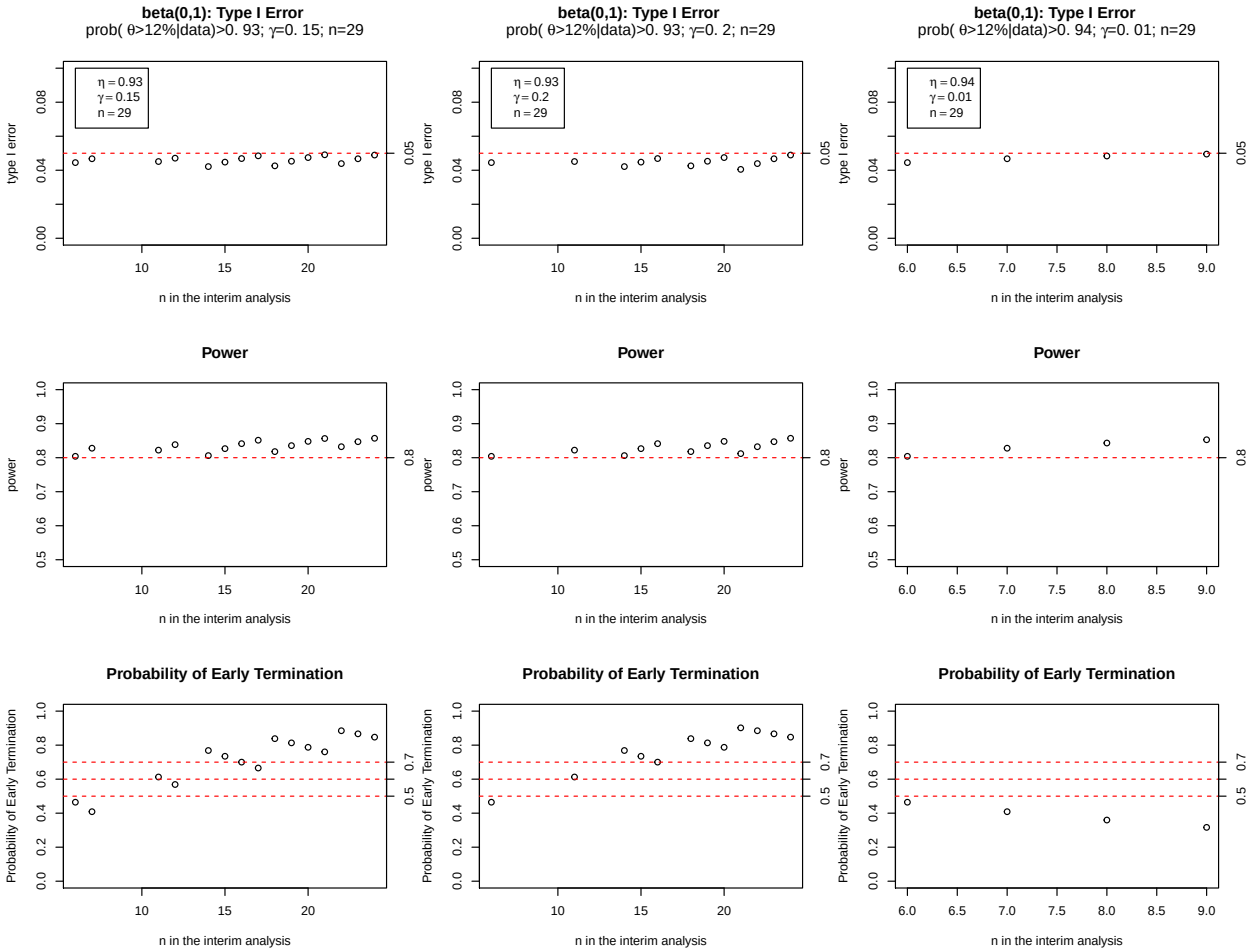
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beta(0,1): Type I Error
prob(θ>12%|data)>0. 94; γ=0. 01; n=29
η = 0.94
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type I error
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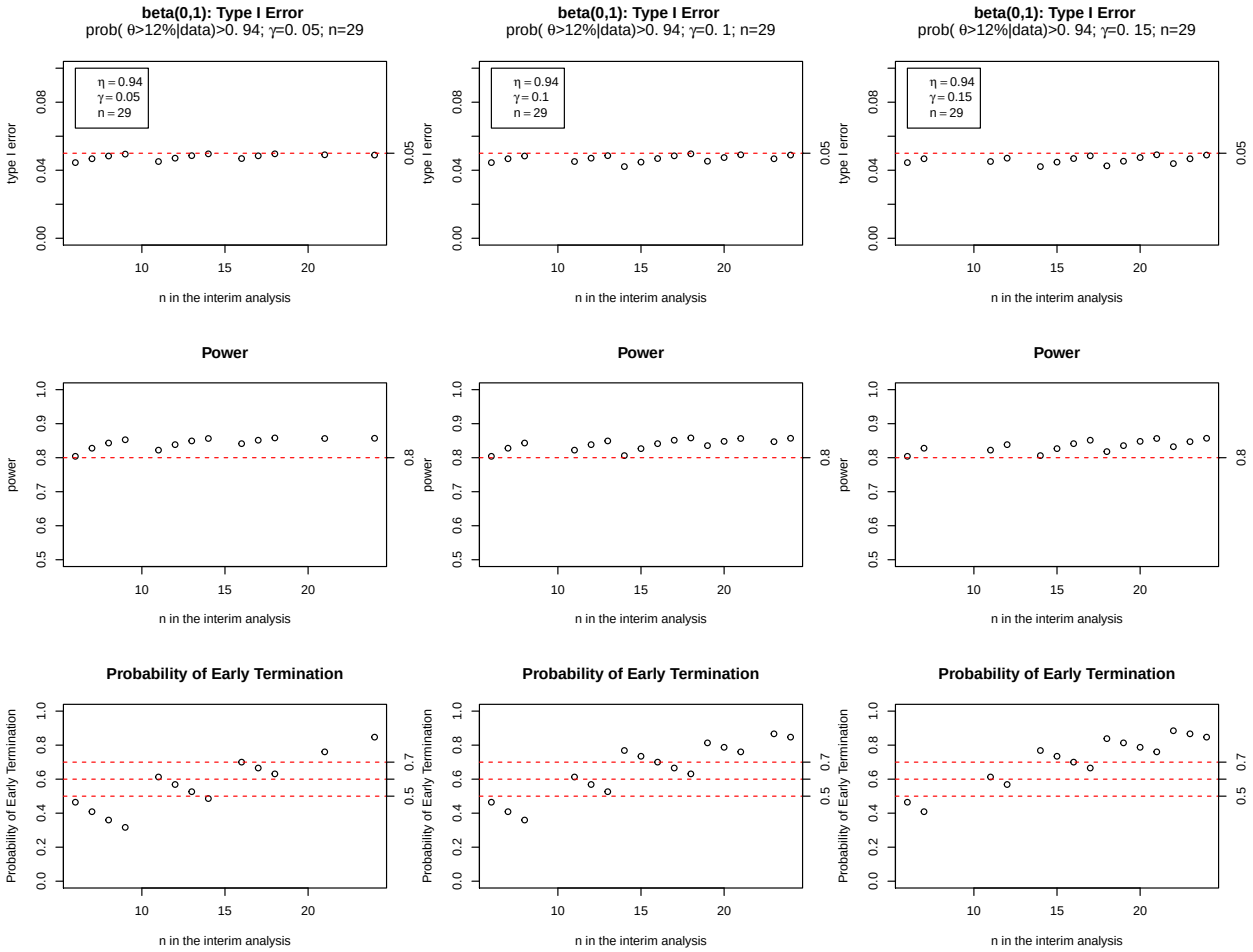
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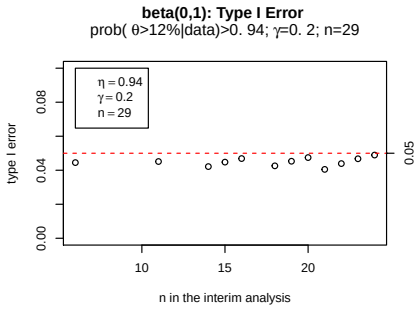
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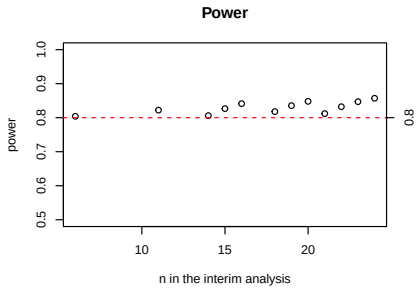
0.04
0.08
0.05
10
15
20
n in the interim analysis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1.0
0.8
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15
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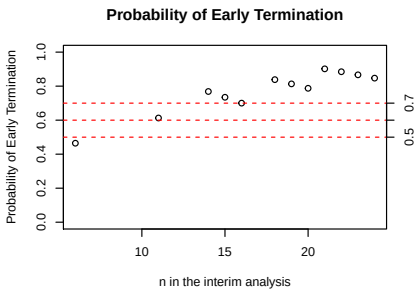
n in the interim analysis


Probability of Early Termination
Probability of Early Termination
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0.5
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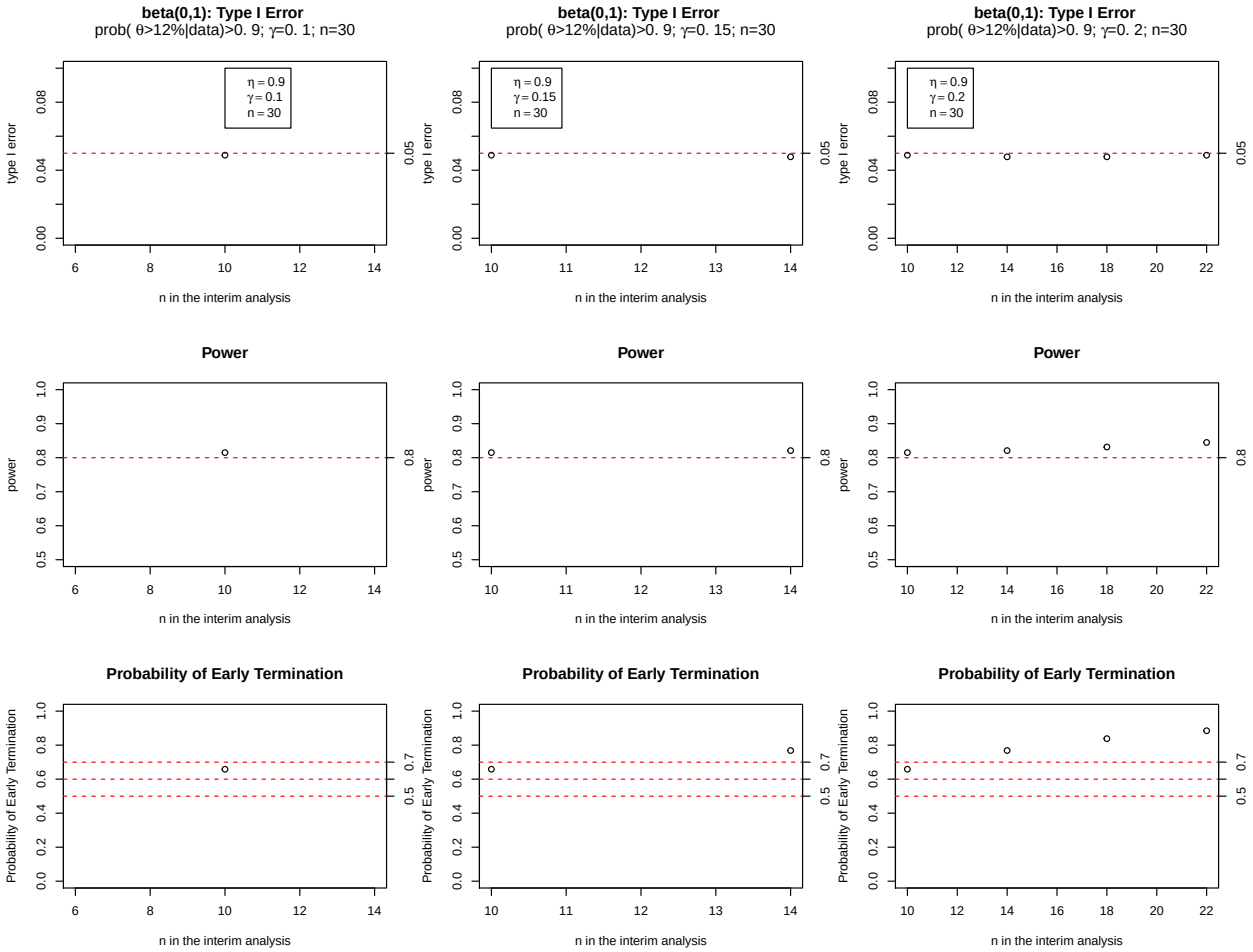
20
n in the interim analysis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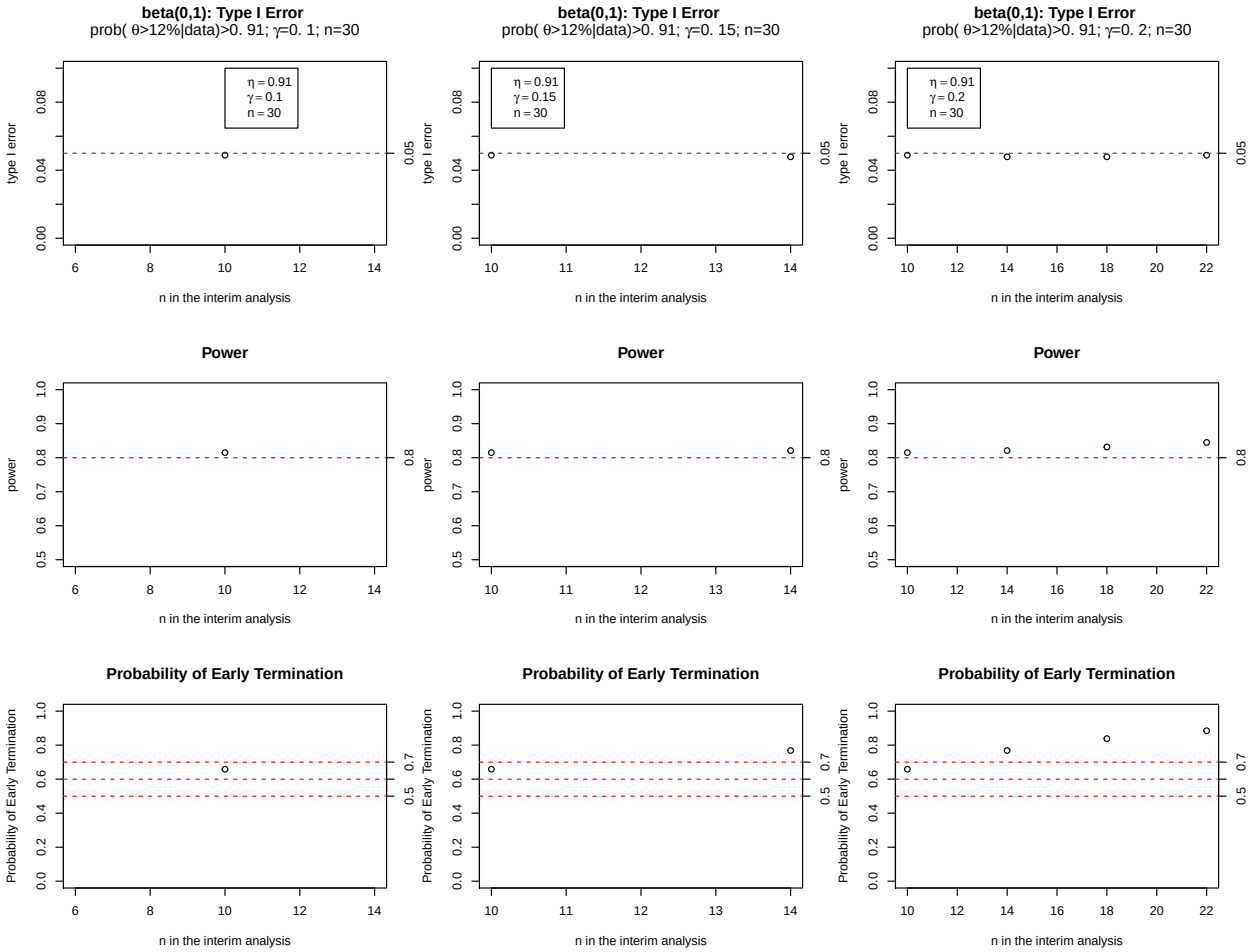
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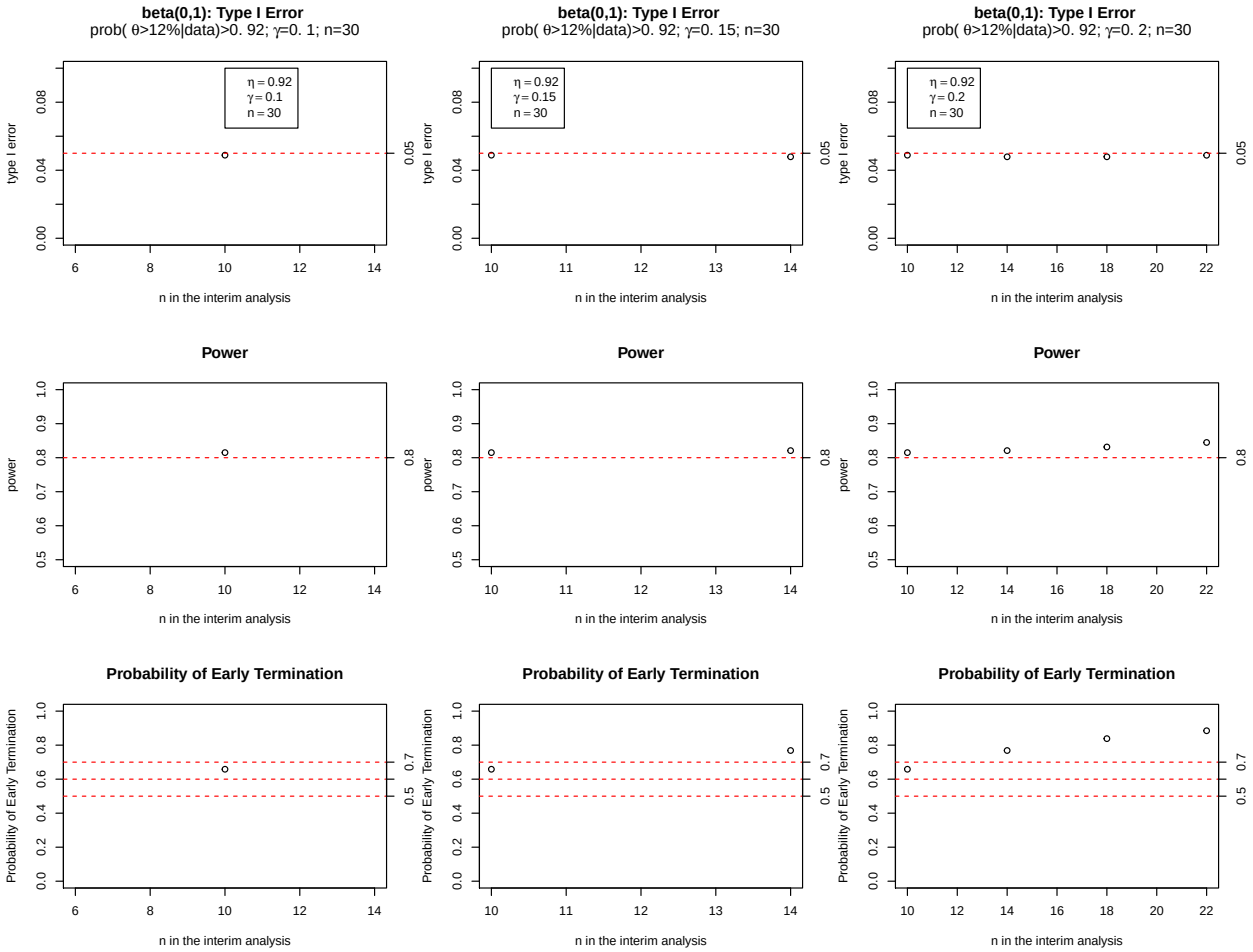
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Probability of Early Termination
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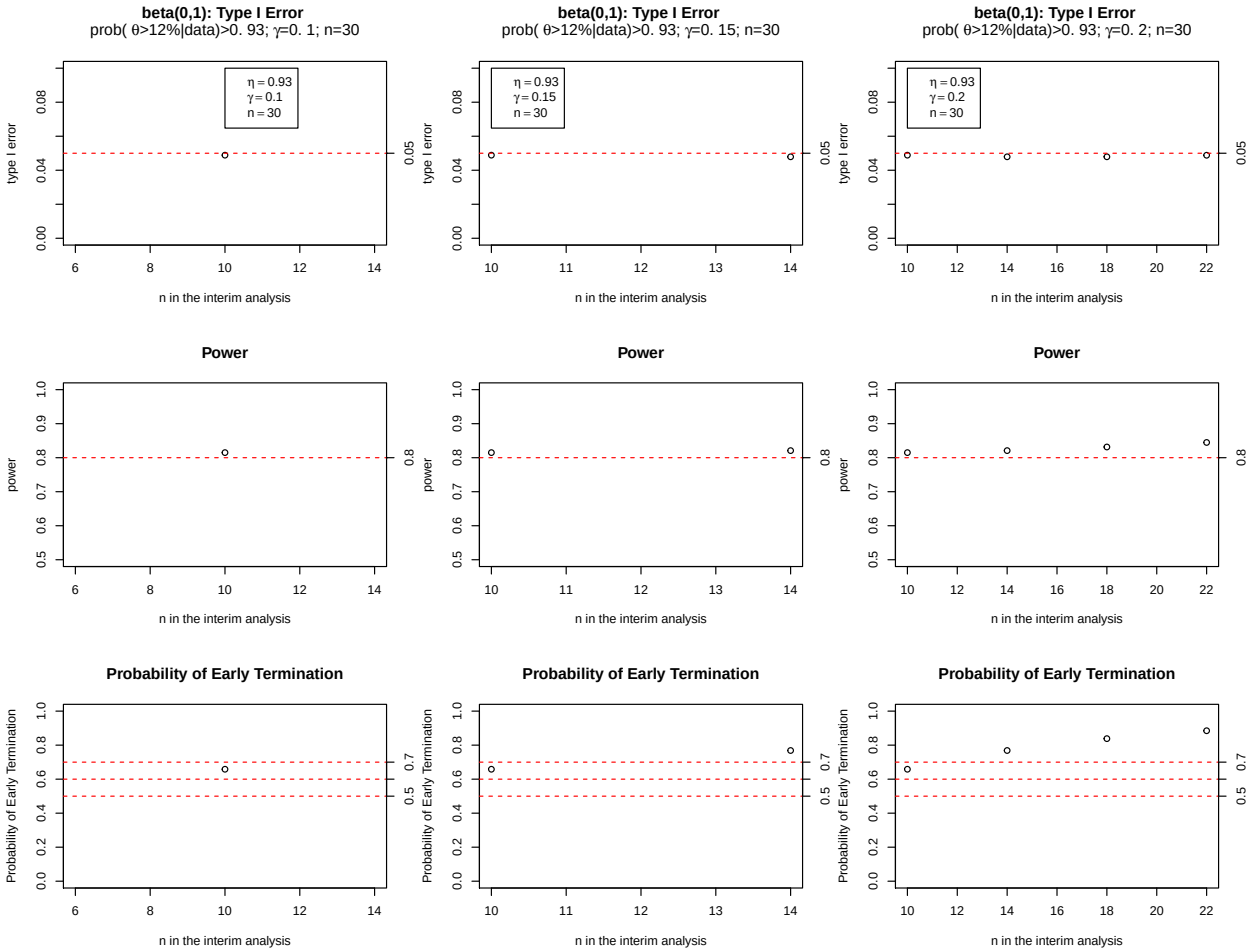
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis


beta(0,1): Type I Error
prob(θ>12%|data)>0. 93; γ=0. 1; n=30
η = 0.93
γ = 0.1
n = 30
type I error
n in the interim analysis
beta(0,1): Type I Error
prob(θ>12%|data)>0. 93; γ=0. 15; n=30
η = 0.93
γ = 0.15
n = 30
type I error
n in the interim analysis
beta(0,1): Type I Error
prob(θ>12%|data)>0. 93; γ=0. 2; n=30
η = 0.93
γ = 0.2
n = 30
type I error
n in the interim analysis
Power
power
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Power
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Power
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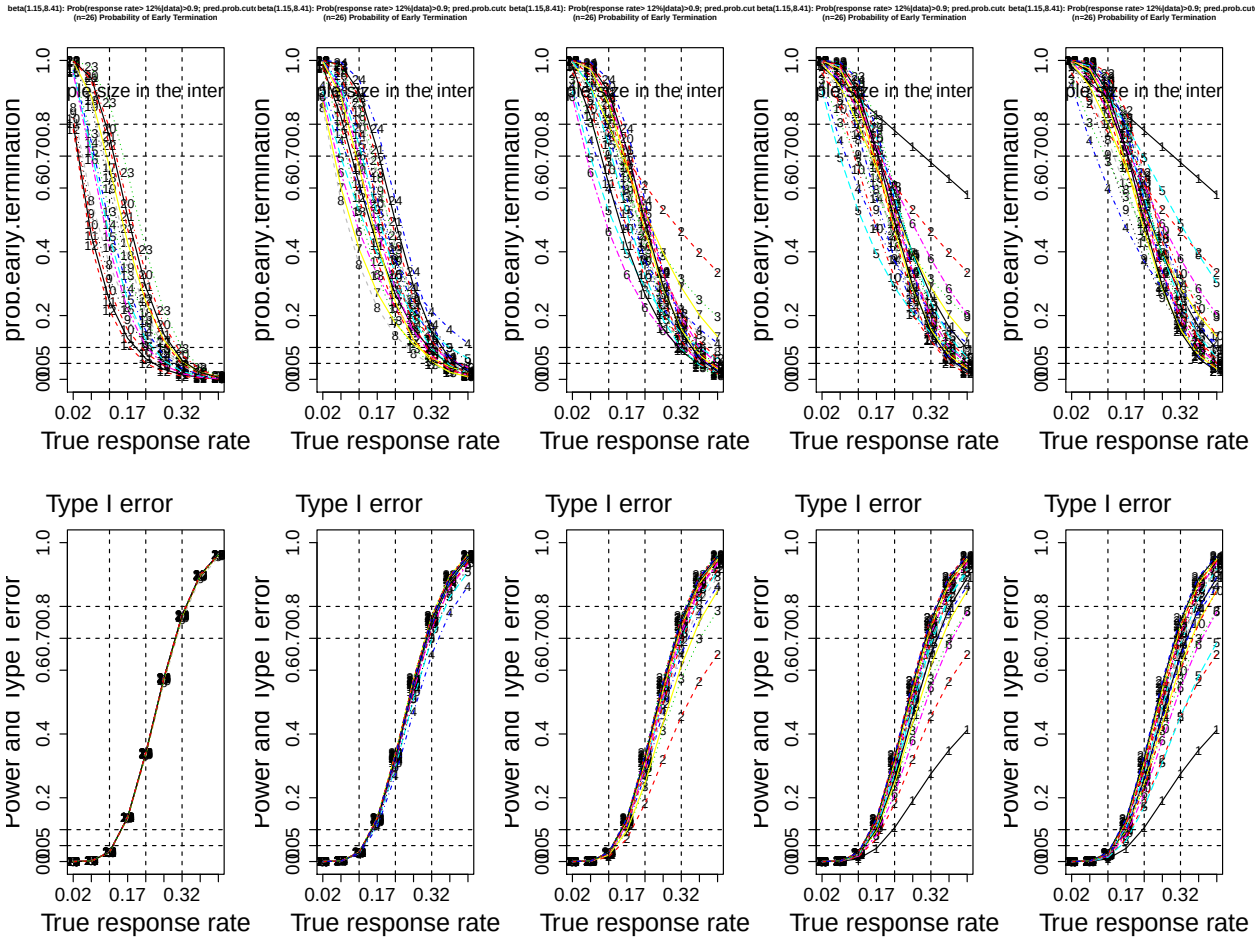
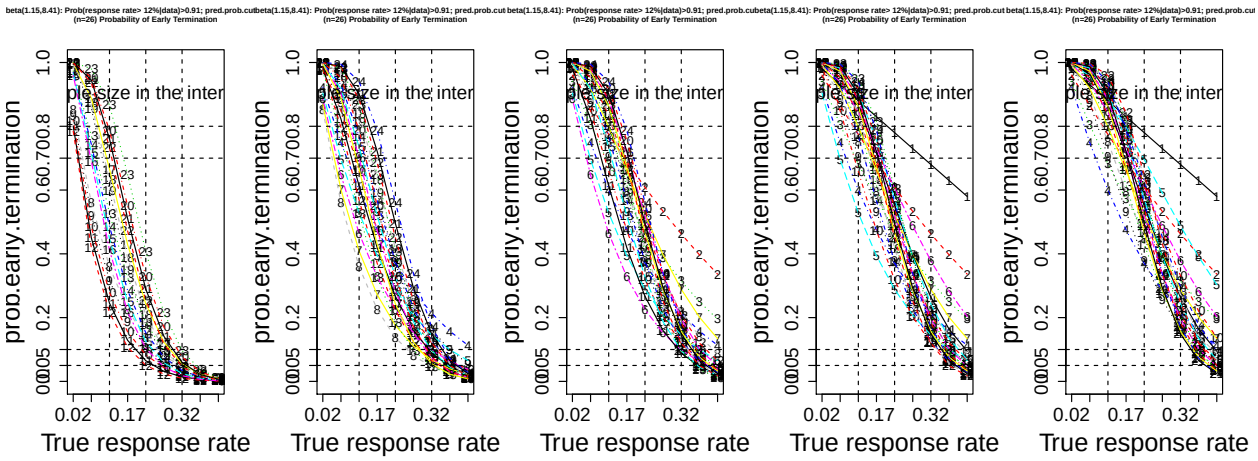
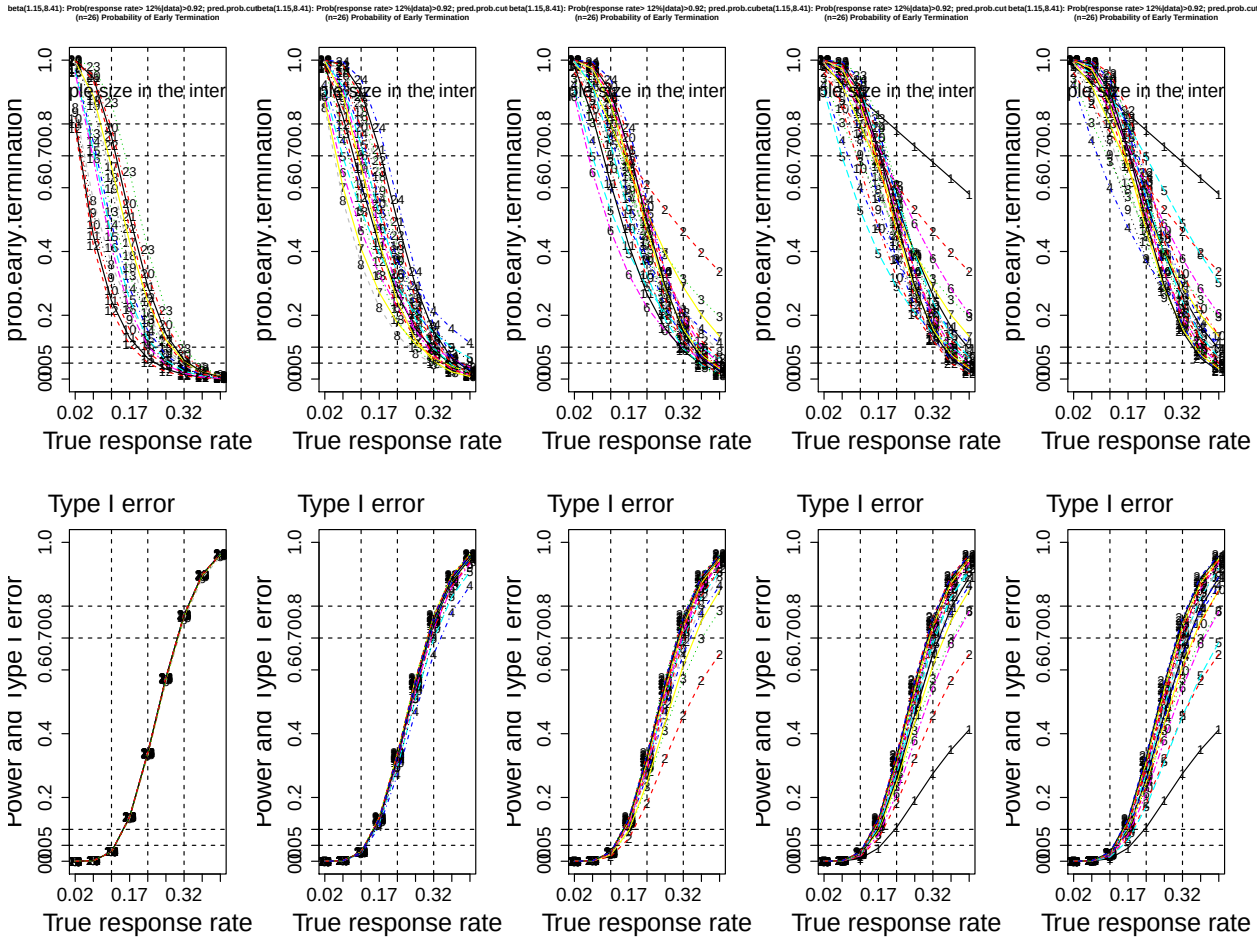
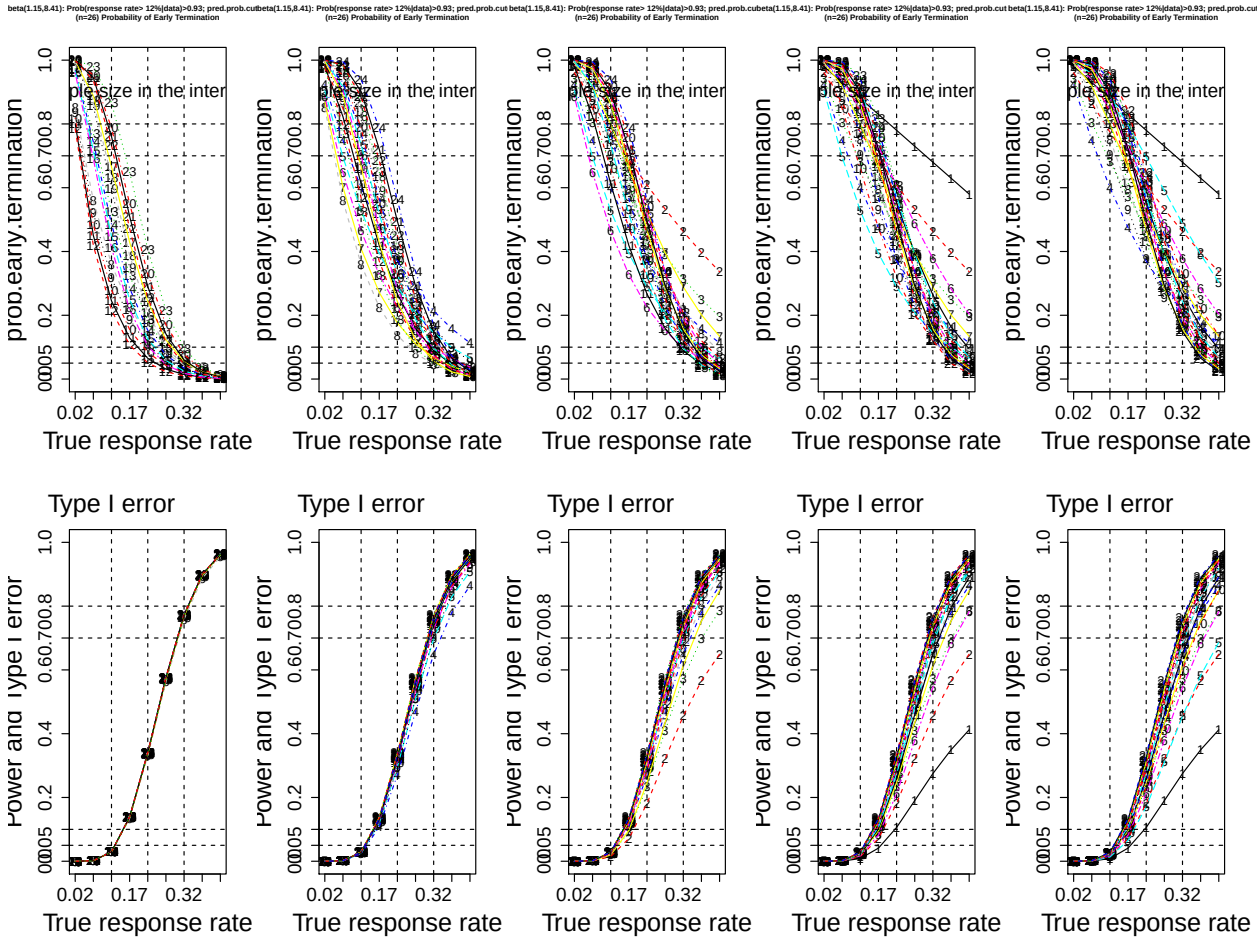
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis

Prior Distribution: beta(1.15,8.41)






beta(1.15,8.41): Prob(response rate> 12%|data)>0.92; pred.prob.cut
(n=26) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02 0.17 0.32
0.0 0.2 0.4 0.6 0.7 0.8 1.0


beta(1.15,8.41): Prob(response rate> 12%|data)>0.93; pred.prob.cut
(n=26) Probability of Early Termination
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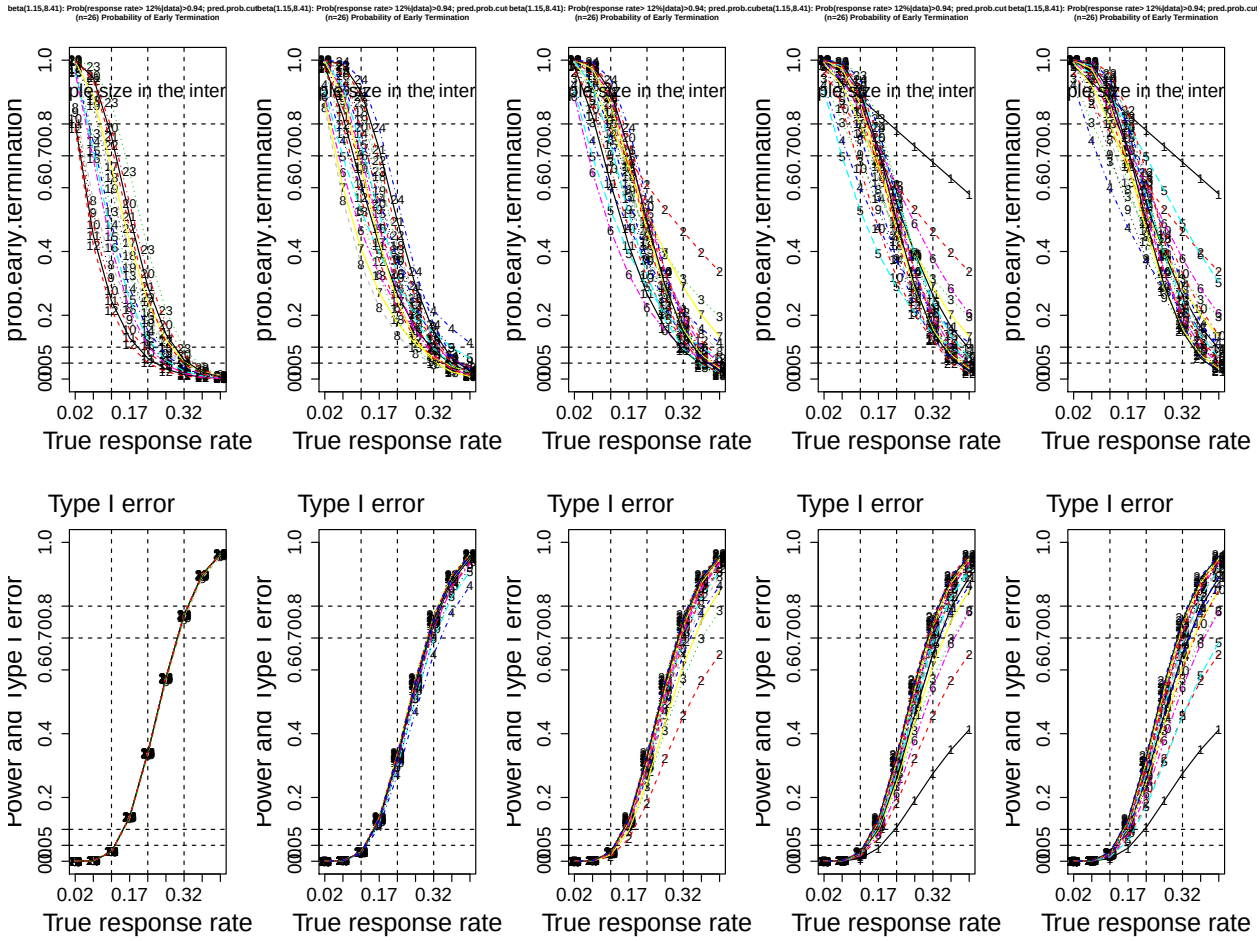
0.02 0.17 0.32
0.0 0.2 0.4 0.6 0.7 0.8 1.0


beta(1.15,8.41): Prob(response rate> 12%|data)>0.94; pred.prob.cut
(n=26) Probability of Early Termination
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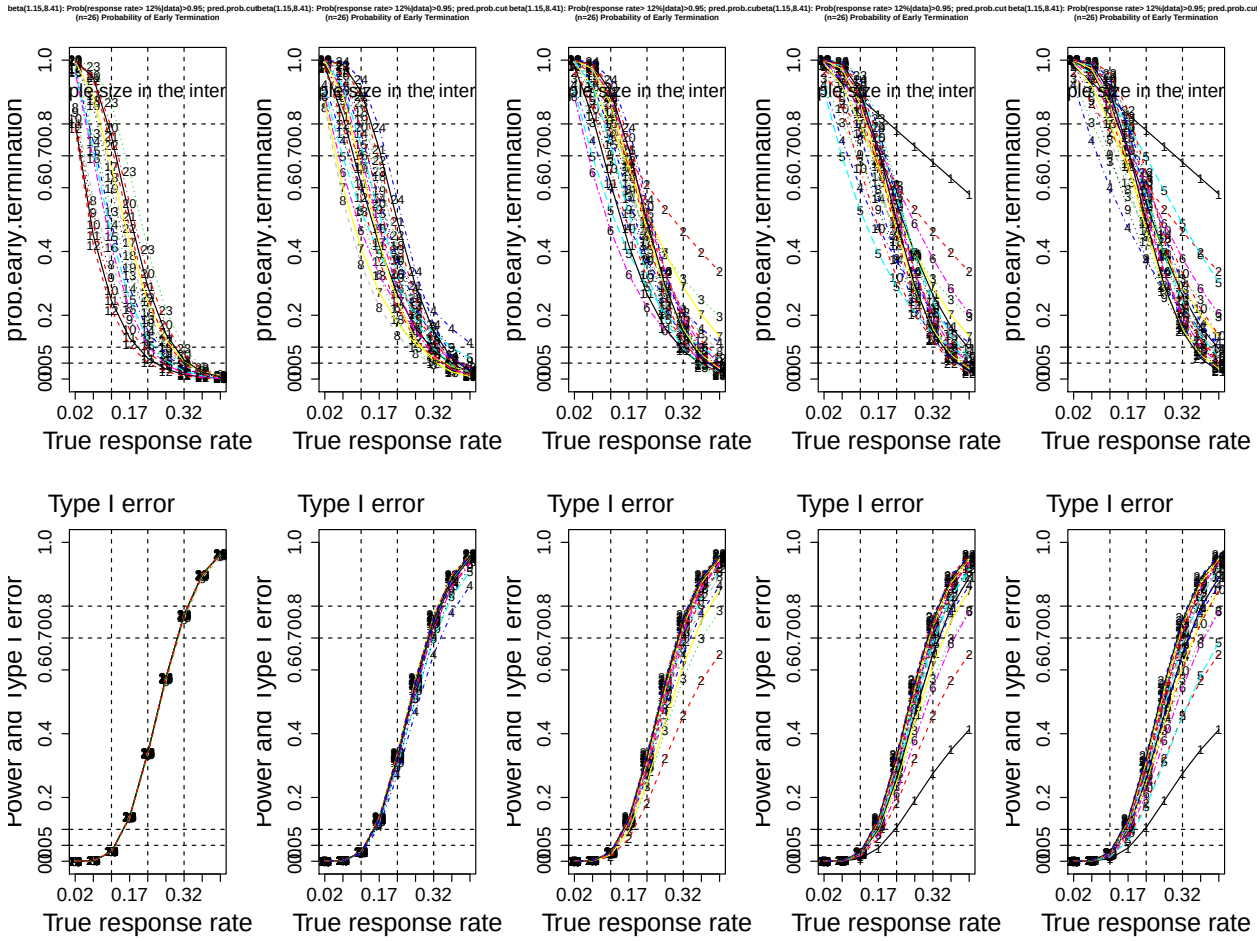
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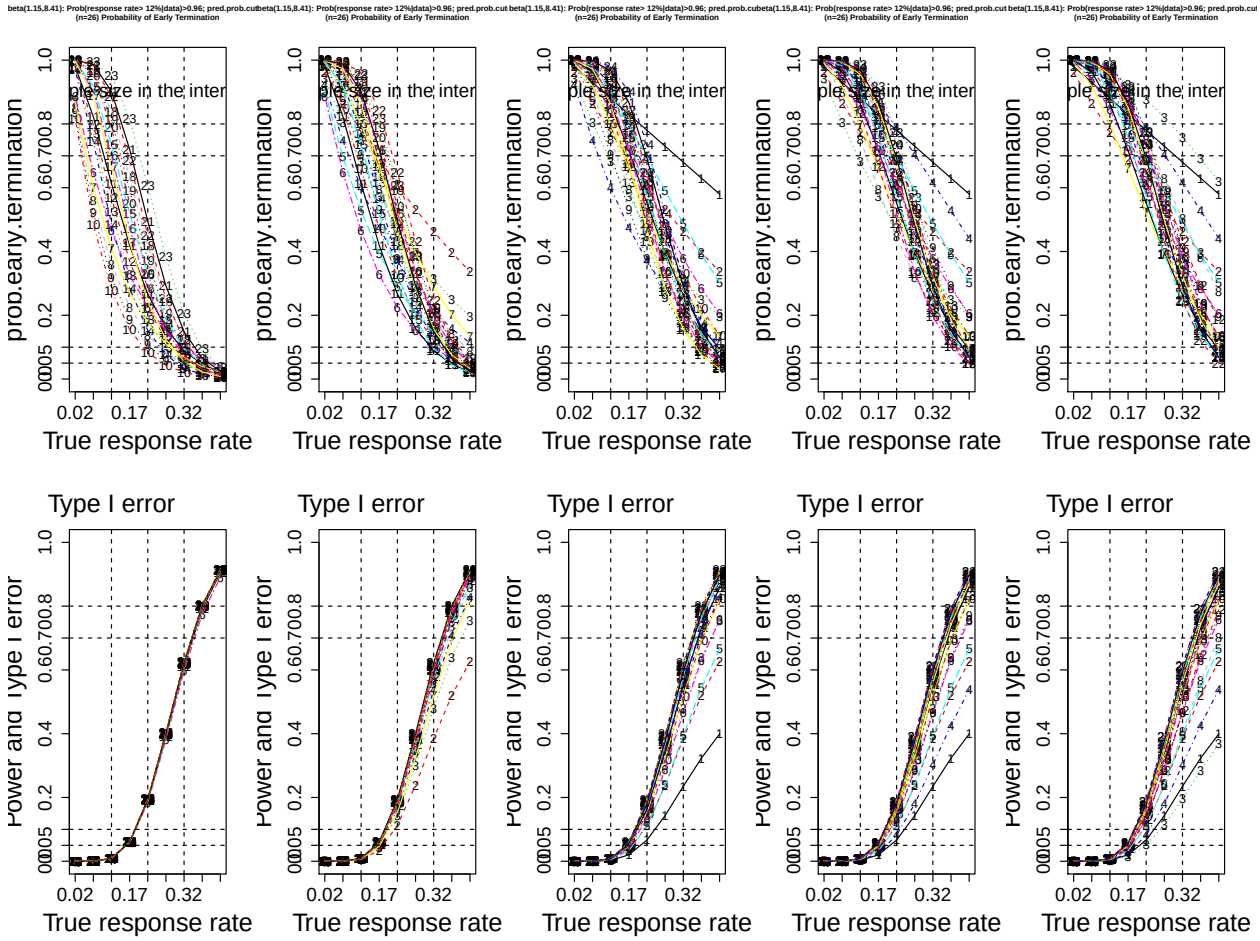
beta(1.15,8.41): Prob(response rate> 12%|data)>0.96; pred.prob.cut
(n=26) Probability of Early Termination
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Type I error
Power and Type I error
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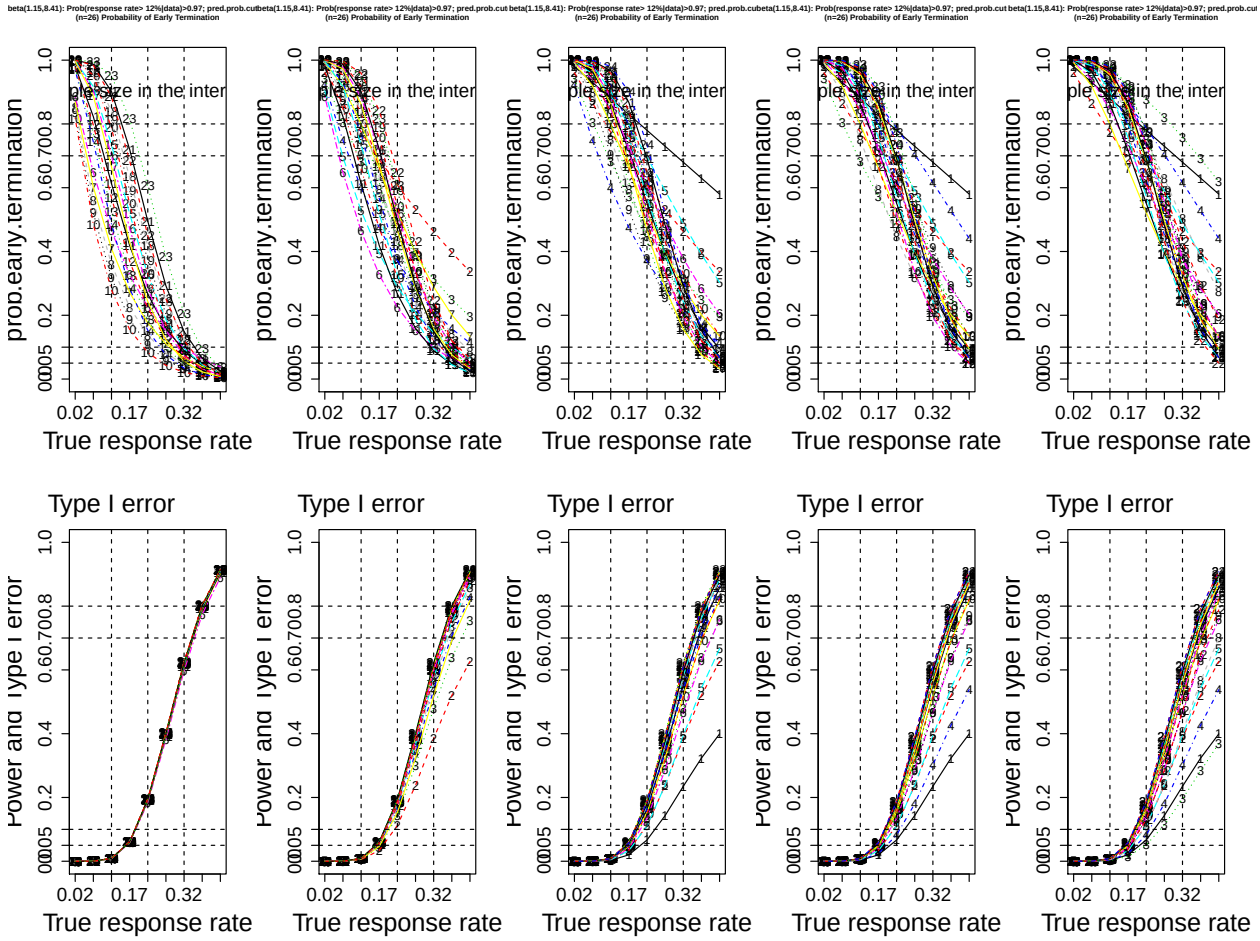
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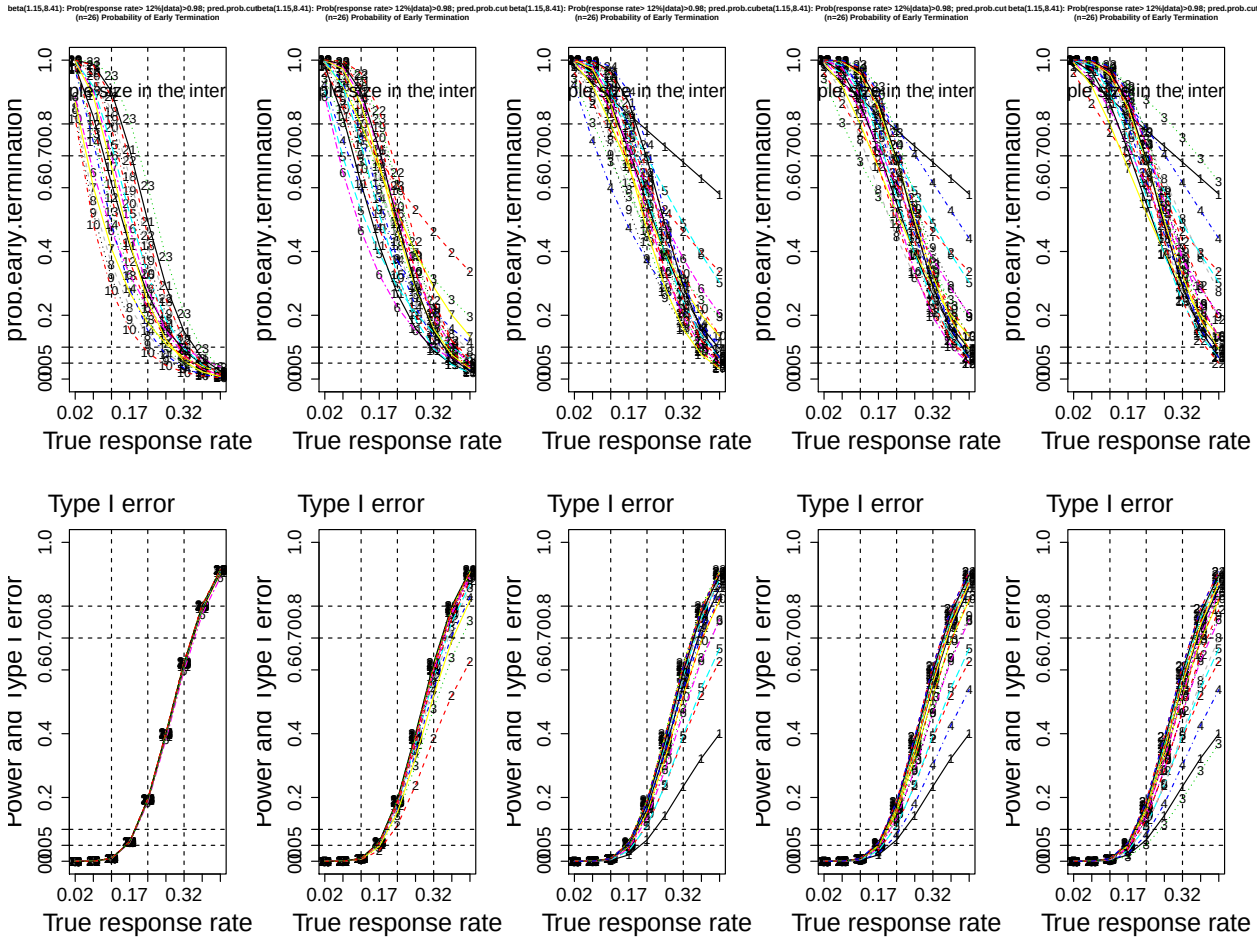
beta(1.15,8.41): Prob(response rate> 12%|data)>0.98; pred.prob.cut
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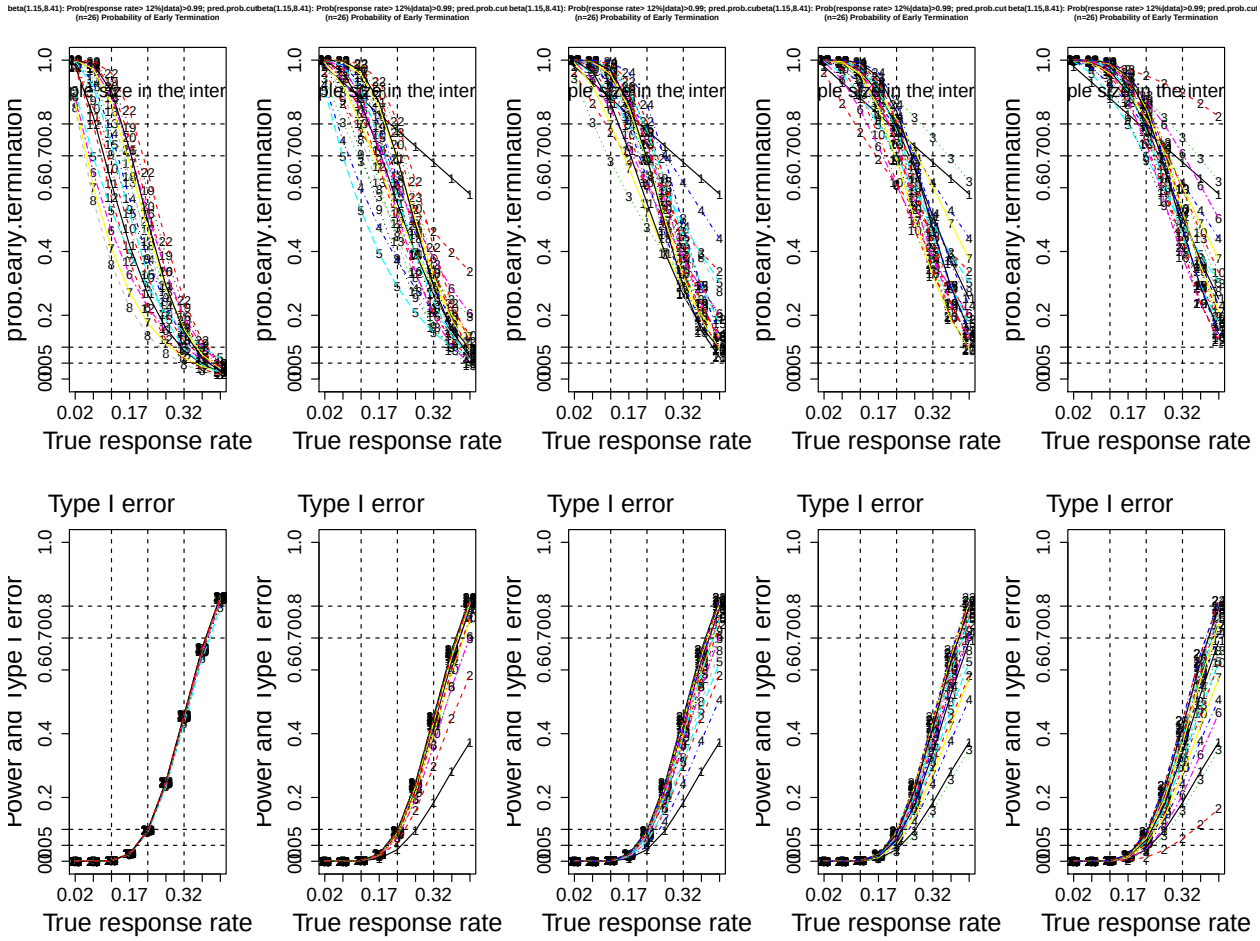
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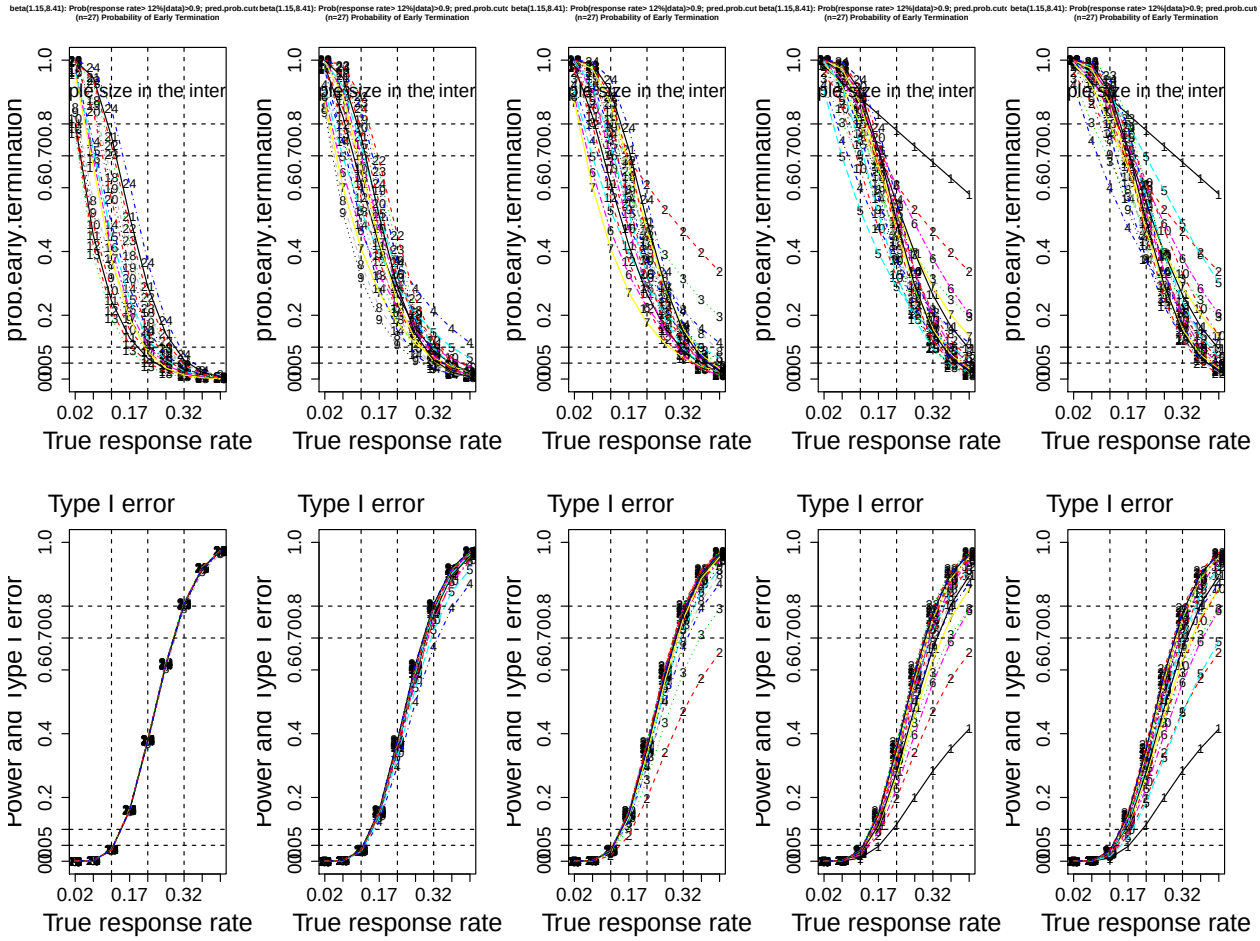
beta(1.15,8.41): Prob(response rate> 12%|data)>0.9; pred.prob.cut
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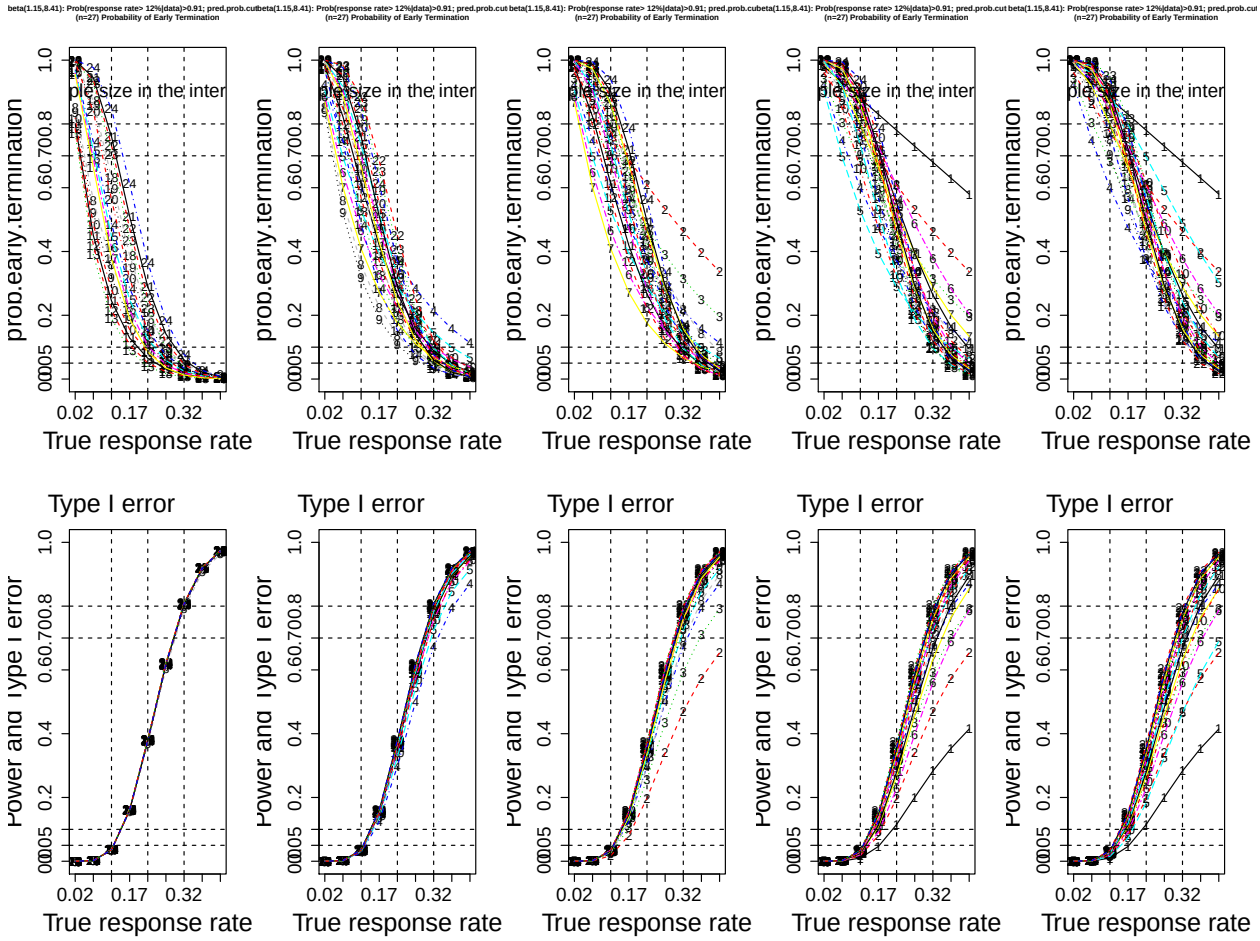
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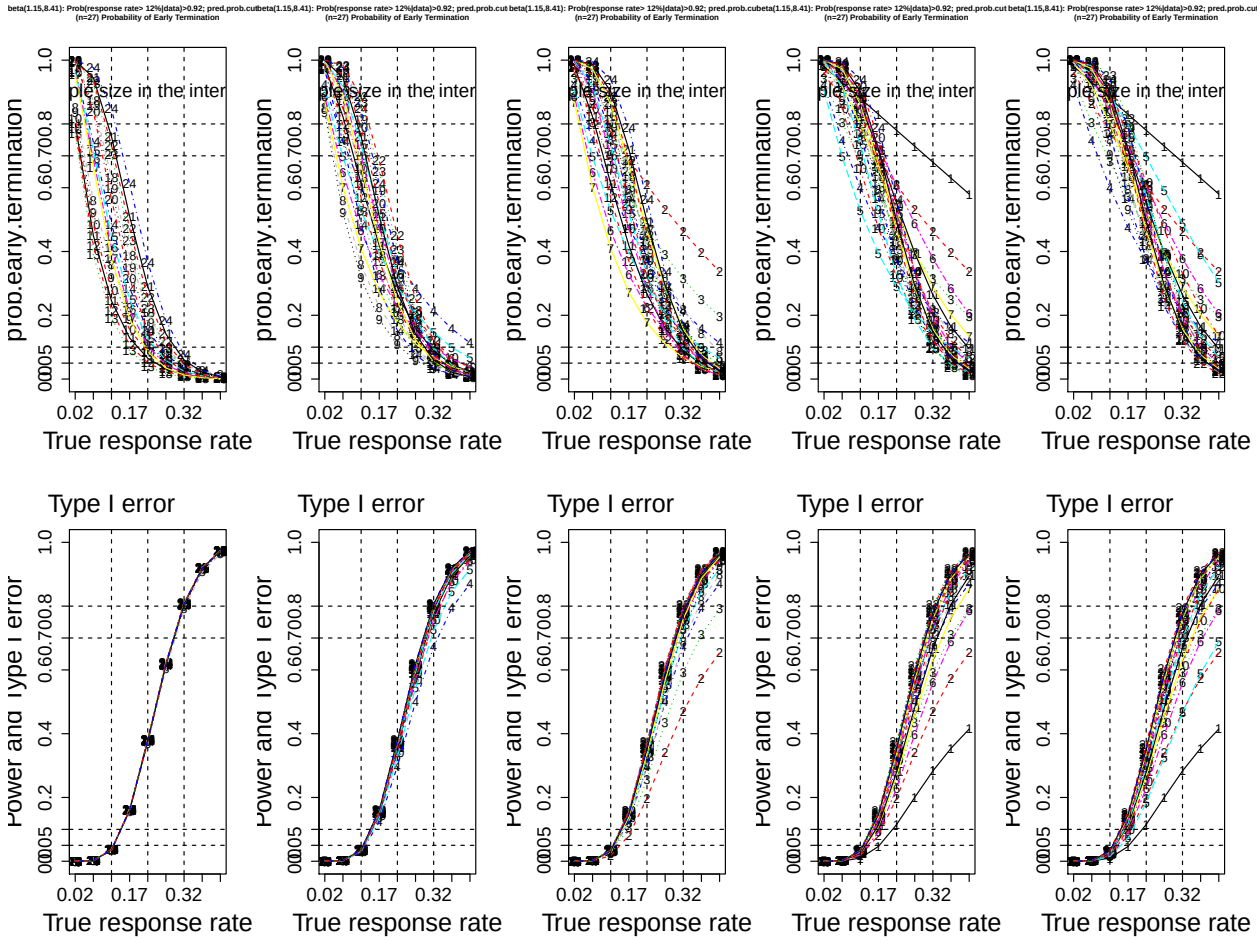
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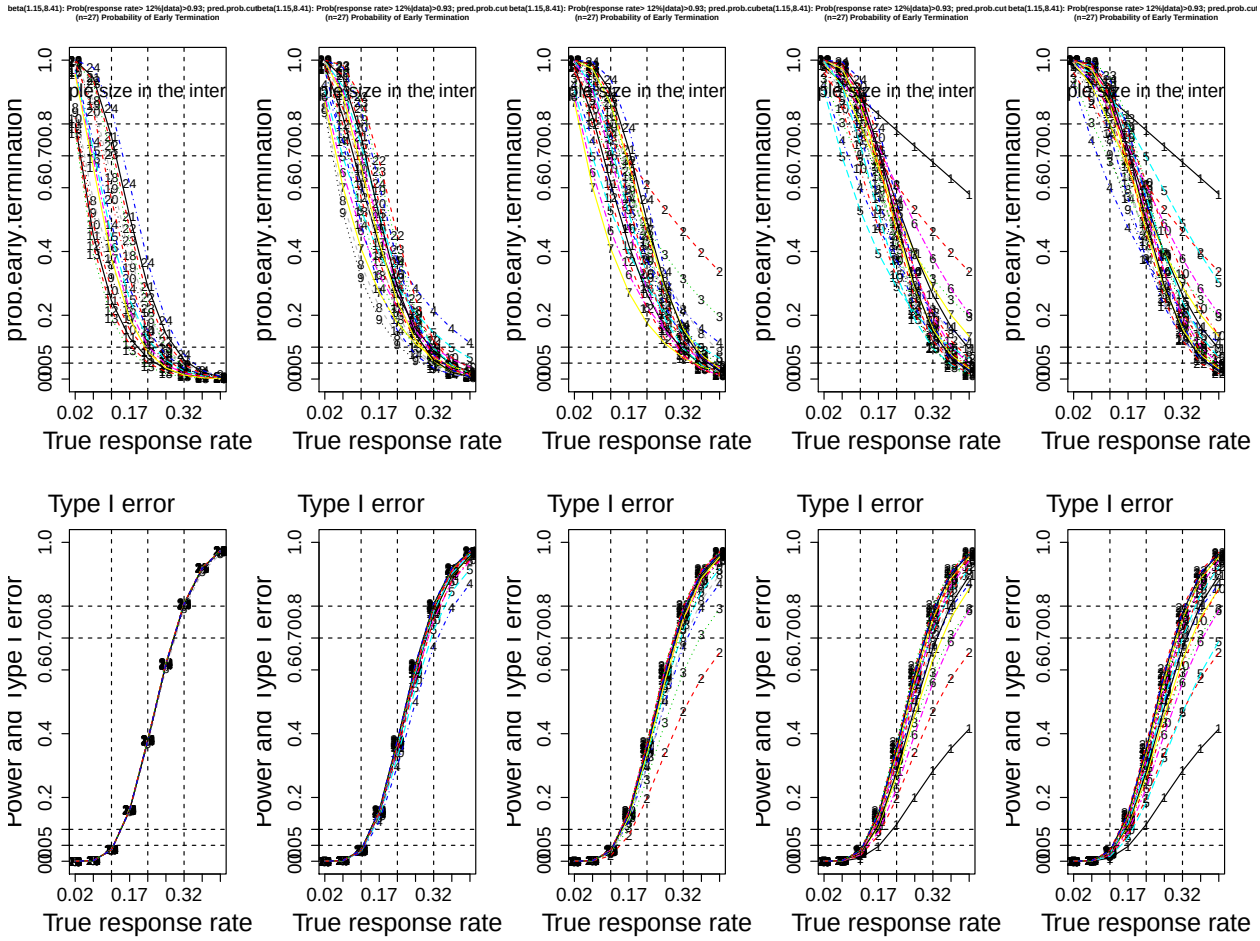
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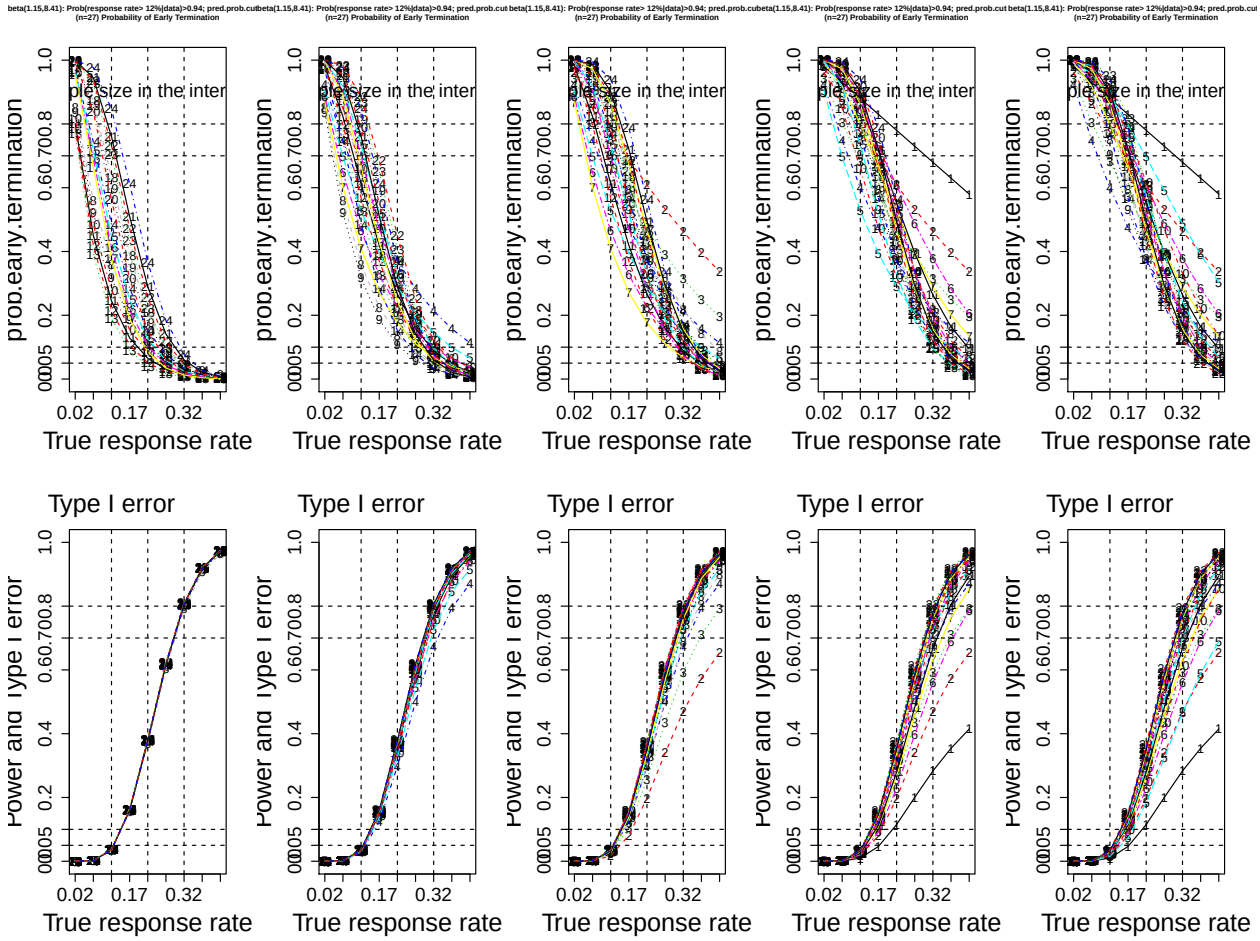
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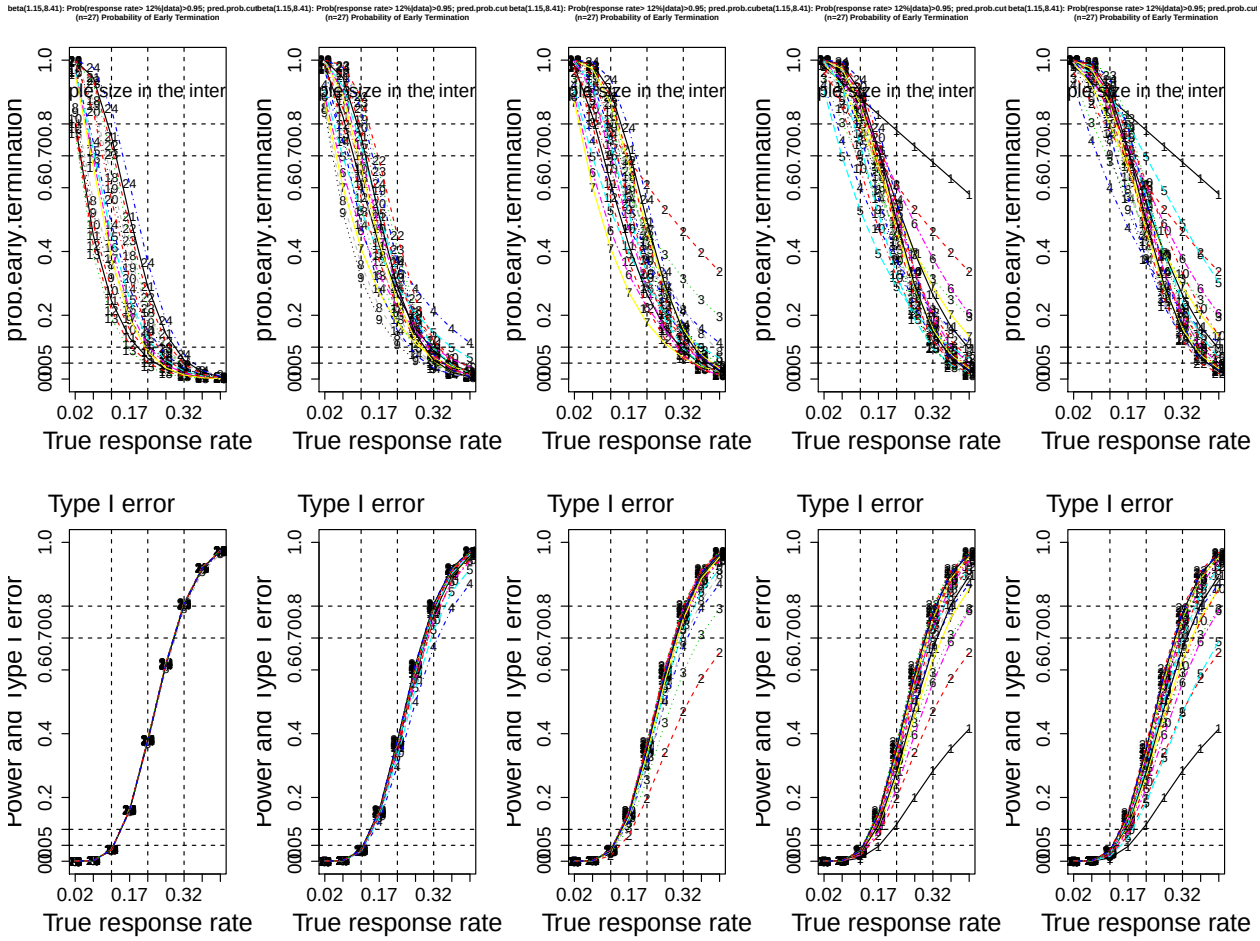
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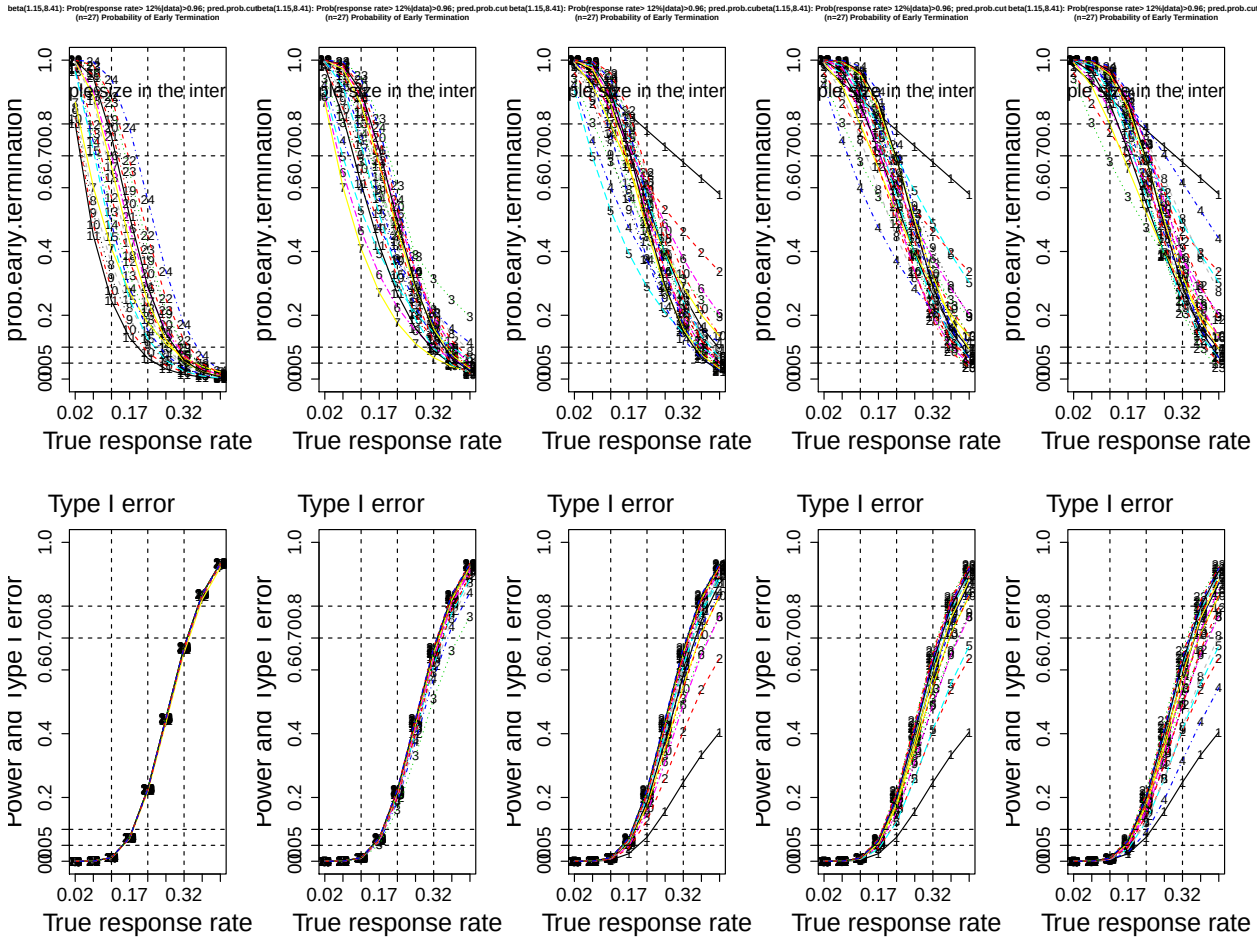
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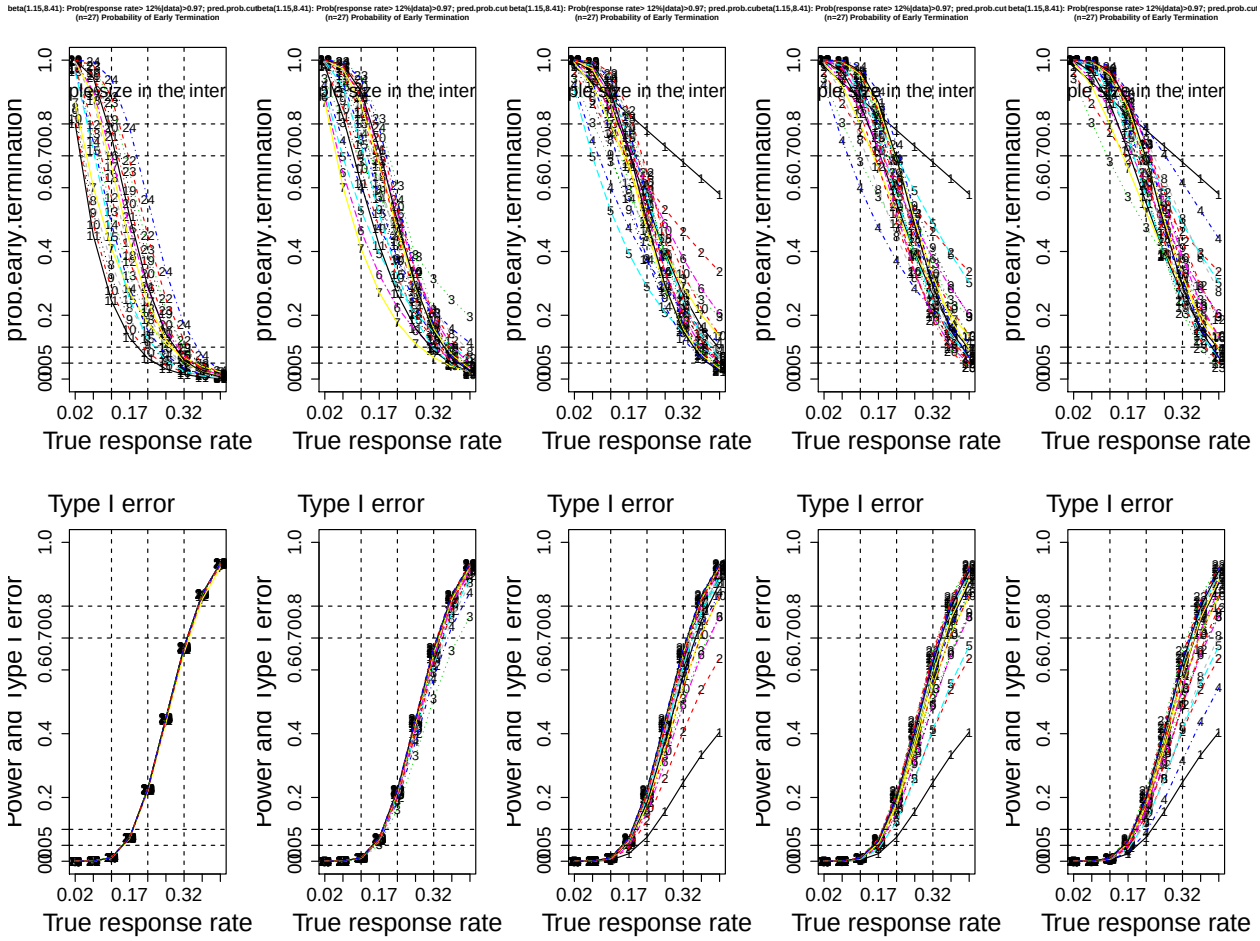
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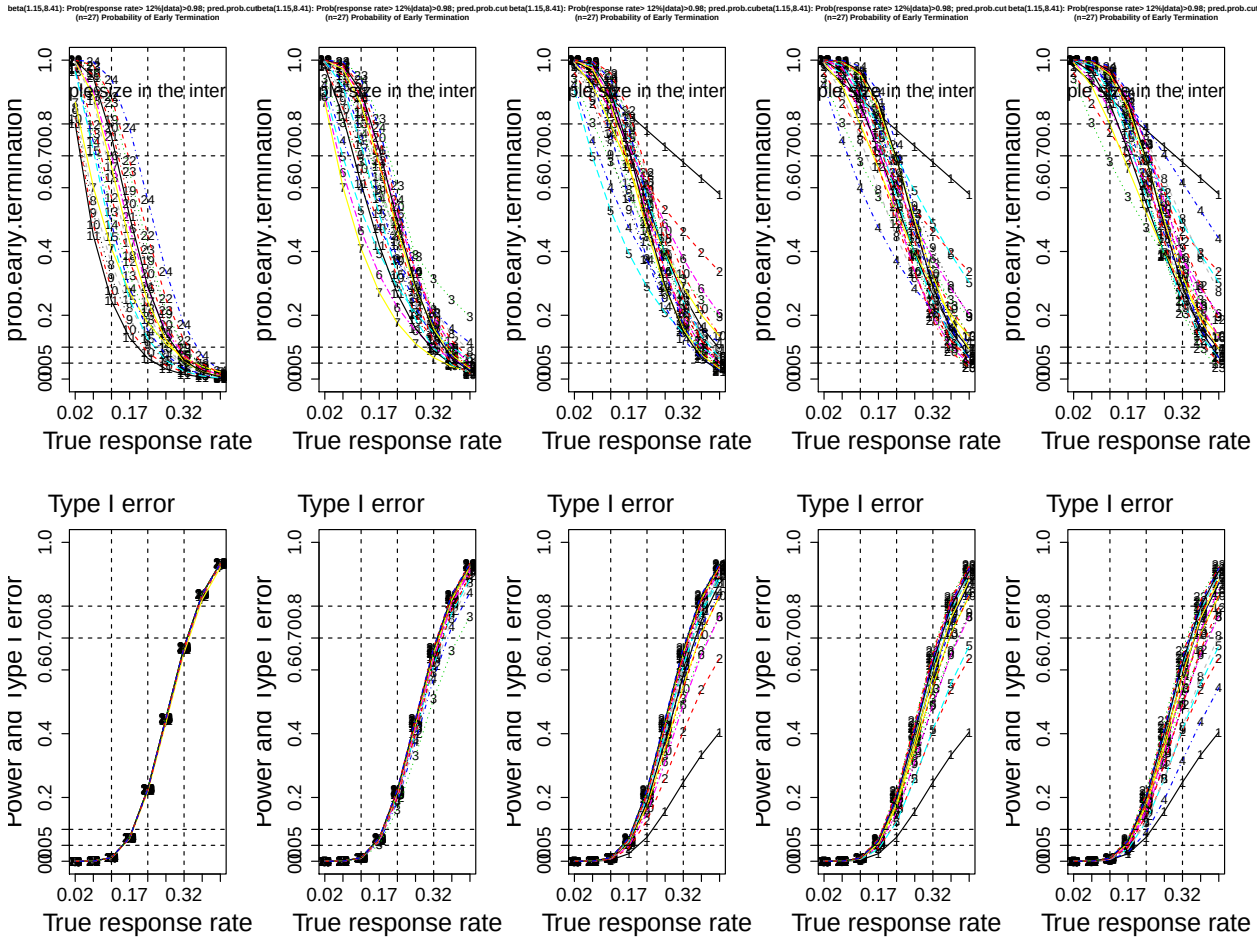
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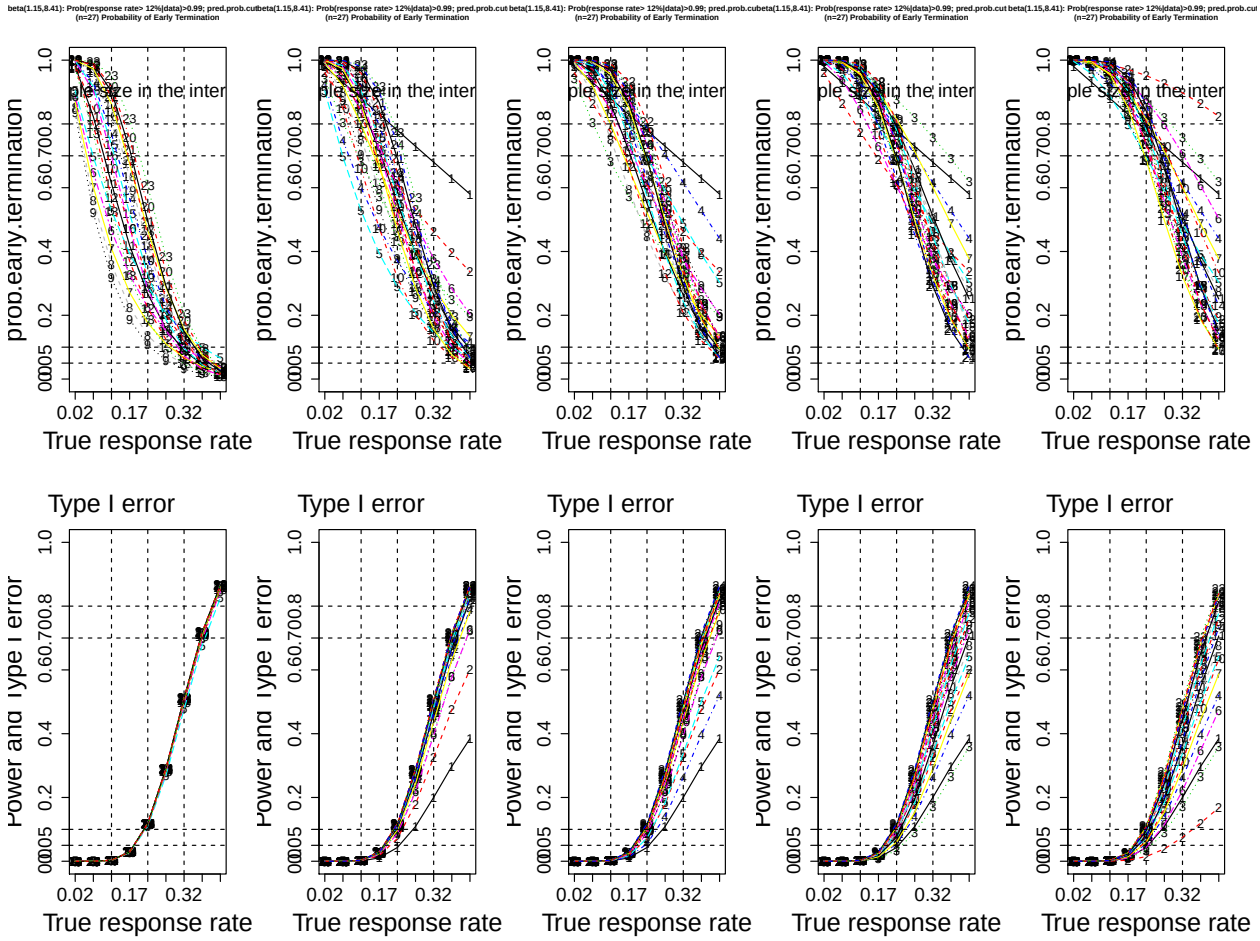
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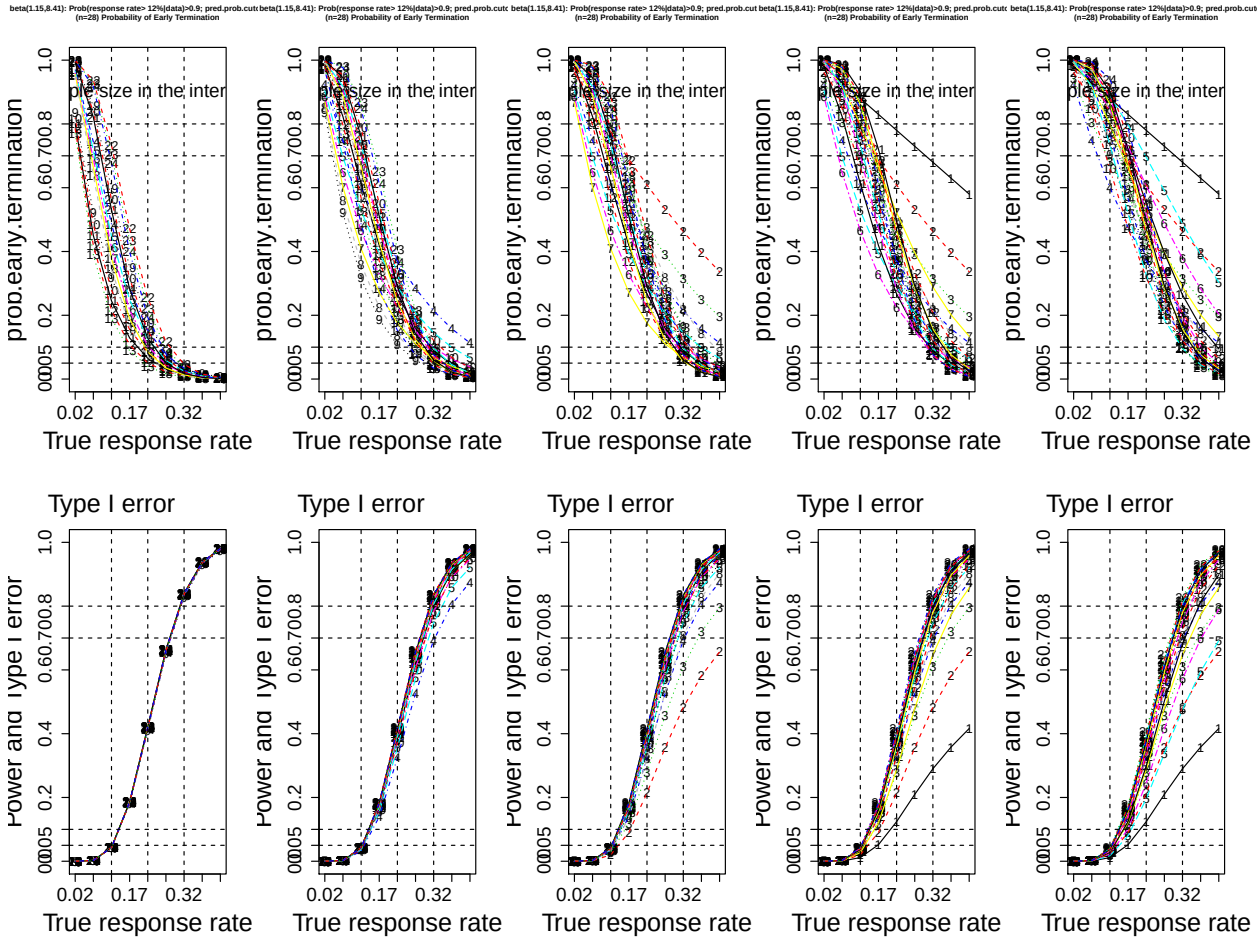
beta(1.15,8.41): Prob(response rate> 12%|data)>0.9; pred.prob.cut
(n=28) Probability of Early Termination
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True response rate
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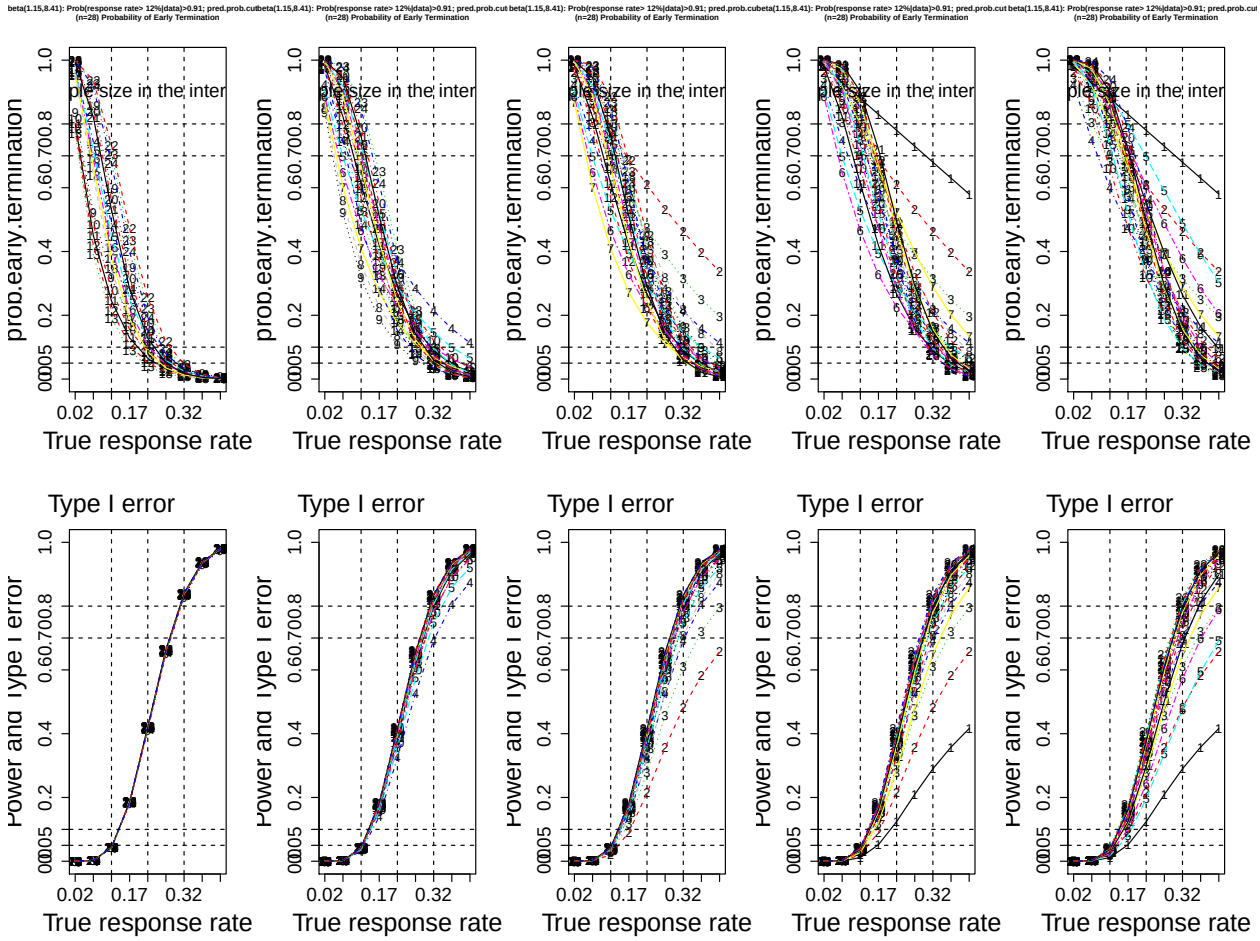
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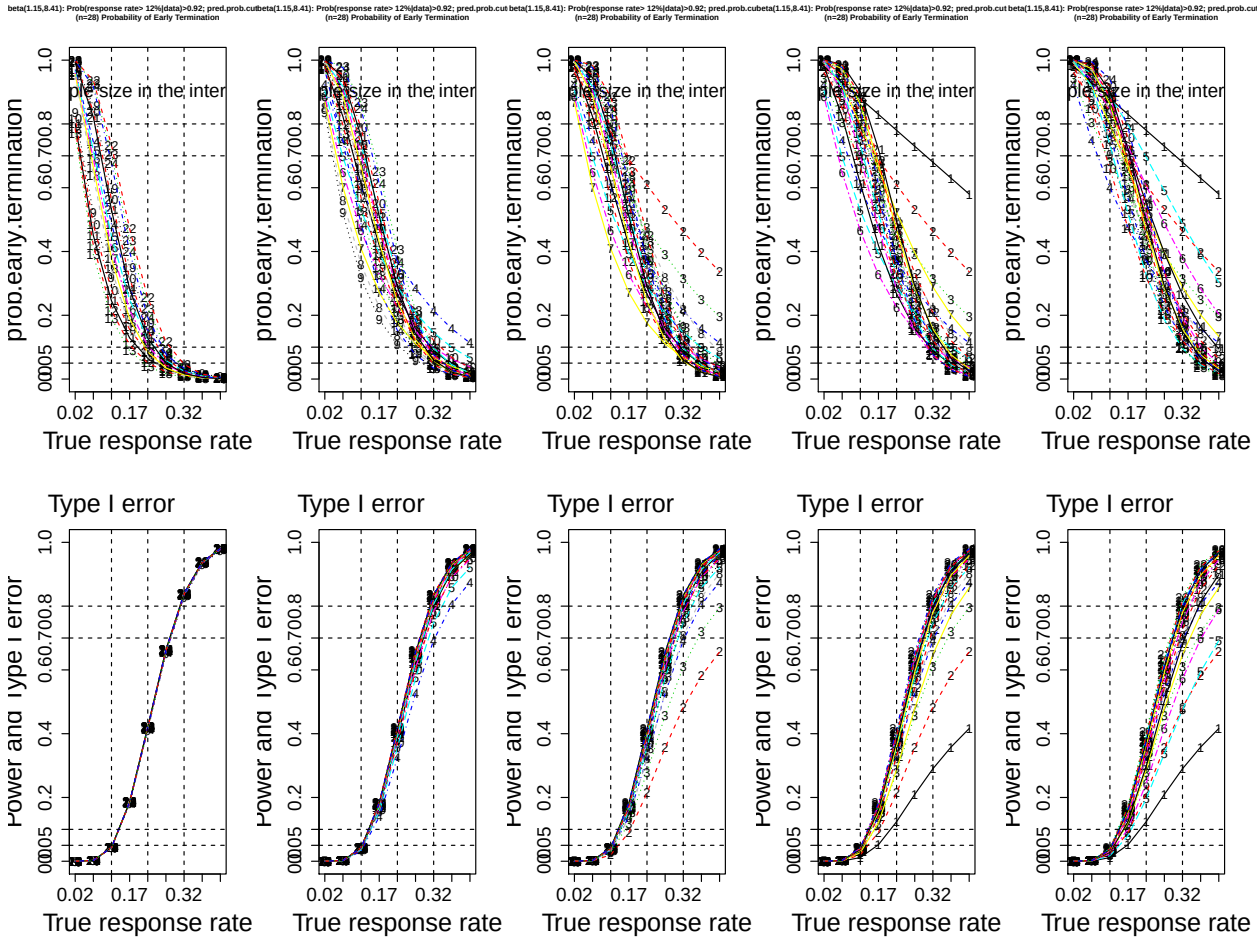
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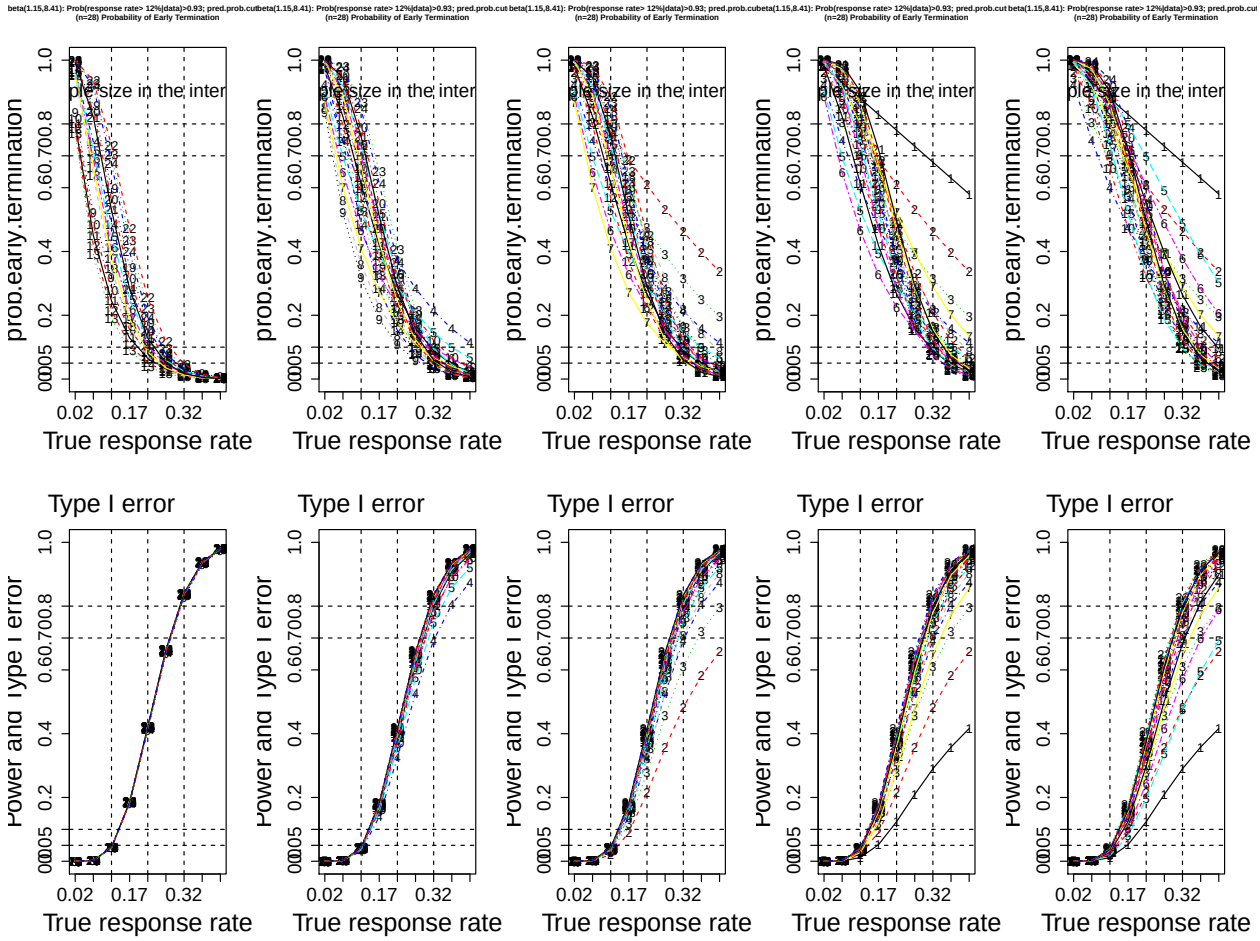
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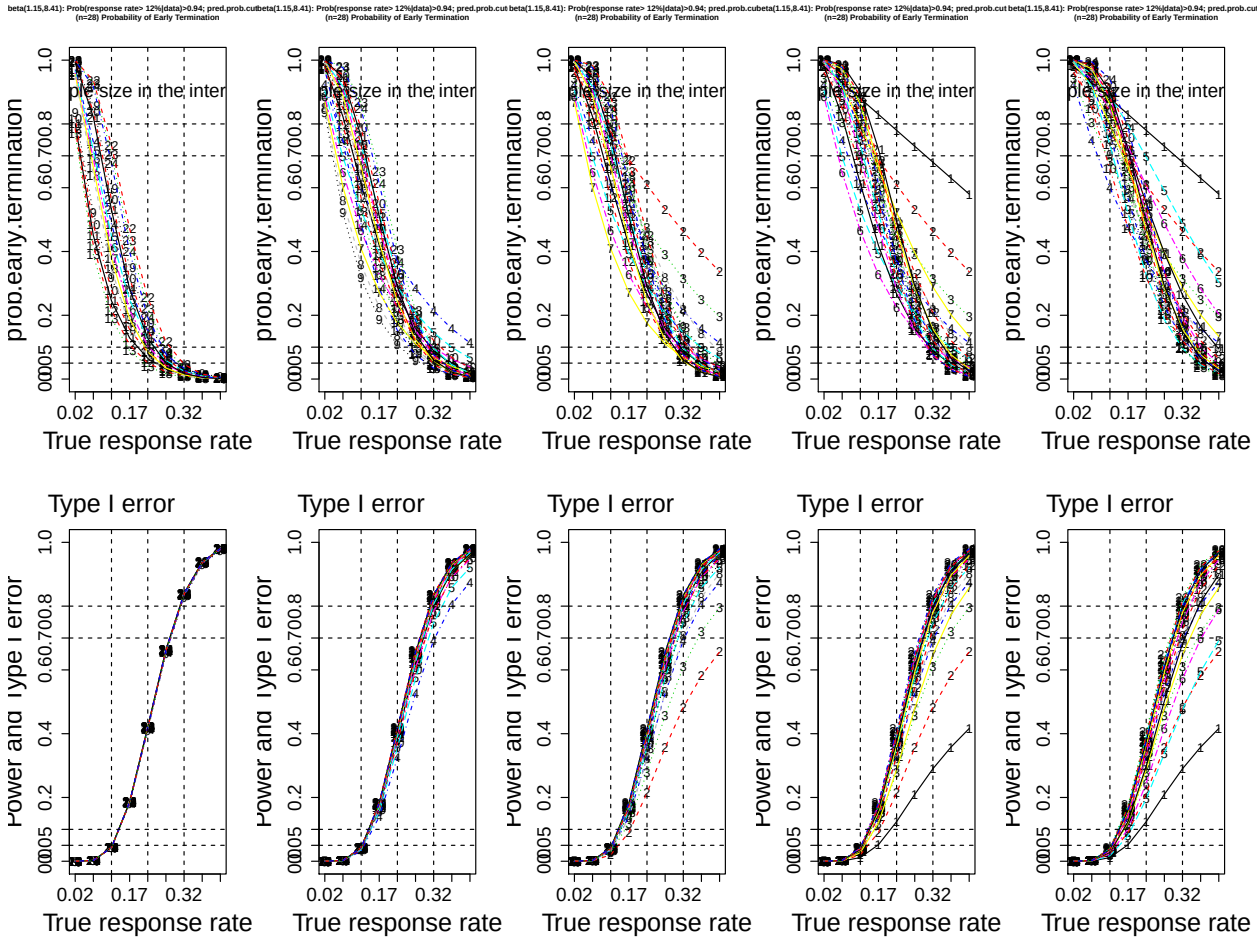
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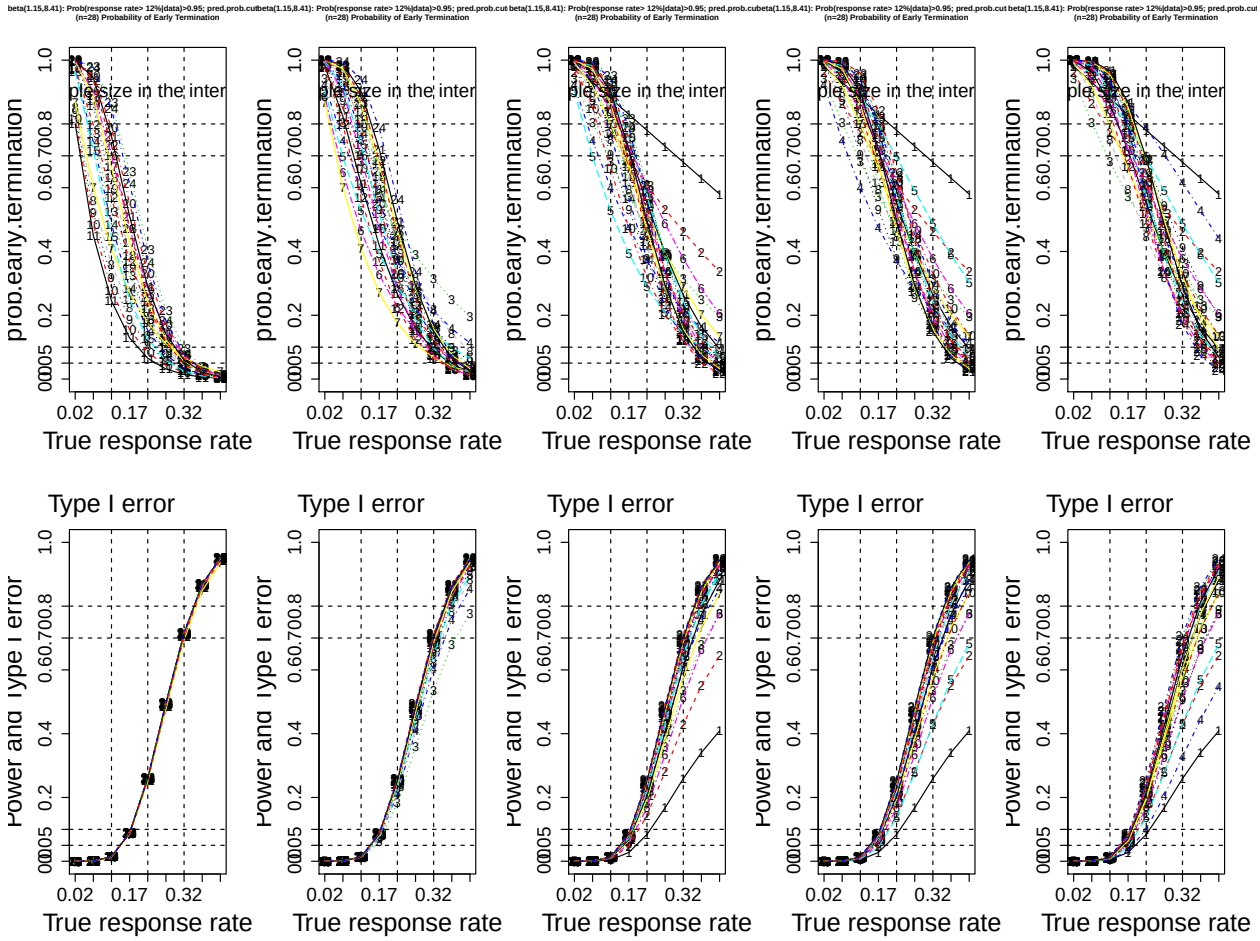
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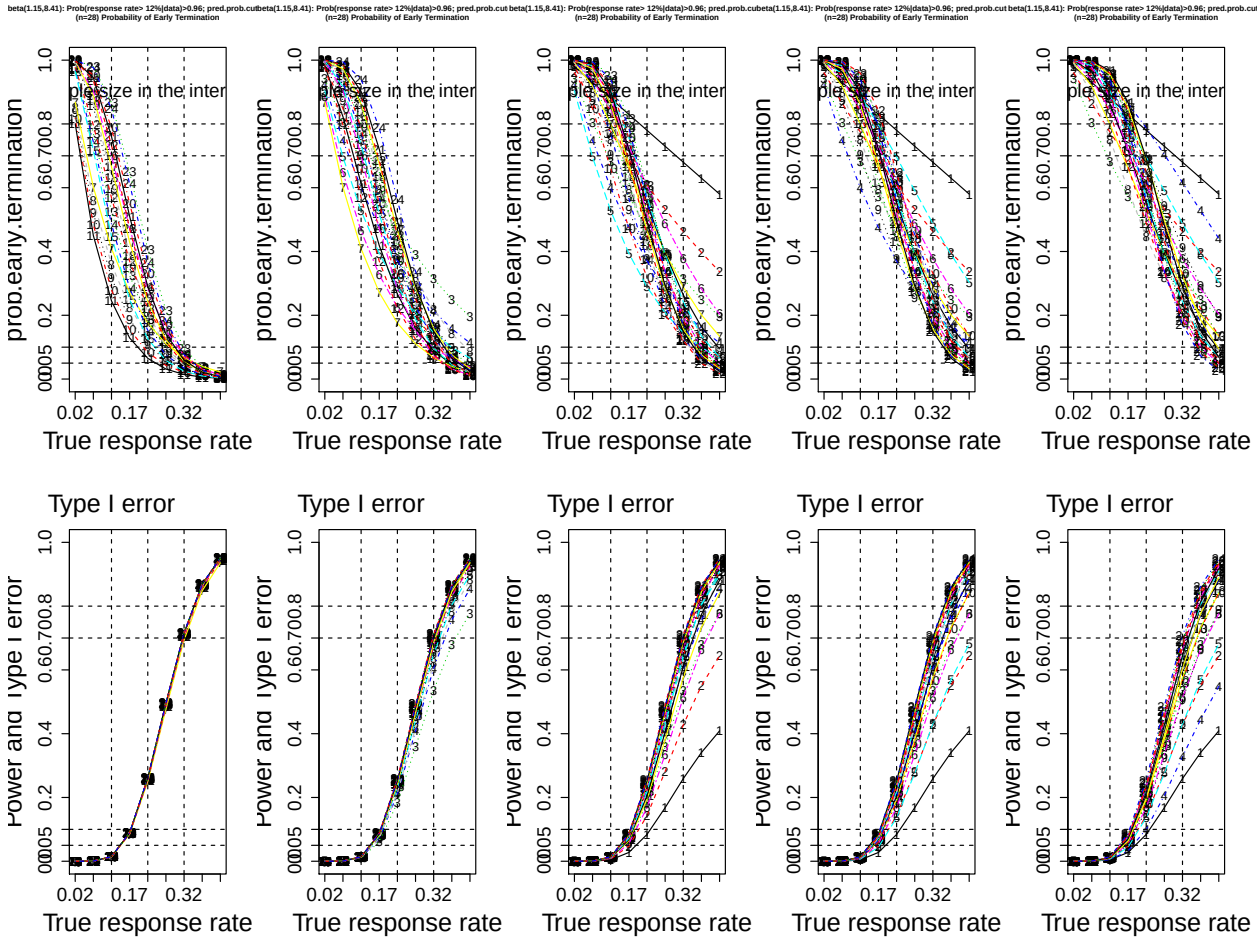
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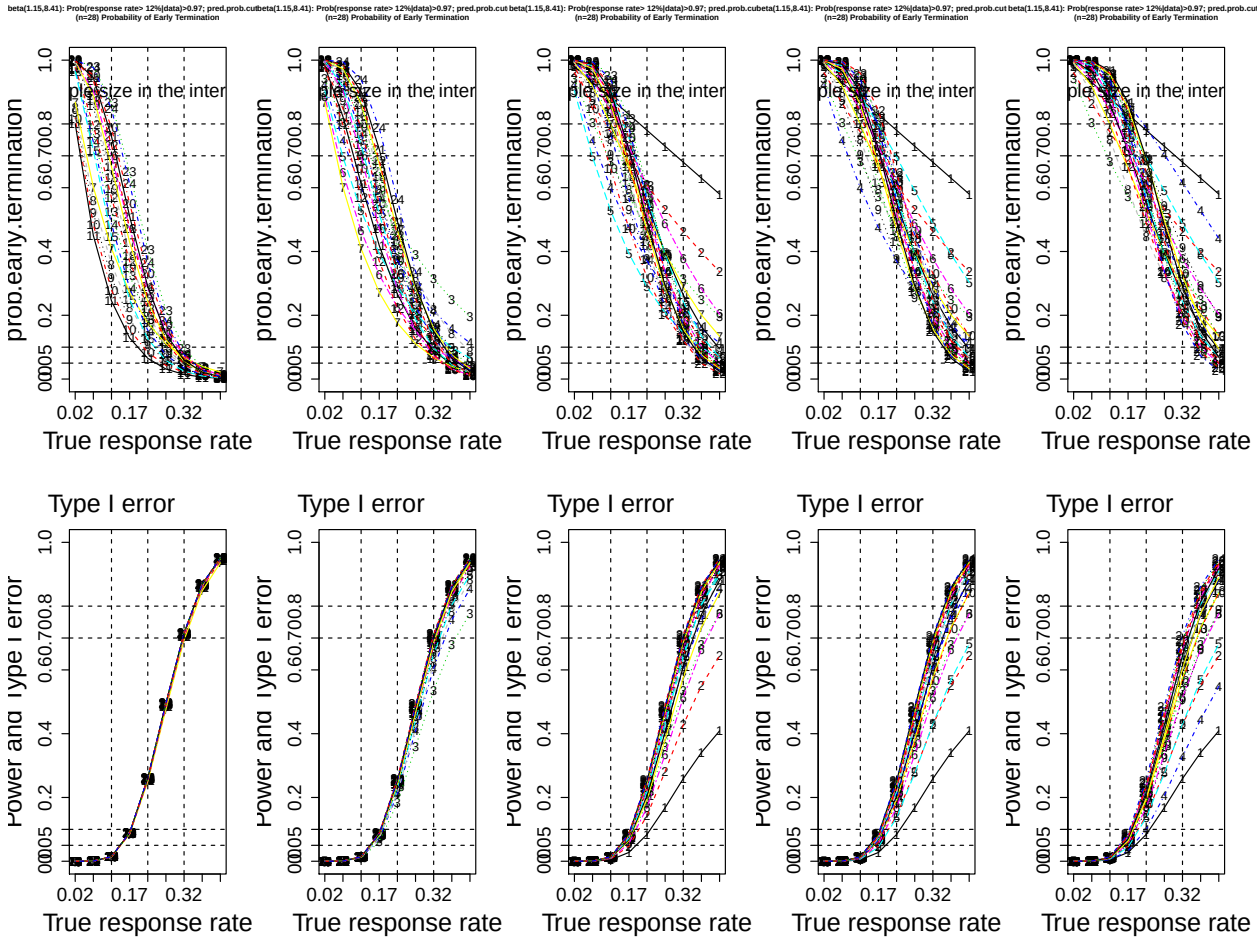
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True response rate
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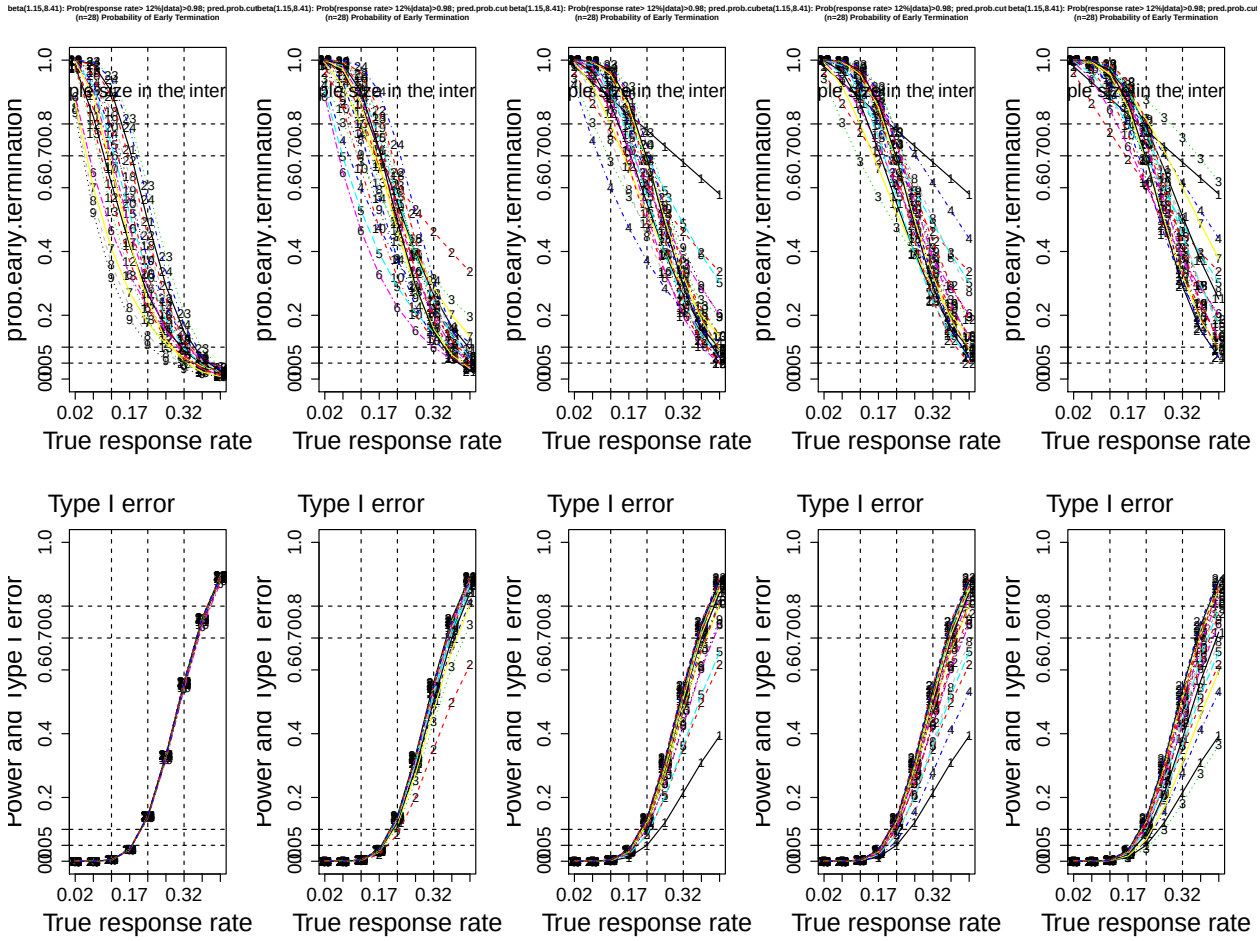
beta(1.15,8.41): Prob(response rate> 12%|data)>0.98; pred.prob.cut
(n=28) Probability of Early Termination
prob.early.termination
Type I error
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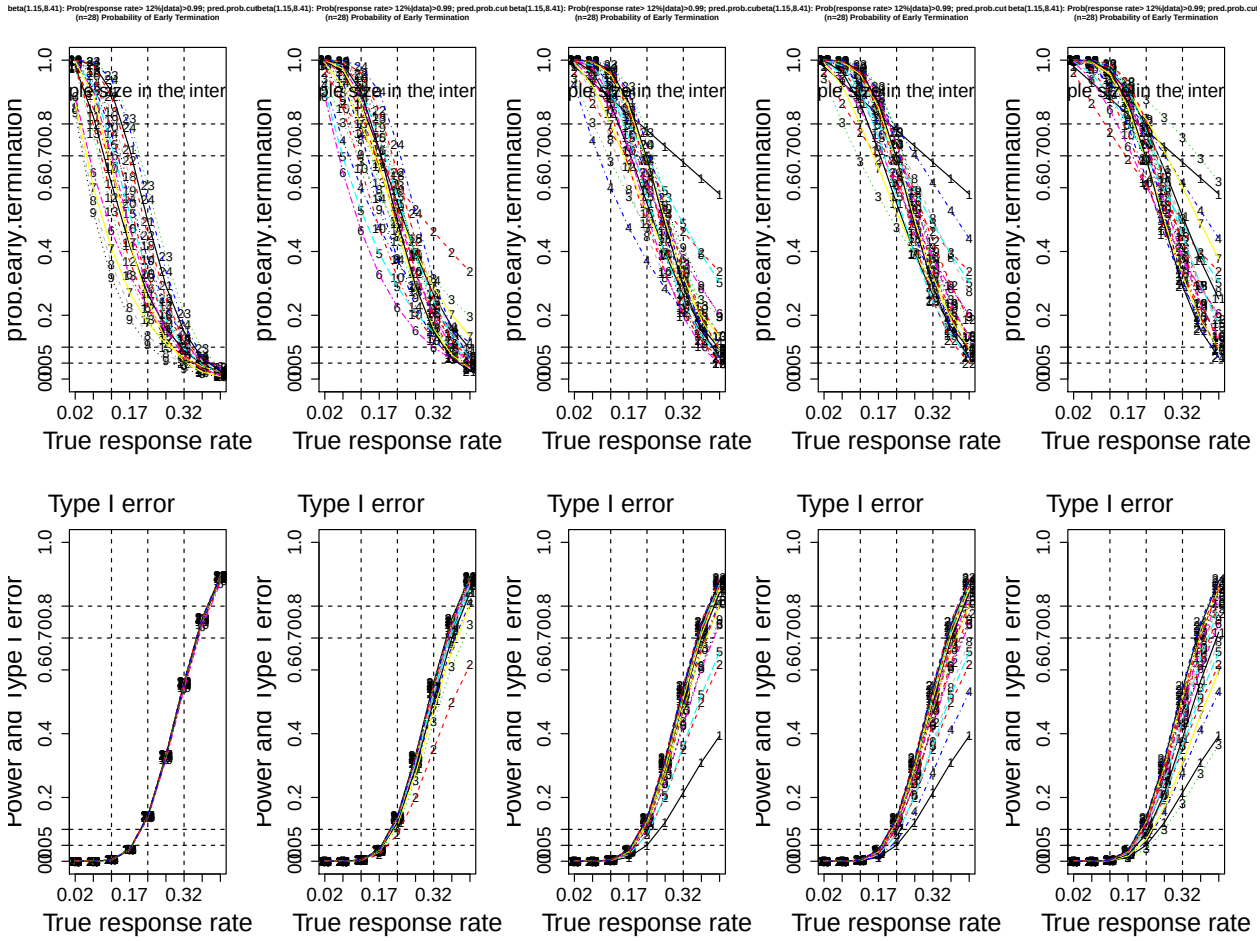
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prob.early.termination
Type I error
Power and Type I error
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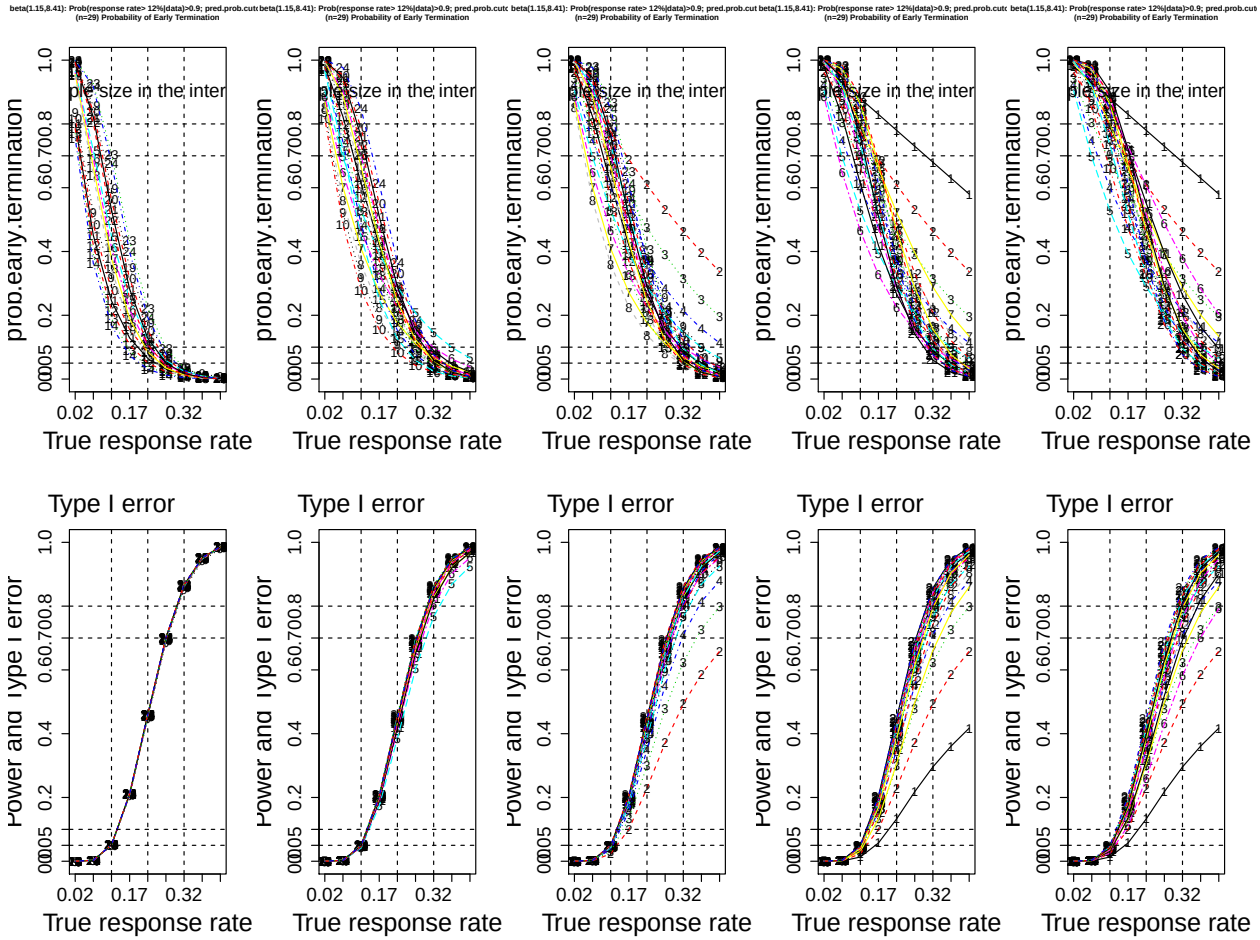
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(n=29) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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0.32
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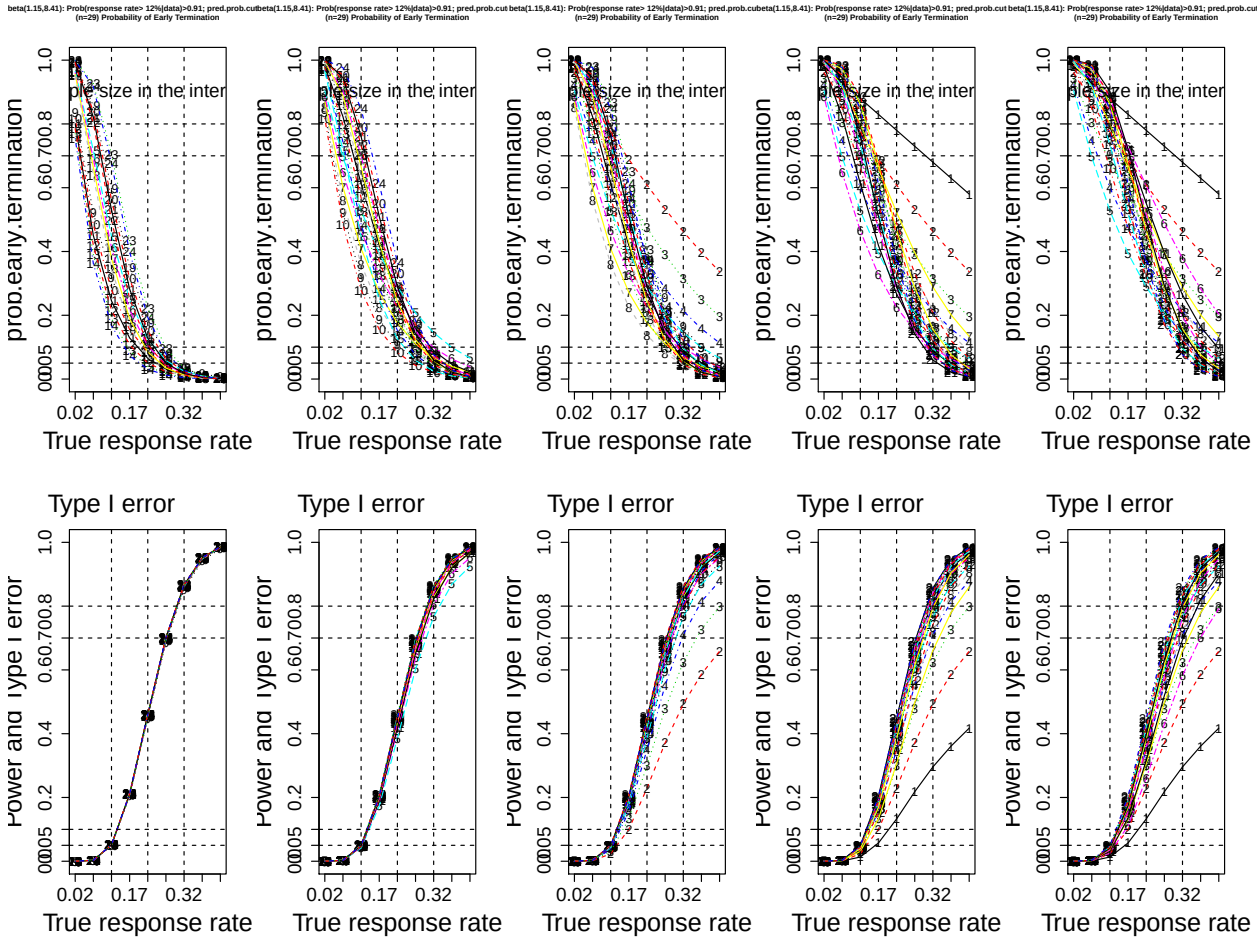
beta(1.15,8.41): Prob(response rate> 12%|data)>0.91; pred.prob.cut
(n=29) Probability of Early Termination
prob.early.termination
Power and Type I error
Type I error
True response rate
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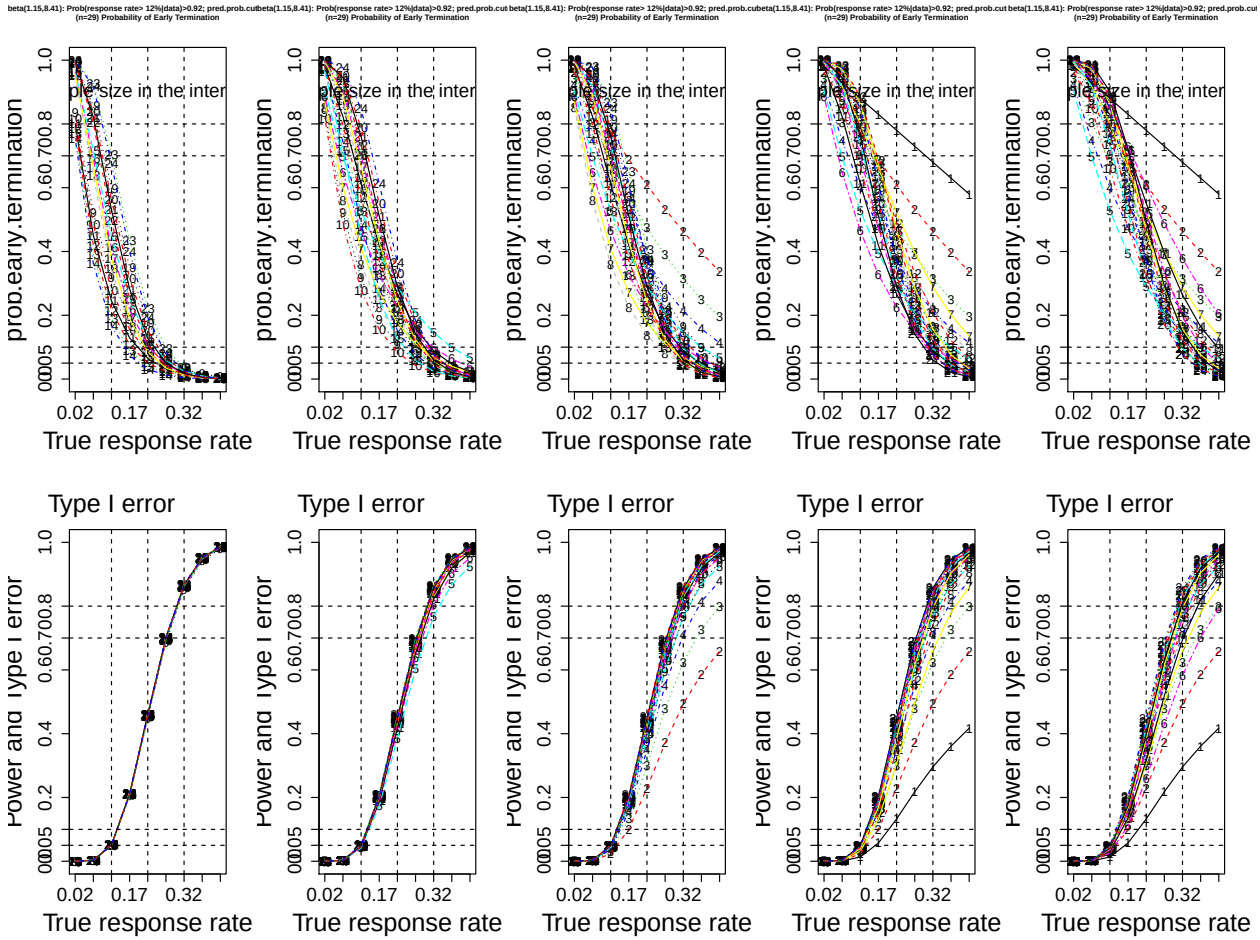
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prob.early.termination
Type I error
Power and Type I error
True response rate
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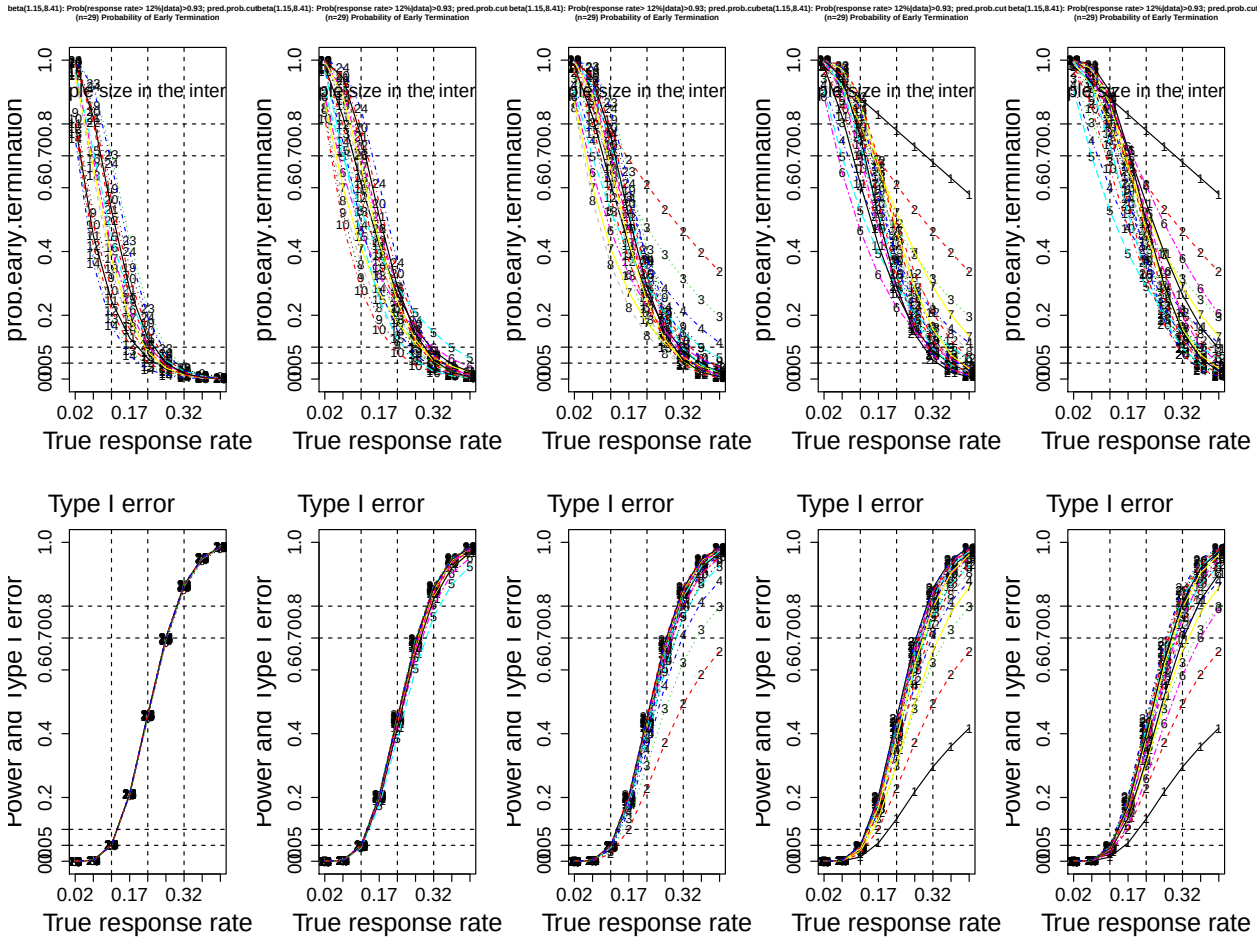
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(n=29) Probability of Early Termination
prob.early.termination
Power and Type I error
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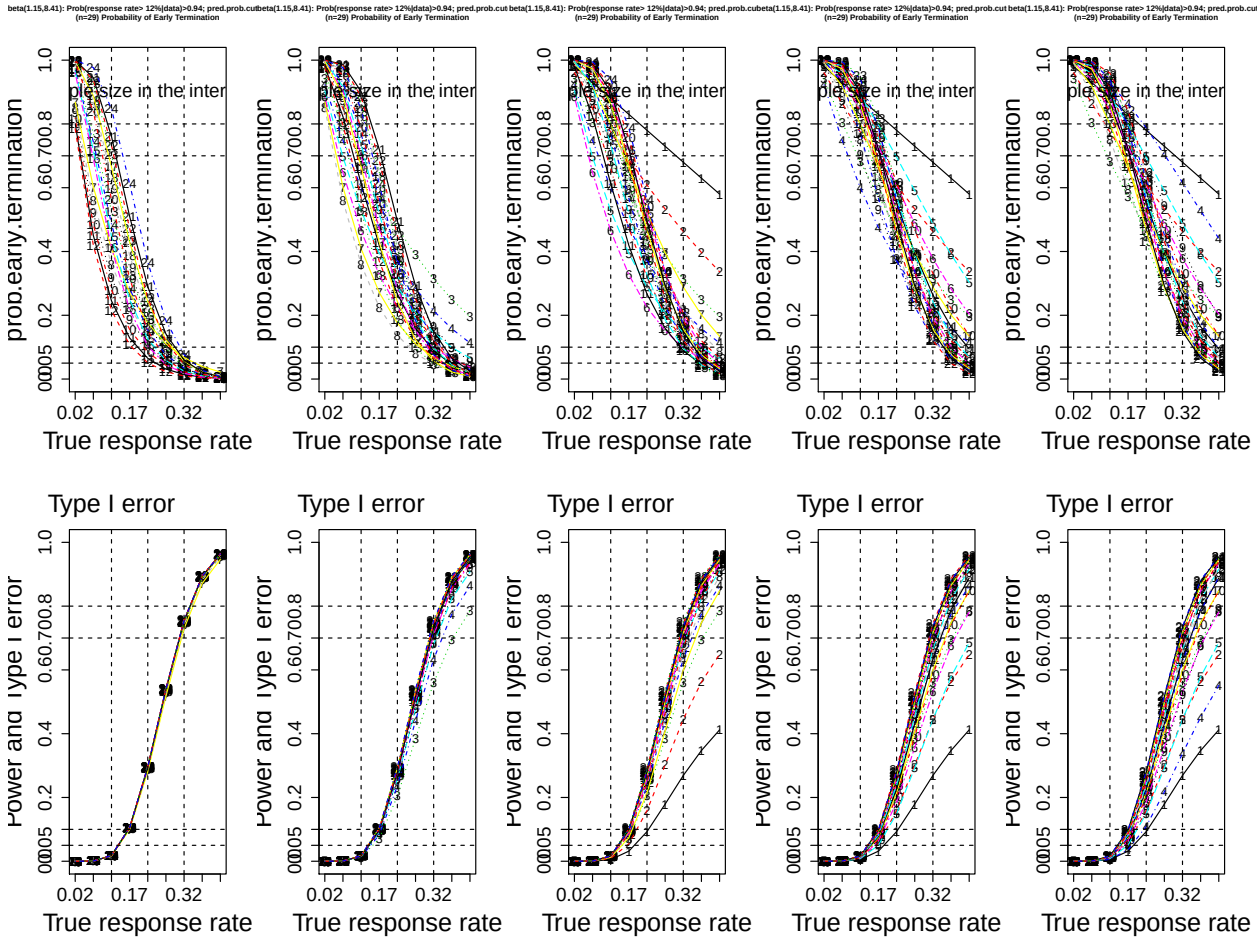
beta(1.15,8.41): Prob(response rate> 12%|data)>0.94; pred.prob.cut
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prob.early.termination
Type I error
Power and Type I error
True response rate
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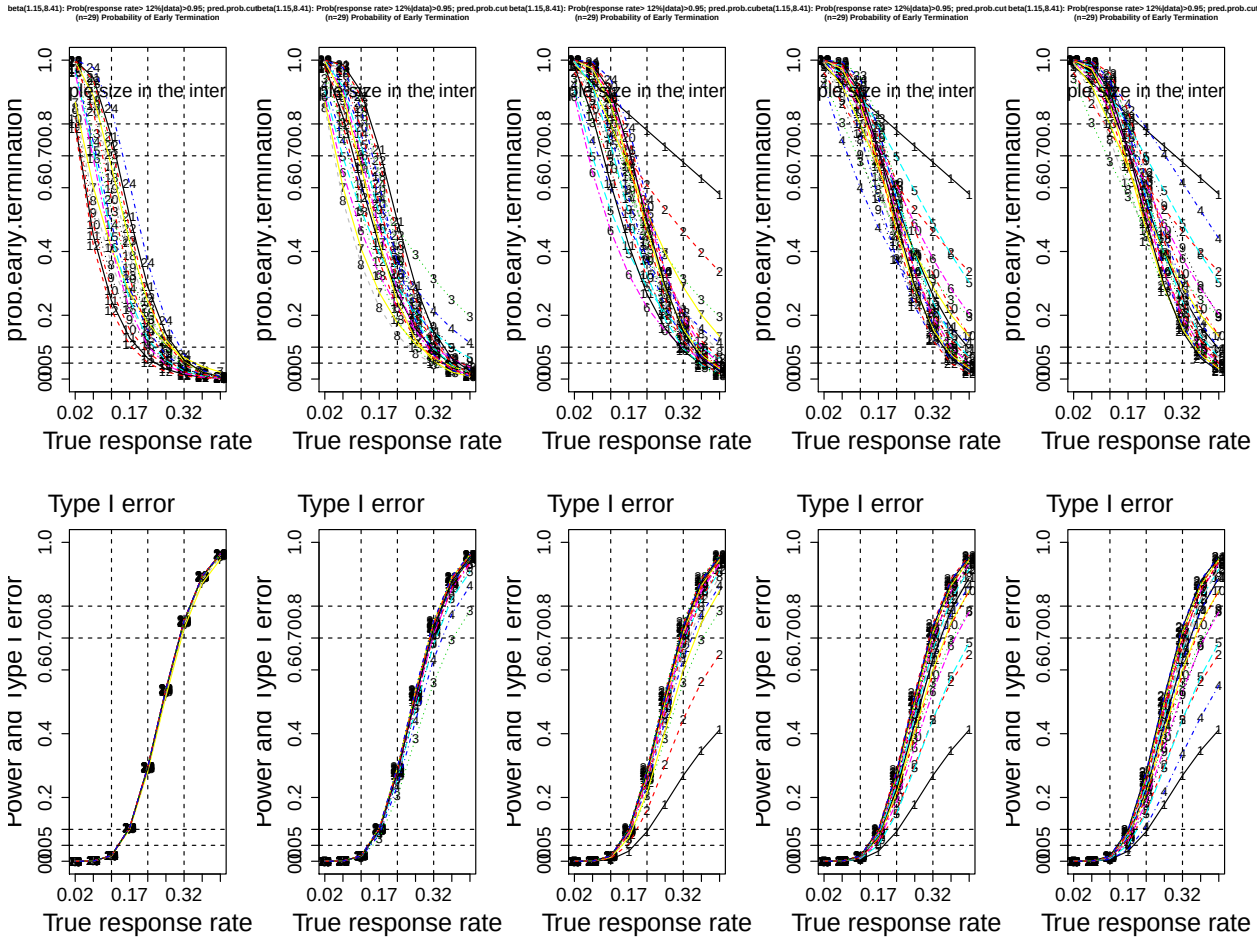
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Type I error
Power and Type I error
True response rate
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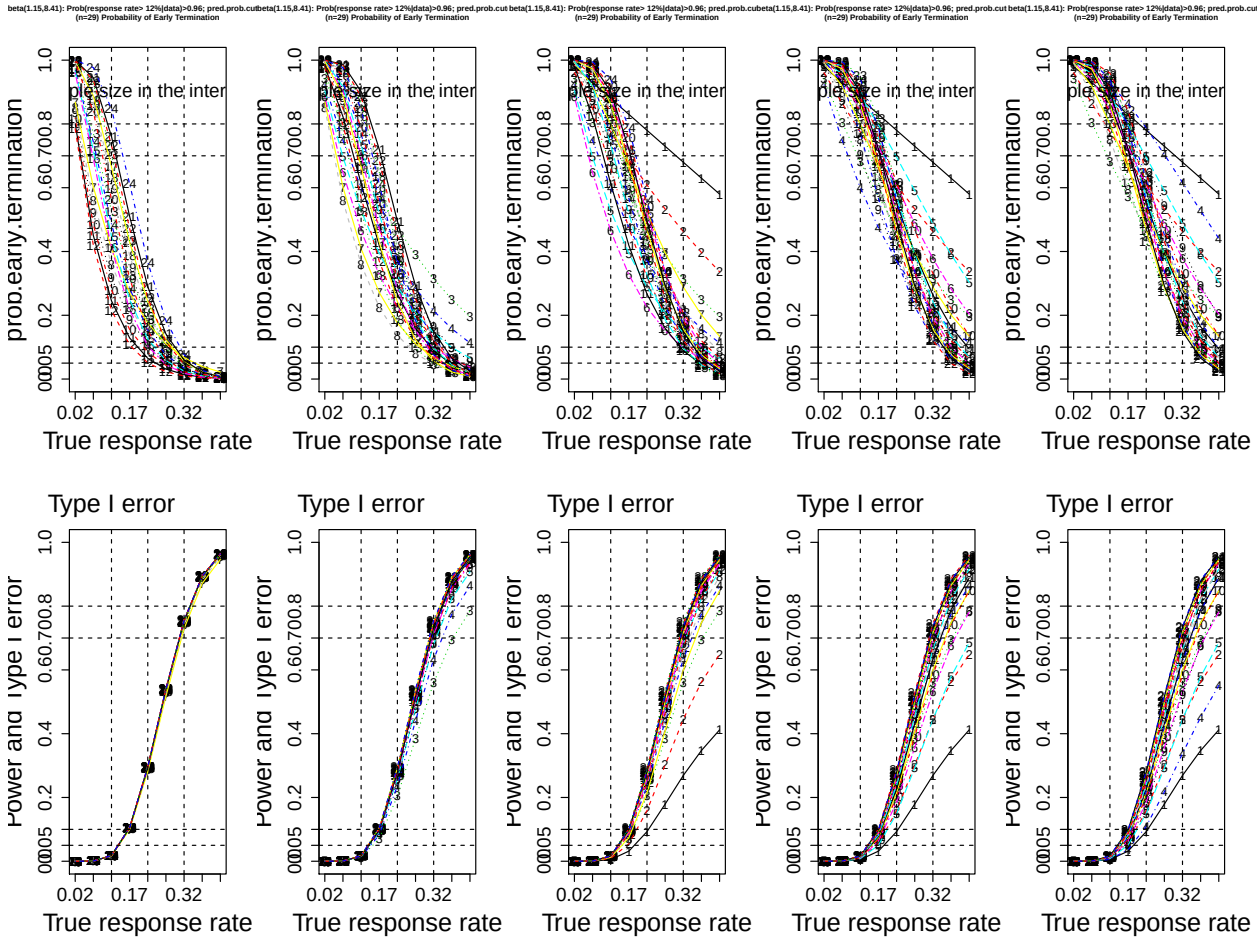
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prob.early.termination
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Power and Type I error
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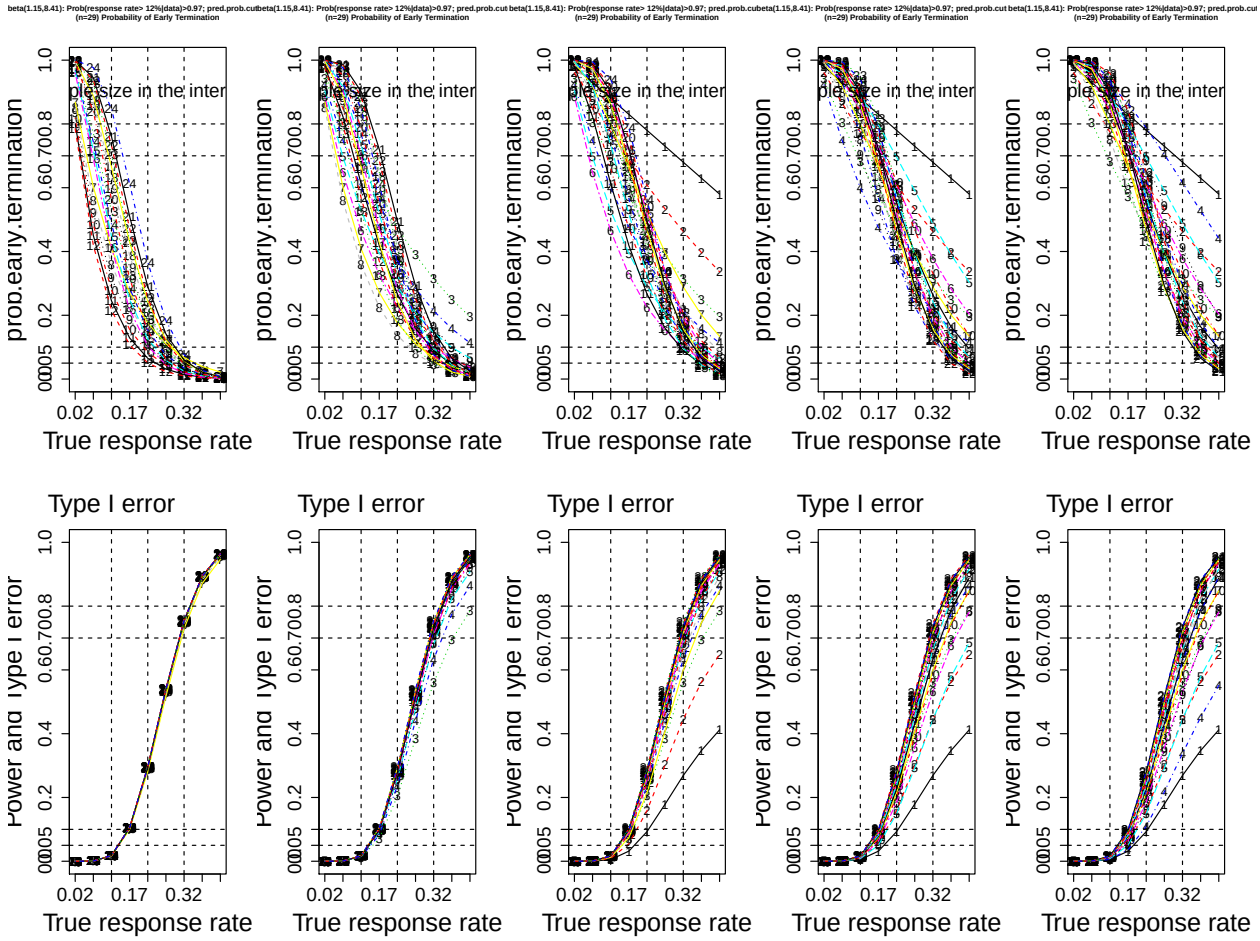
beta(1.15,8.41): Prob(response rate> 12%|data)>0.97; pred.prob.cut
(n=29) Probability of Early Termination
prob.early.termination
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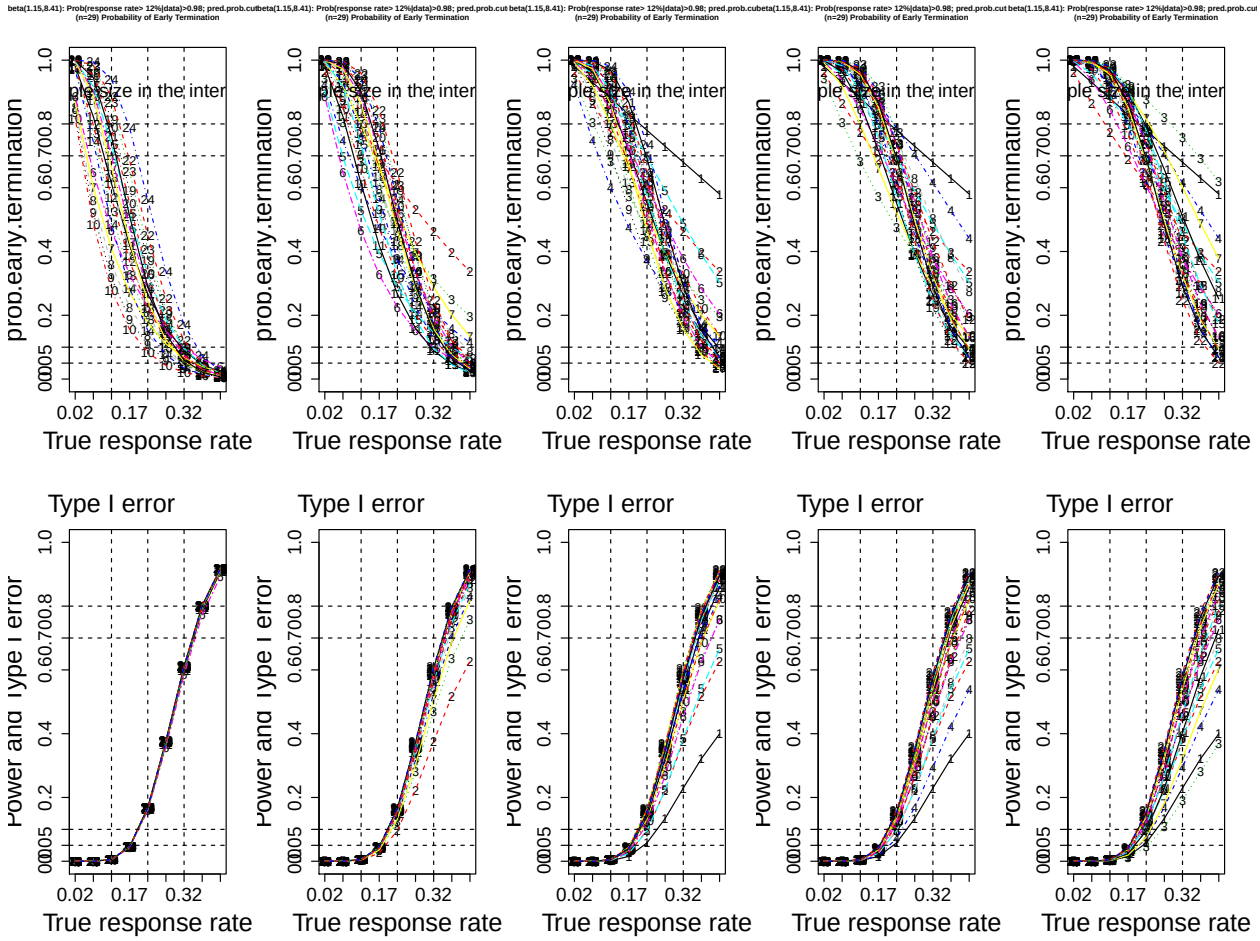
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(n=29) Probability of Early Termination
prob.early.termination
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Power and Type I error
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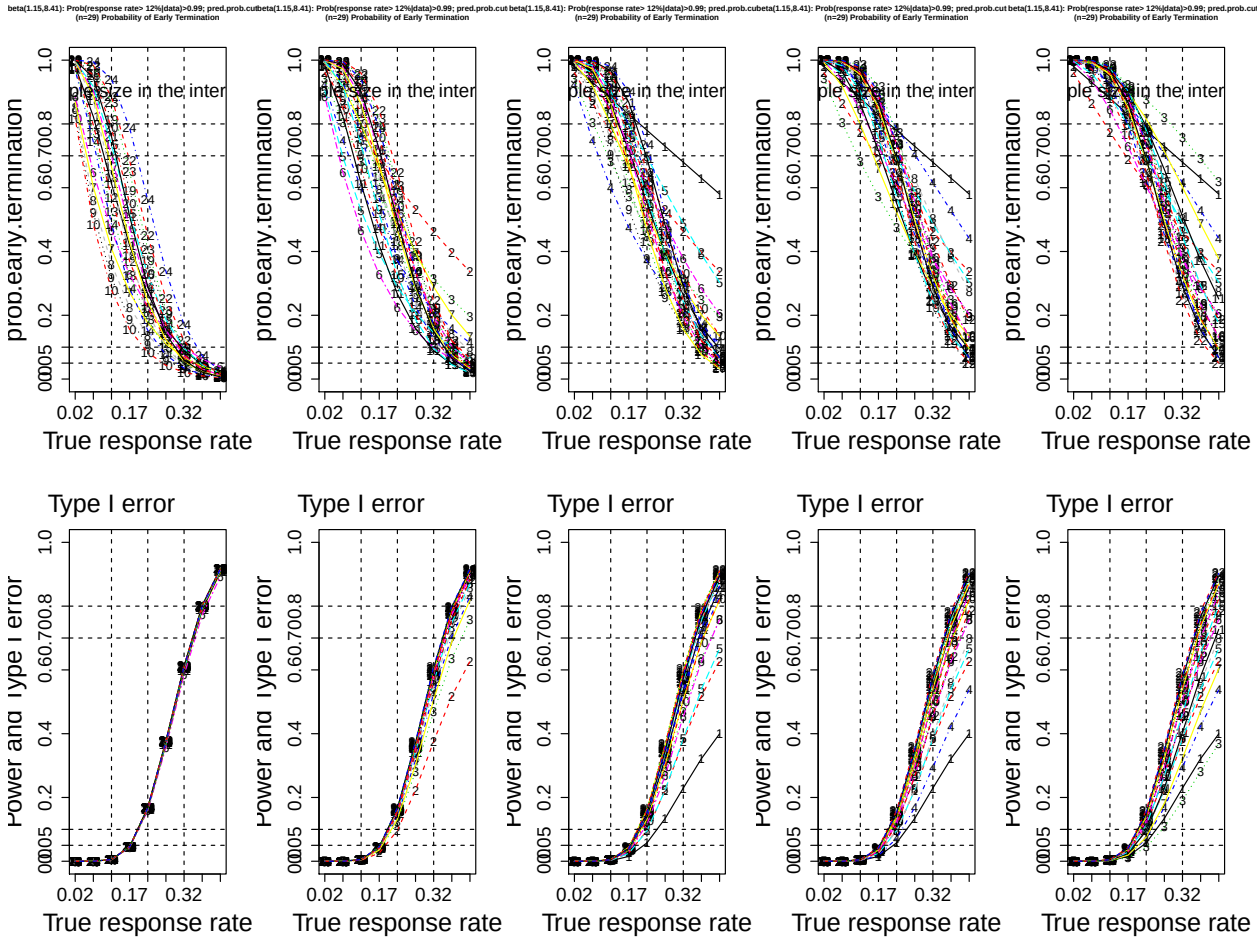
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(n=29) Probability of Early Termination
prob.early.termination
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Power and Type I error
True response rate
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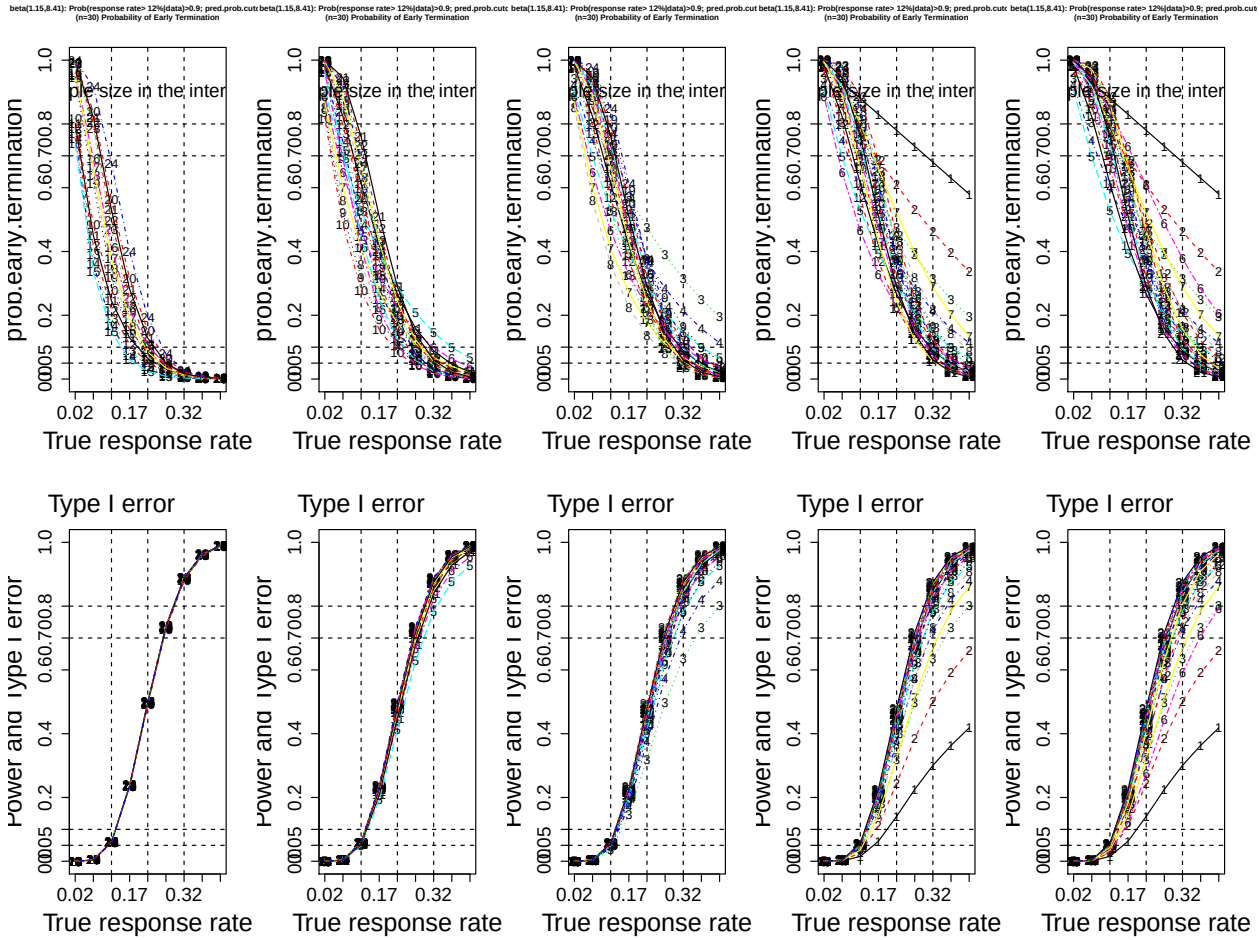
beta(1.15,8.41): Prob(response rate> 12%|data)>0.9; pred.prob.cut
(n=30) Probability of Early Termination
prob.early.termination
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True response rate
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Power and Type I error
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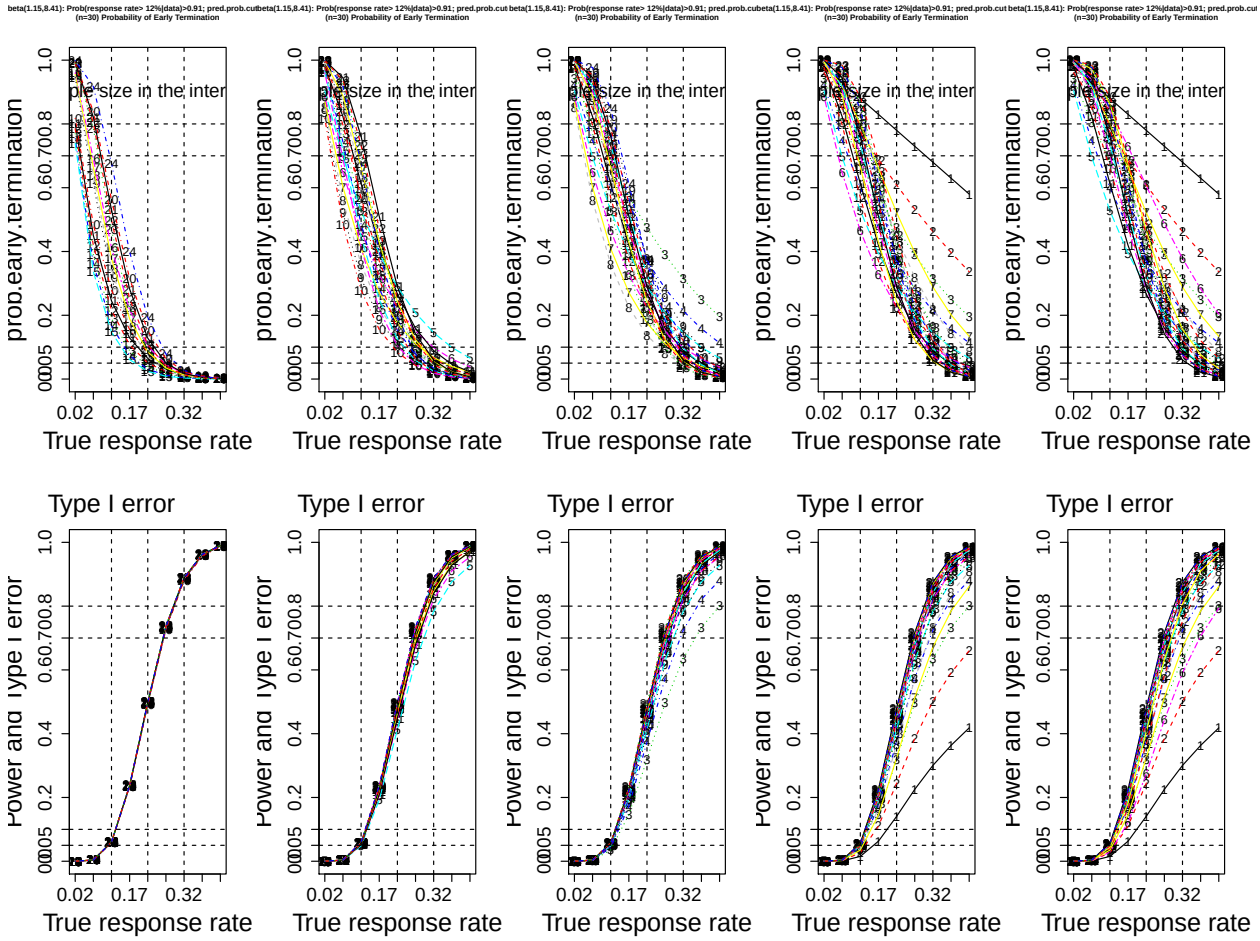
beta(1.15,8.41): Prob(response rate> 12%|data)>0.91; pred.prob.cut
(n=30) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
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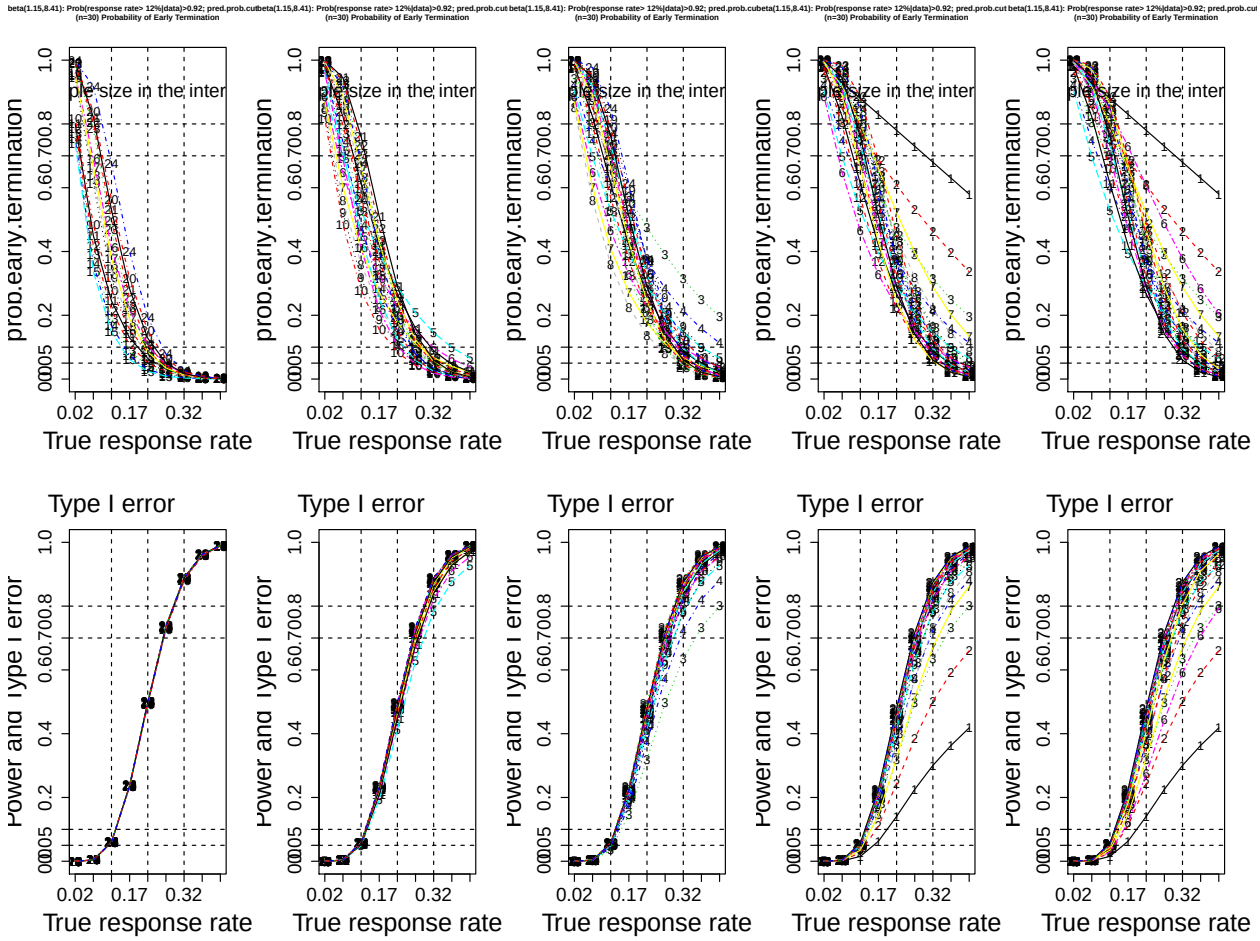
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(n=30) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
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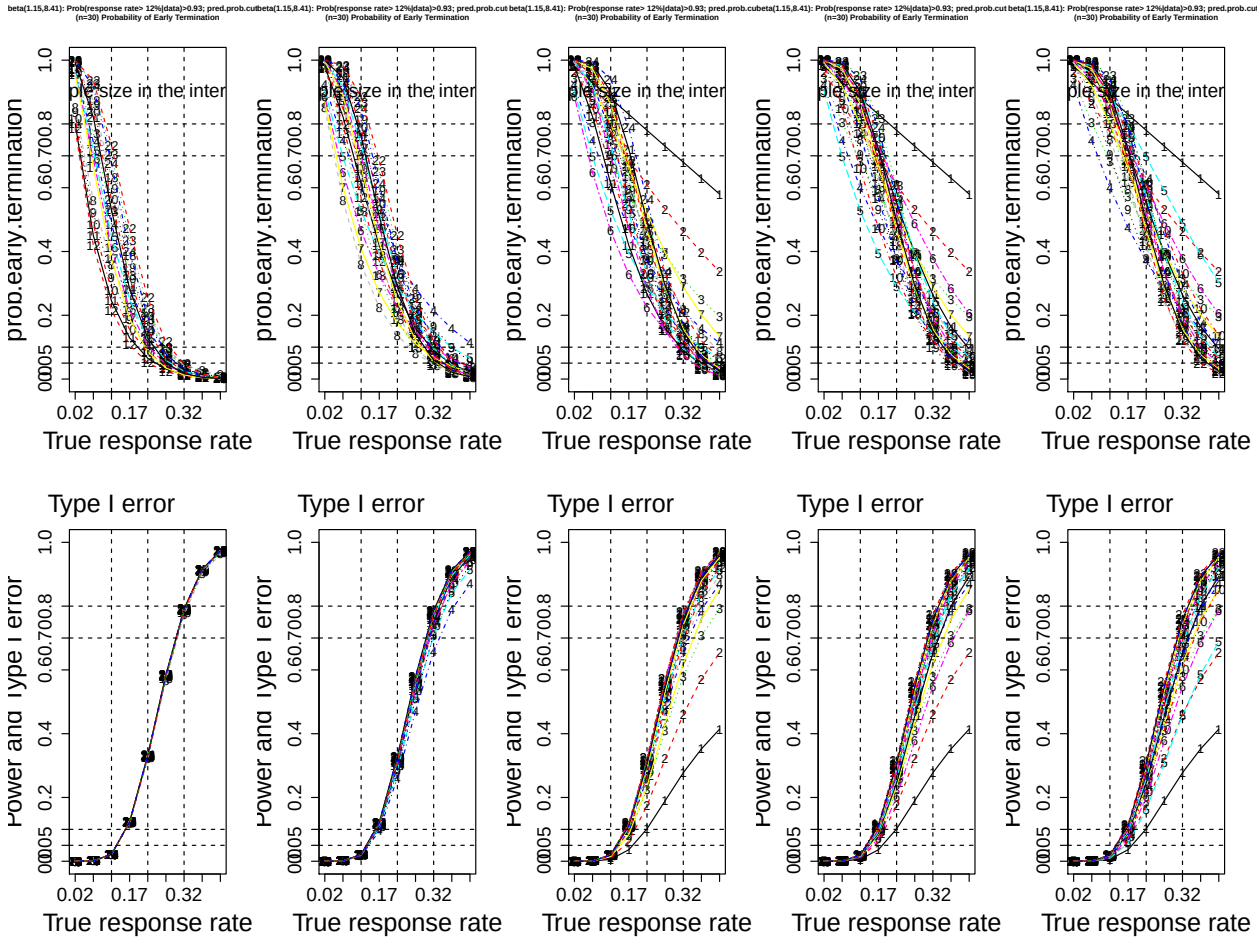
beta(1.15,8.41): Prob(response rate> 12%|data)>0.93; pred.prob.cut
(n=30) Probability of Early Termination
prob.early.termination
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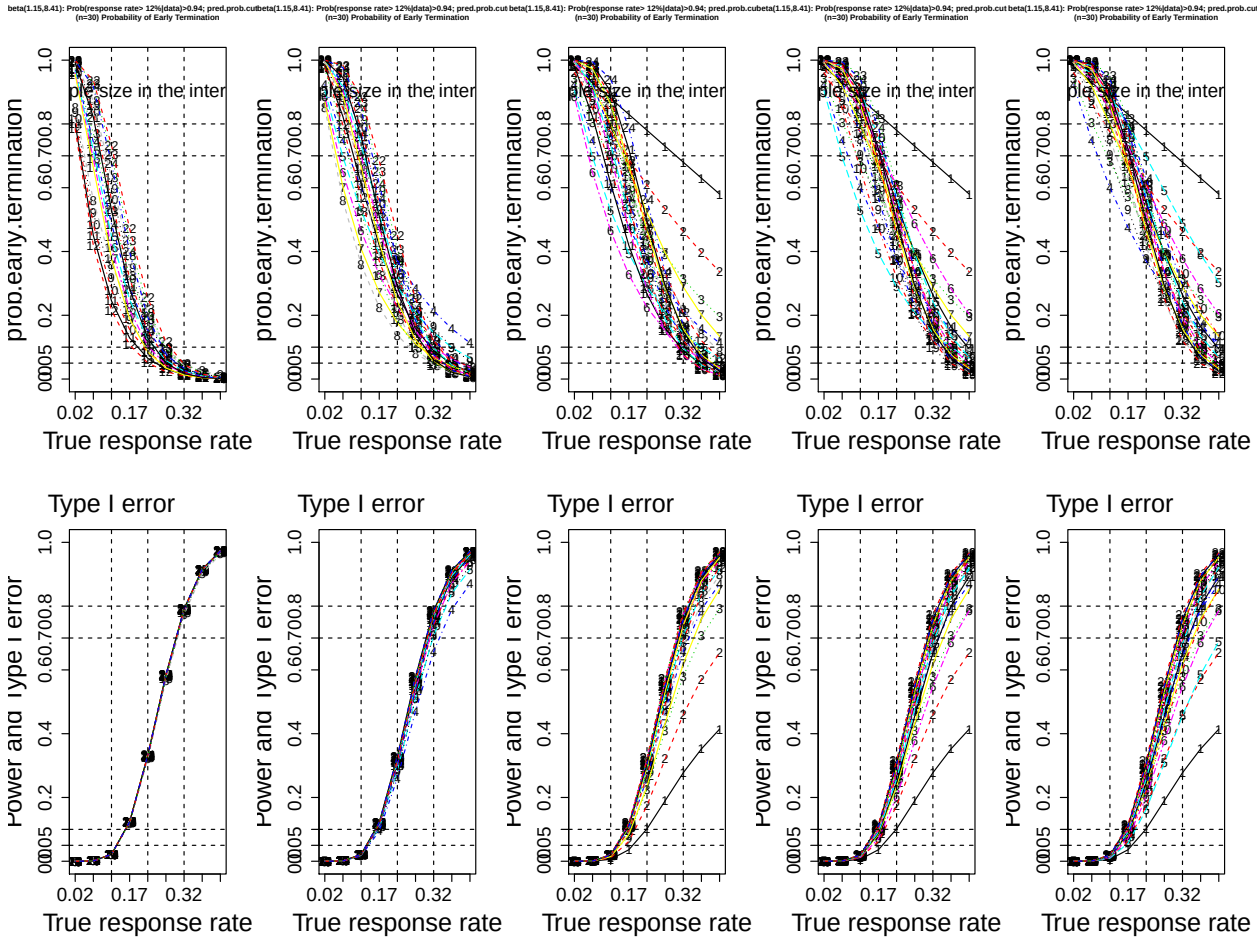
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(n=30) Probability of Early Termination
prob.early.termination
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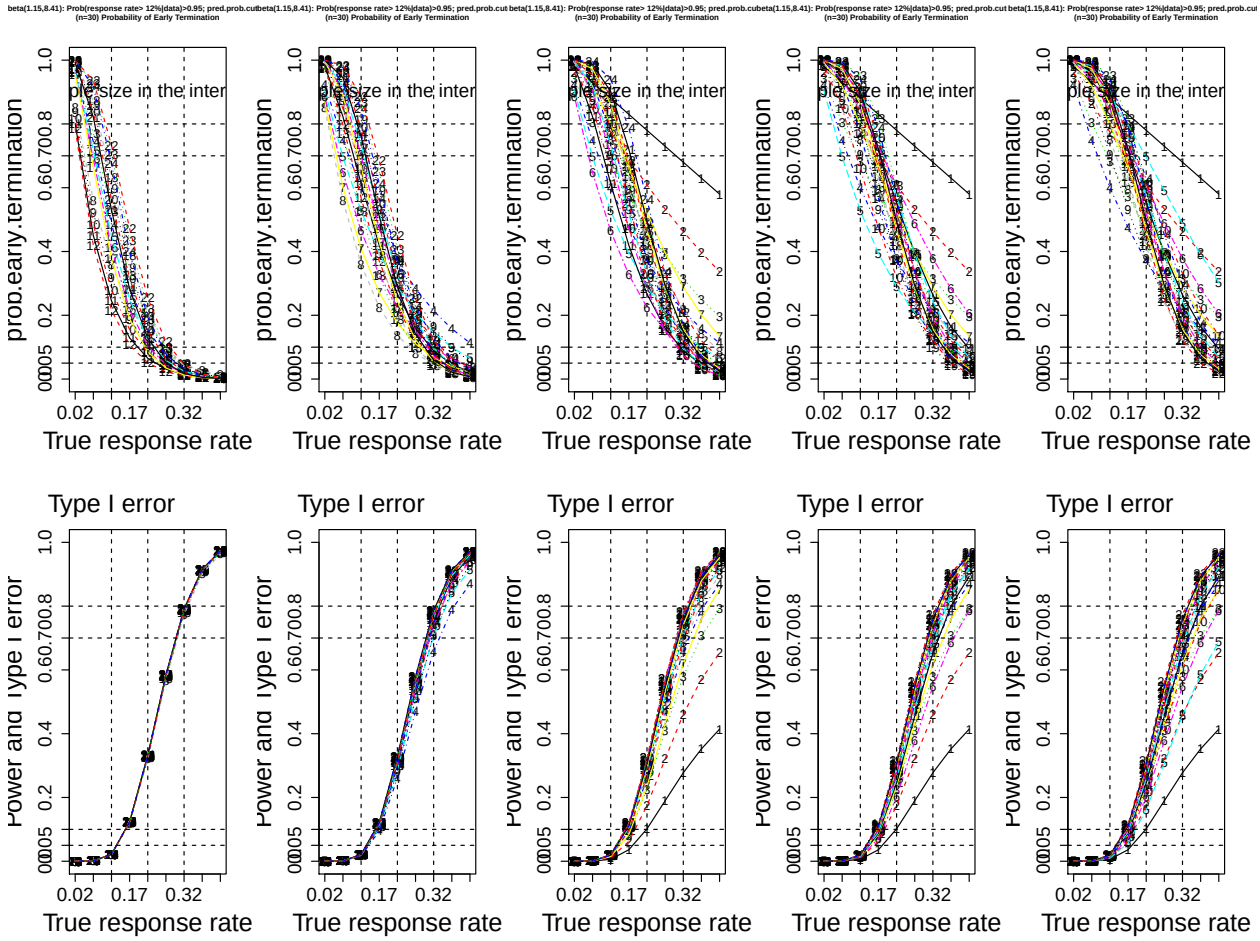
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(n=30) Probability of Early Termination
prob.early.termination
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Power and Type I error
True response rate
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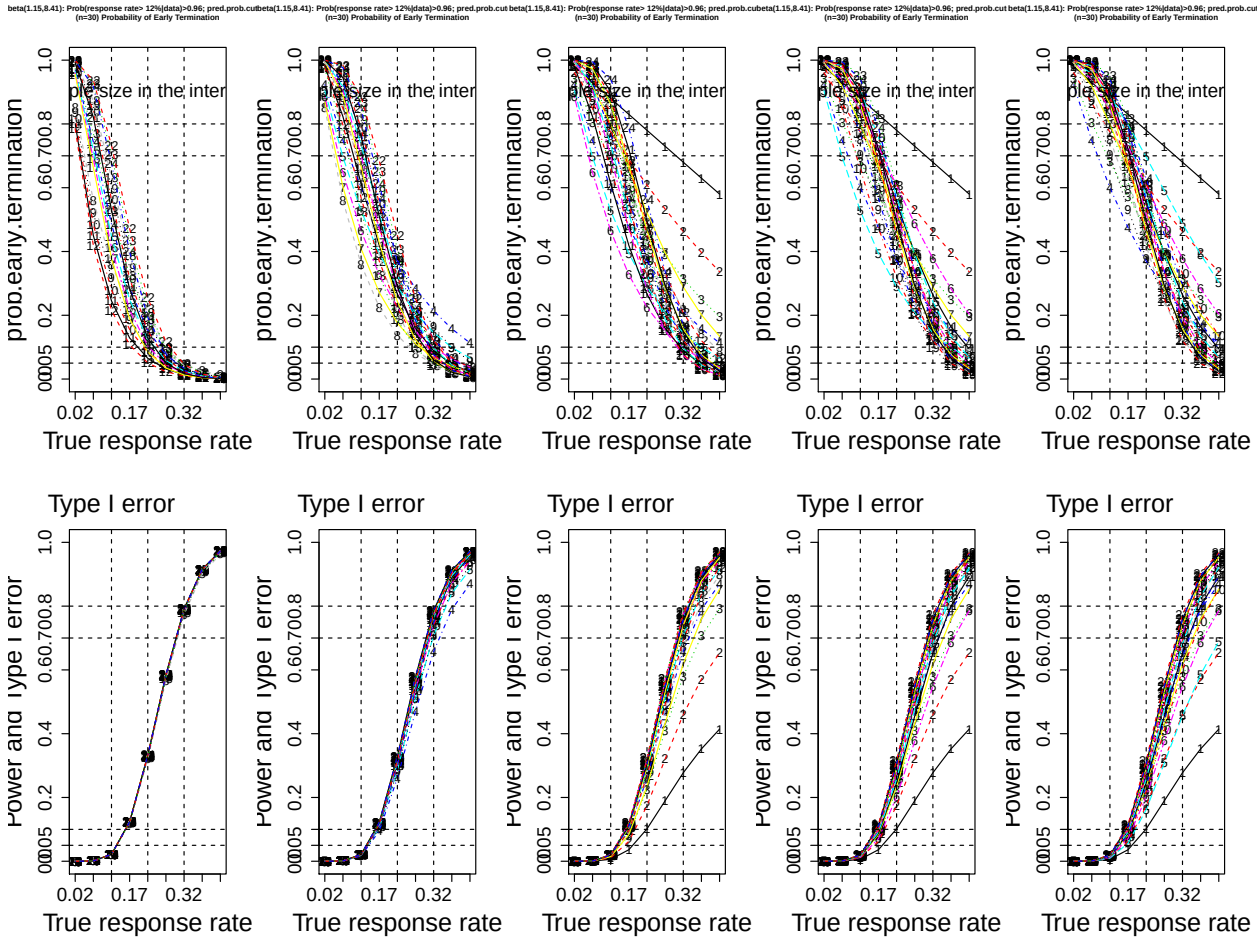
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(n=30) Probability of Early Termination
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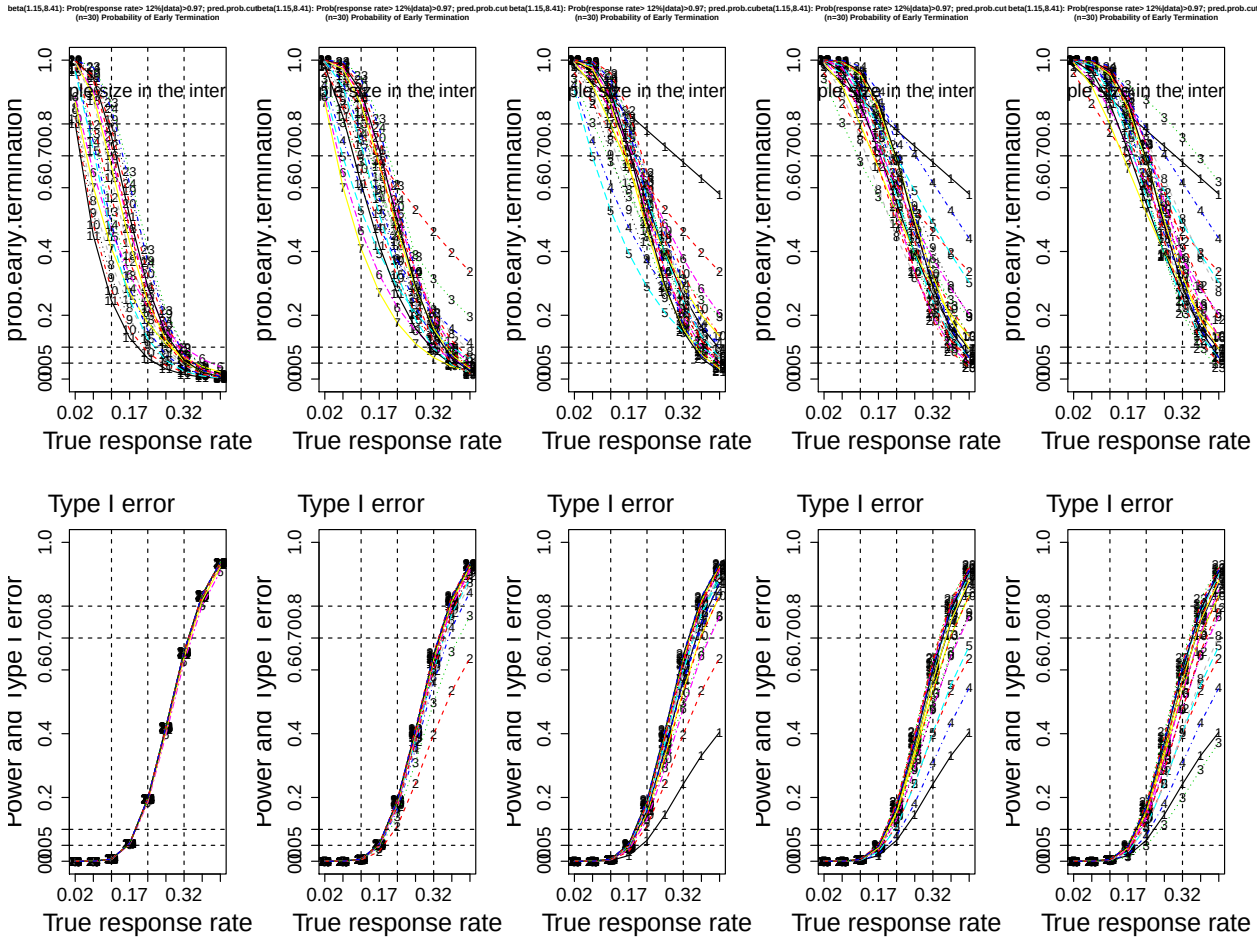
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(n=30) Probability of Early Termination
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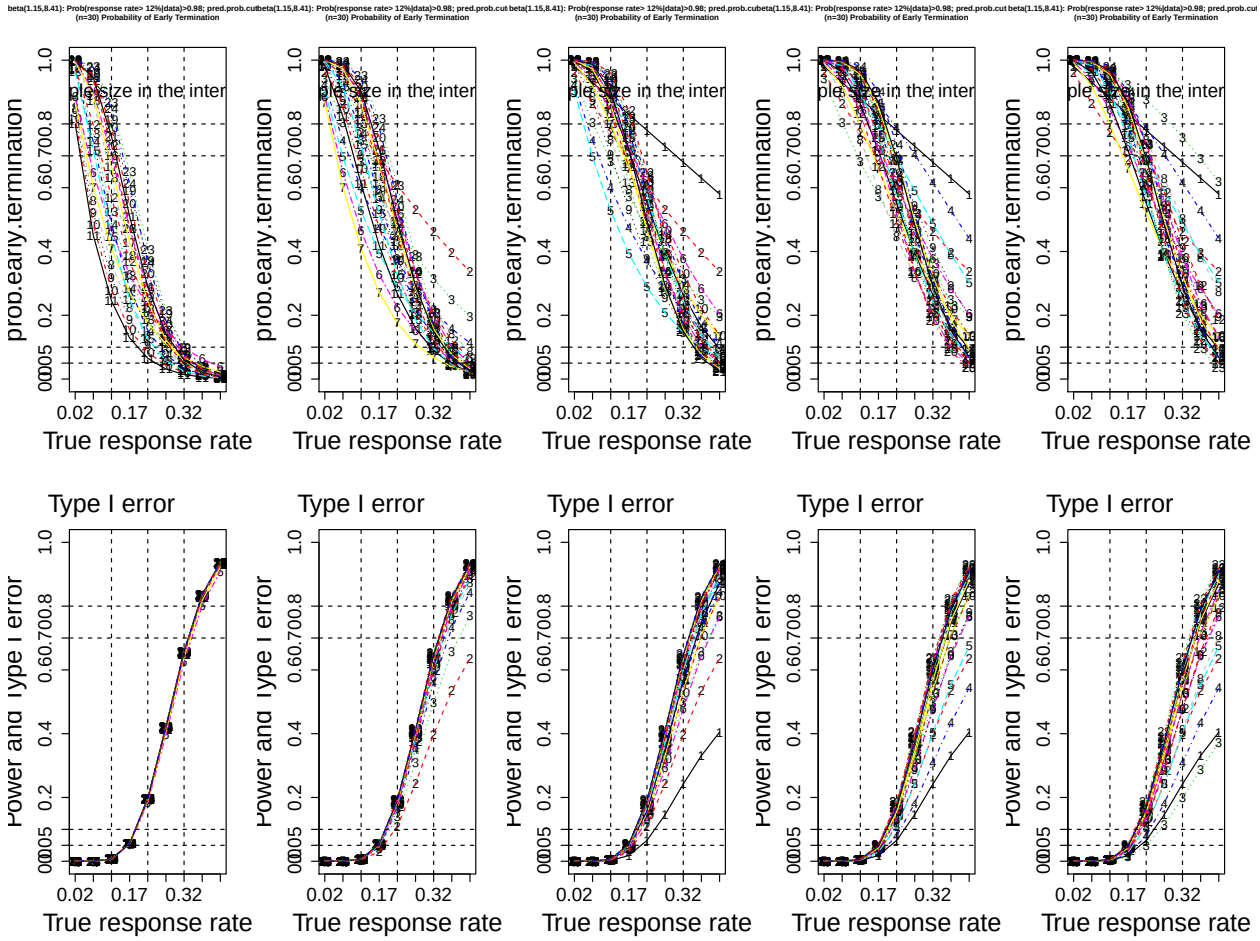
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(n=30) Probability of Early Termination
prob.early.termination
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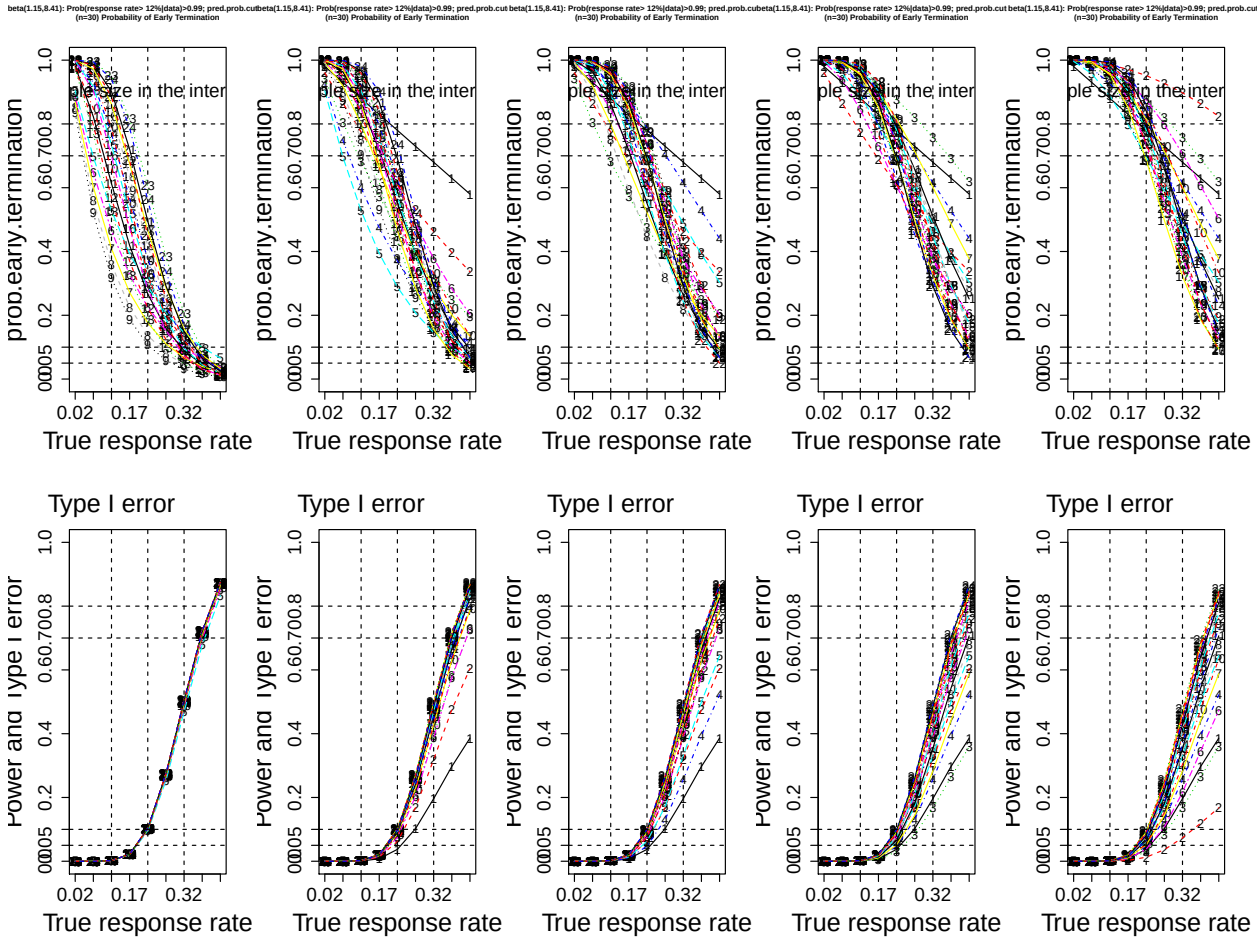
beta(1.15,8.41): Prob(response rate> 12%|data)>0.99; pred.prob.cut
(n=30) Probability of Early Termination
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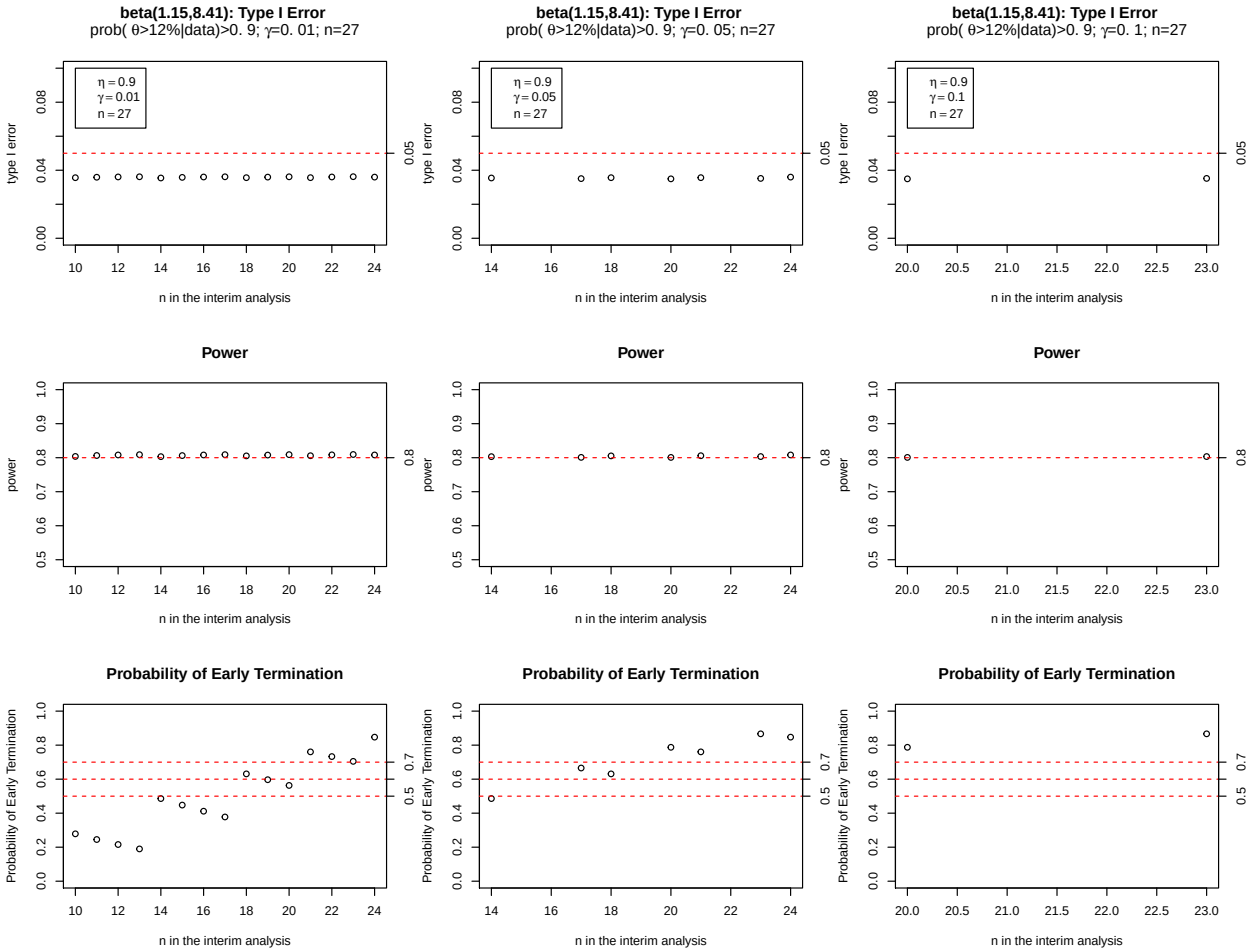
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γ = 0.01
n = 27
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 05; n=27
η = 0.9
γ = 0.05
n = 27
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 1; n=27
η = 0.9
γ = 0.1
n = 27
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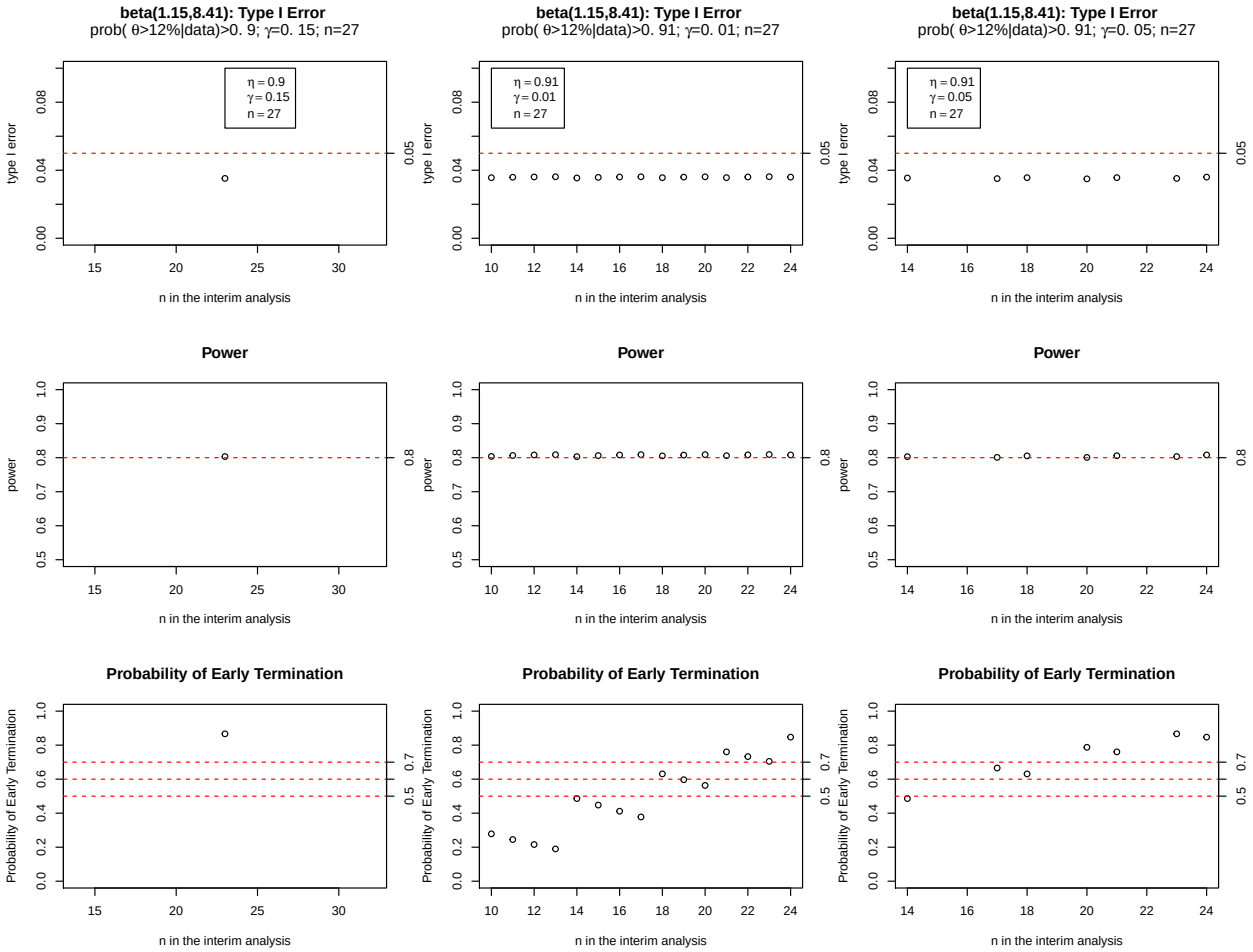
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type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 01; n=27
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 05; n=27
η = 0.91
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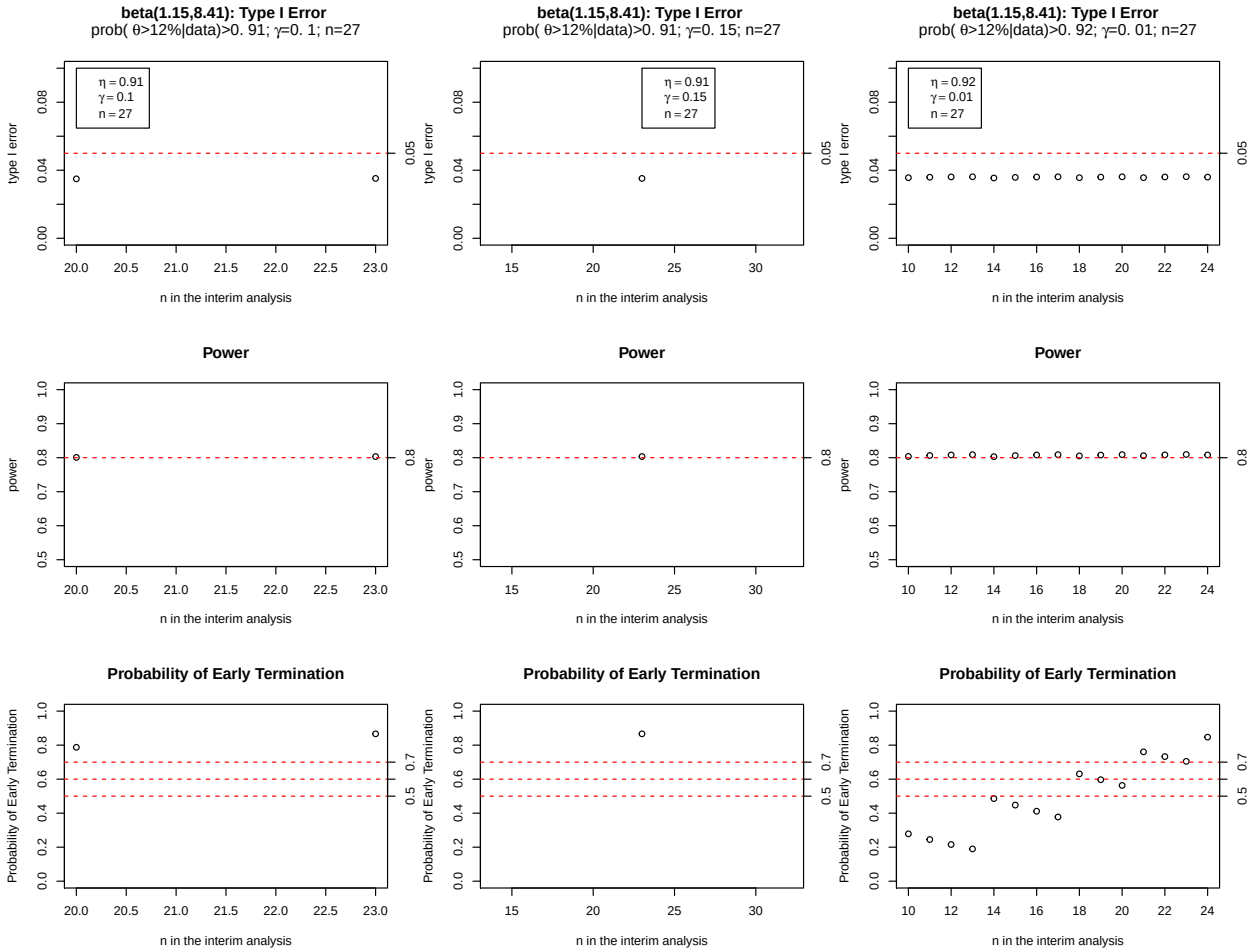
beta(1.15,8.41): Type I Error
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type I error
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beta(1.15,8.41): Type I Error
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γ = 0.15
n = 27
type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 01; n=27
η = 0.92
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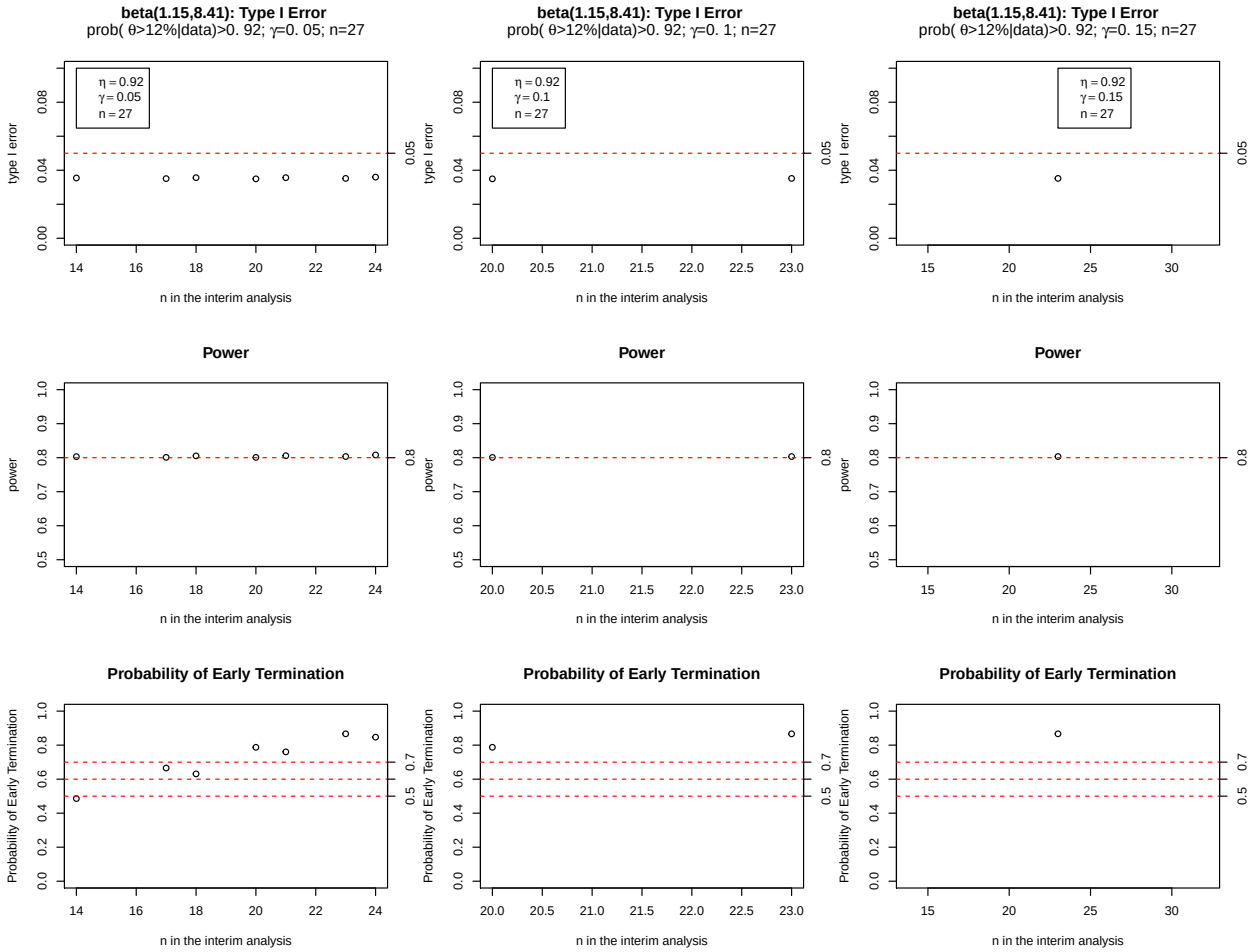
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 05; n=27
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type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 1; n=27
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γ = 0.1
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type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 15; n=27
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γ = 0.15
n = 27
type I error
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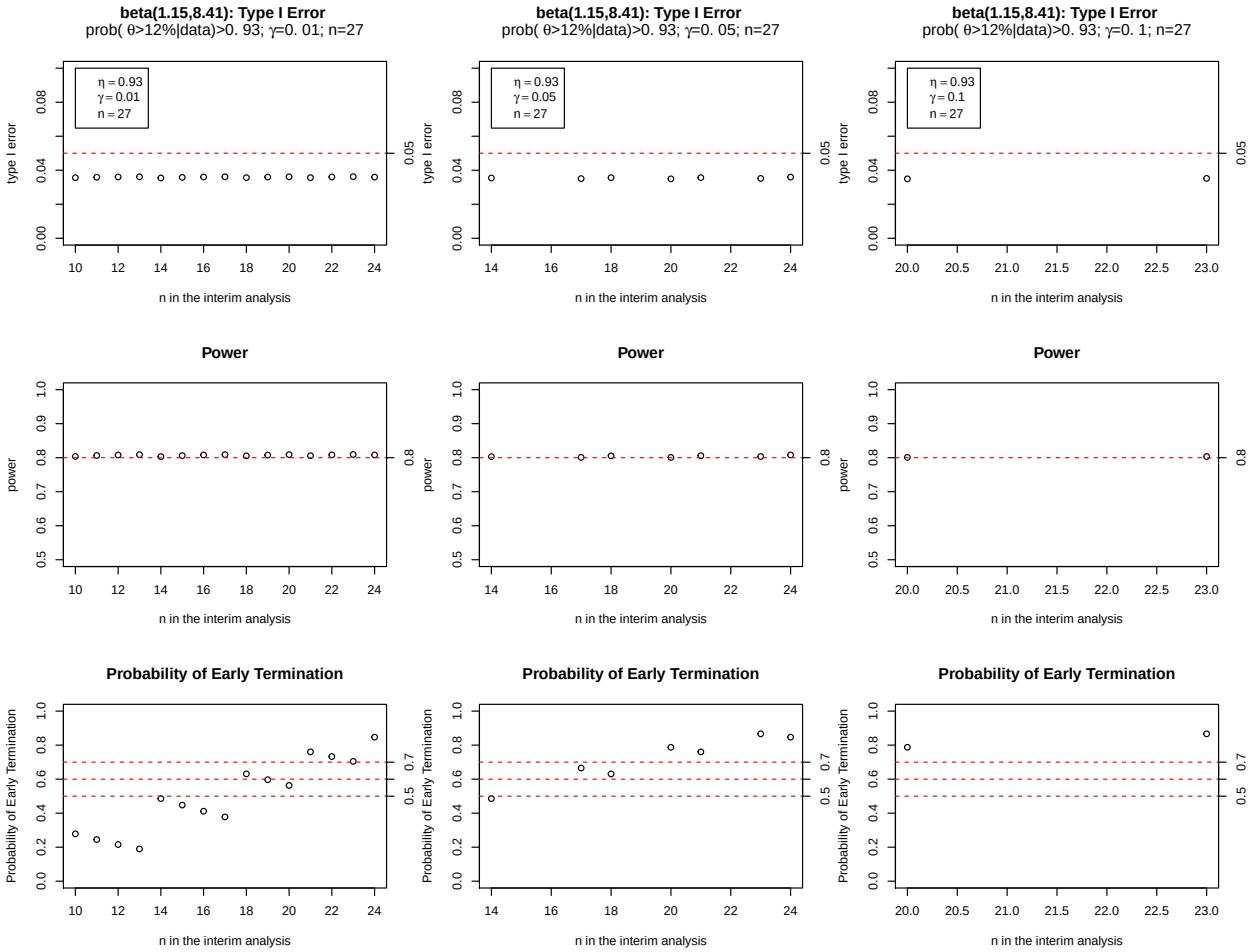
beta(1.15,8.41): Type I Error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 93; γ=0. 05; n=27
η = 0.93
γ = 0.05
n = 27
type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 93; γ=0. 1; n=27
η = 0.93
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n = 27
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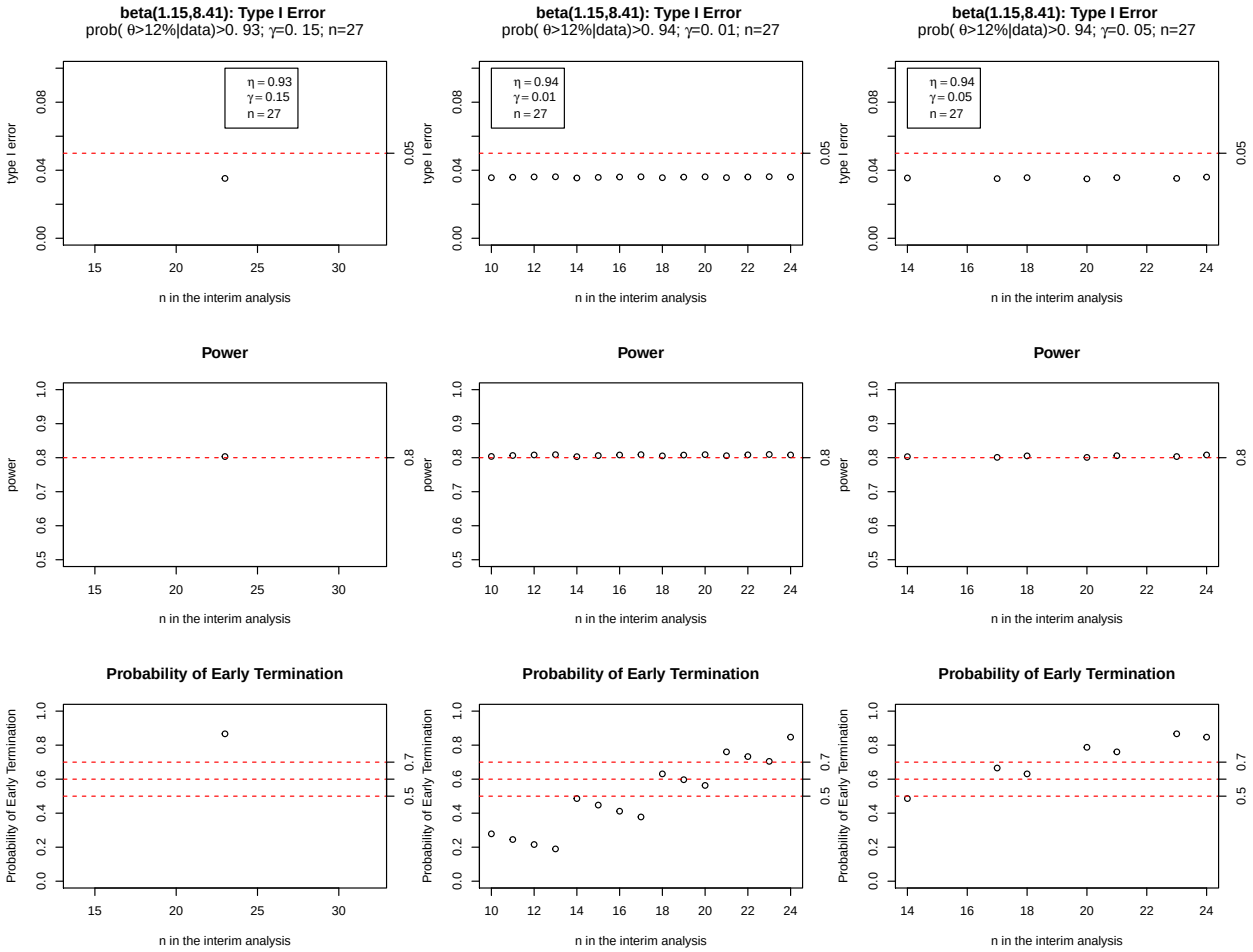
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n in the interim analysis
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beta(1.15,8.41): Type I Error
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η = 0.94
γ = 0.05
n = 27
type I error
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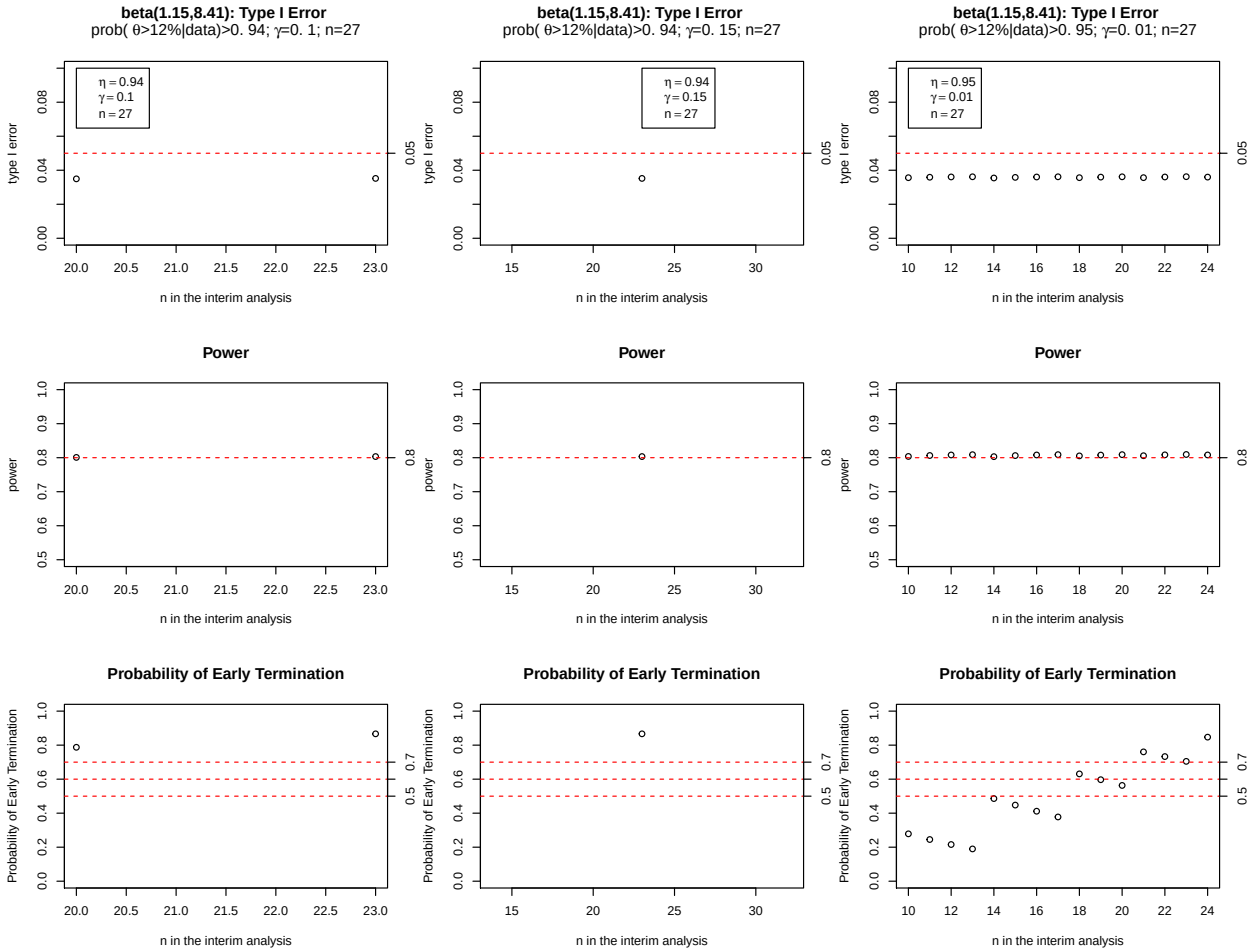
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 94; γ=0. 1; n=27
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γ = 0.1
n = 27
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 94; γ=0. 15; n=27
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γ = 0.15
n = 27
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 01; n=27
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γ = 0.01
n = 27
type I error
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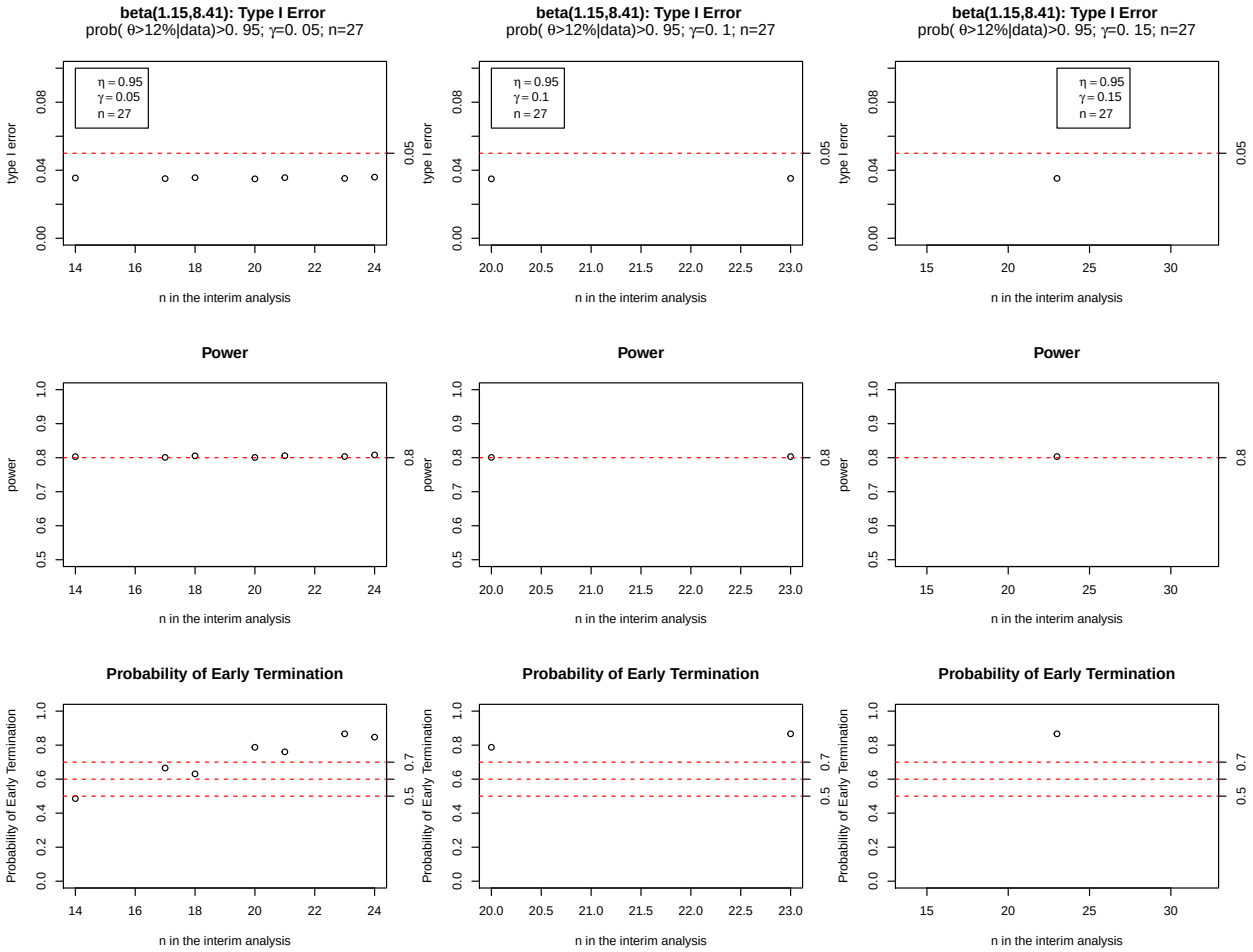
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 05; n=27
η = 0.95
γ = 0.05
n = 27
type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 1; n=27
η = 0.95
γ = 0.1
n = 27
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 15; n=27
η = 0.95
γ = 0.15
n = 27
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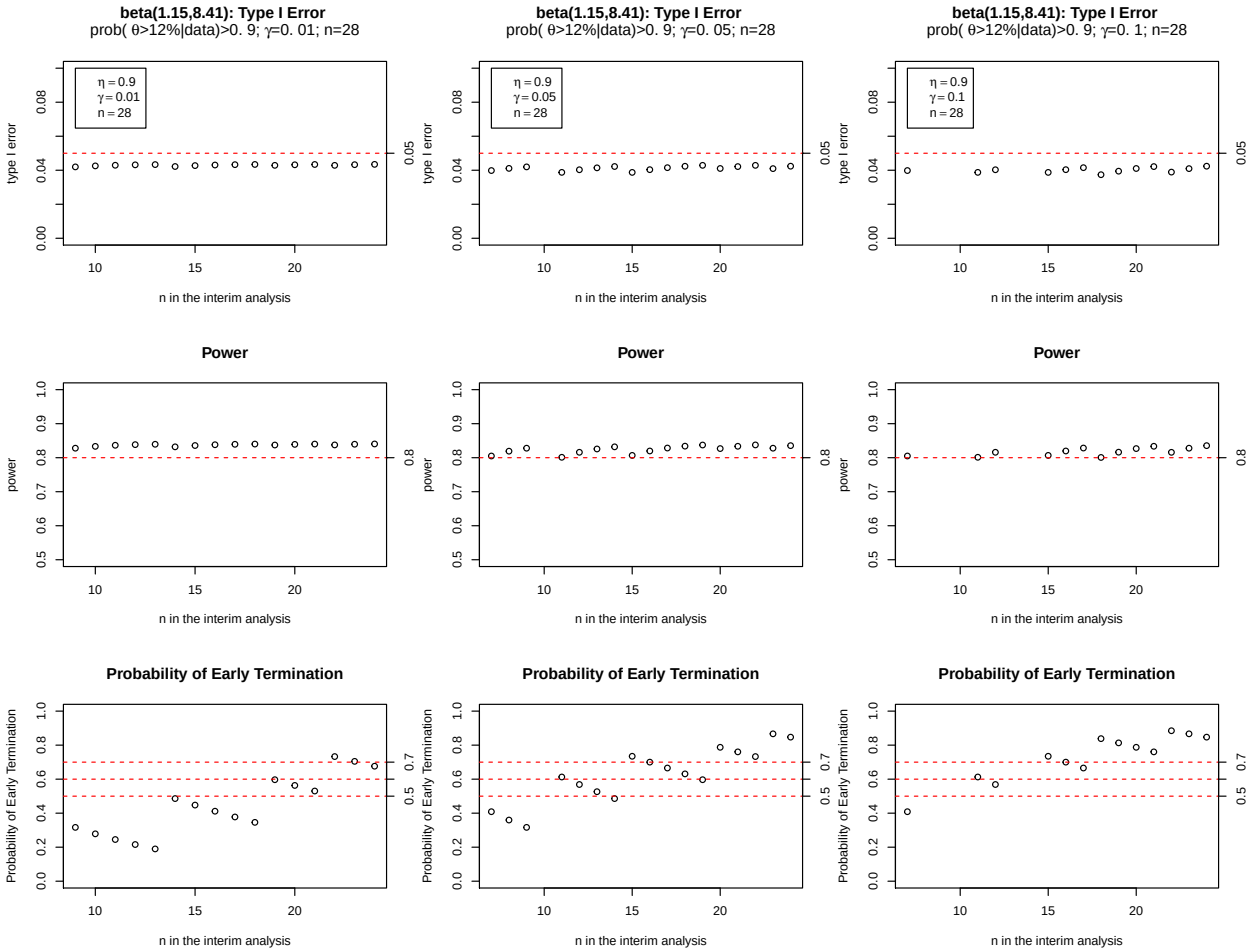
beta(1.15,8.41): Type I Error
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γ = 0.01
n = 28
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 05; n=28
η = 0.9
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 1; n=28
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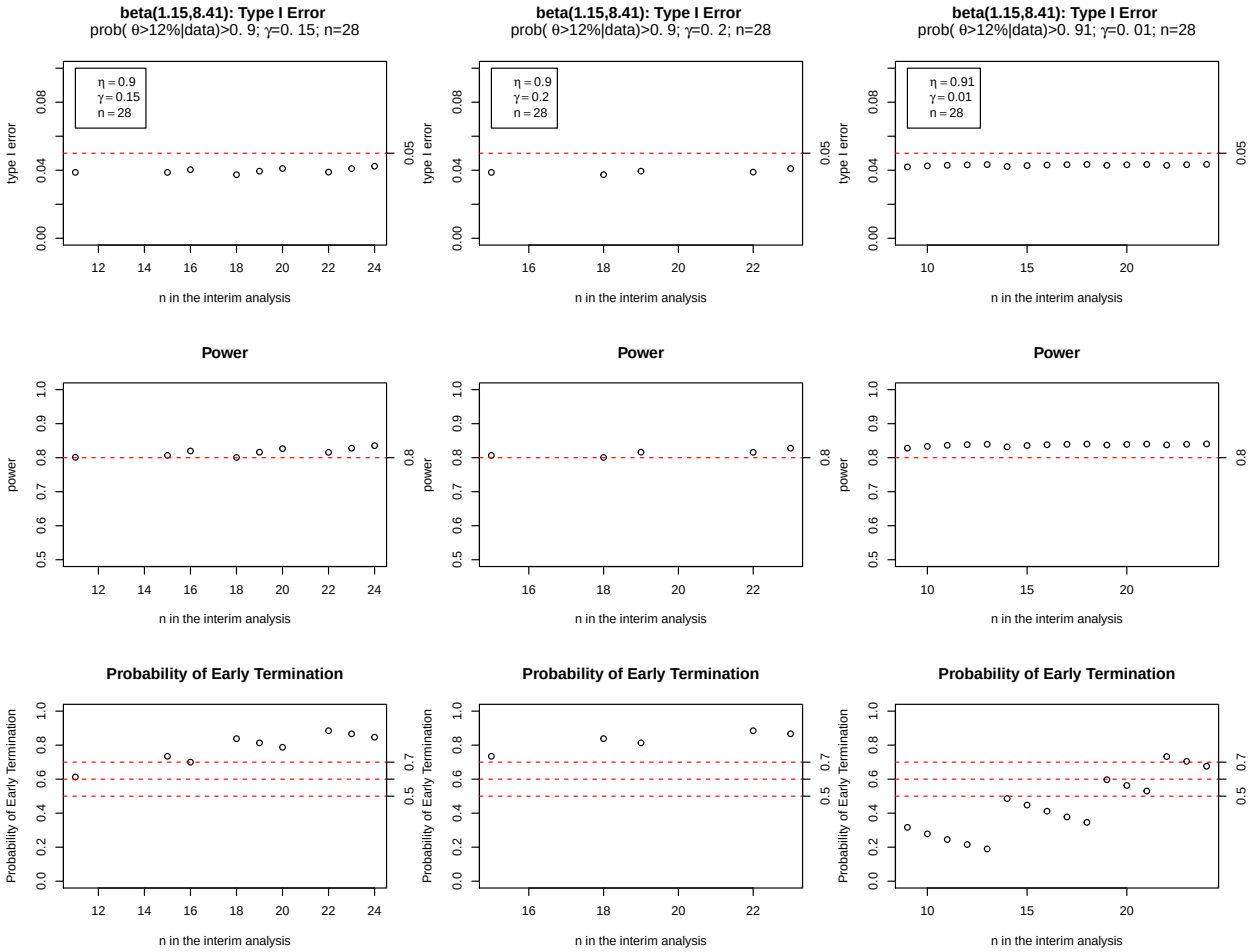
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type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 01; n=28
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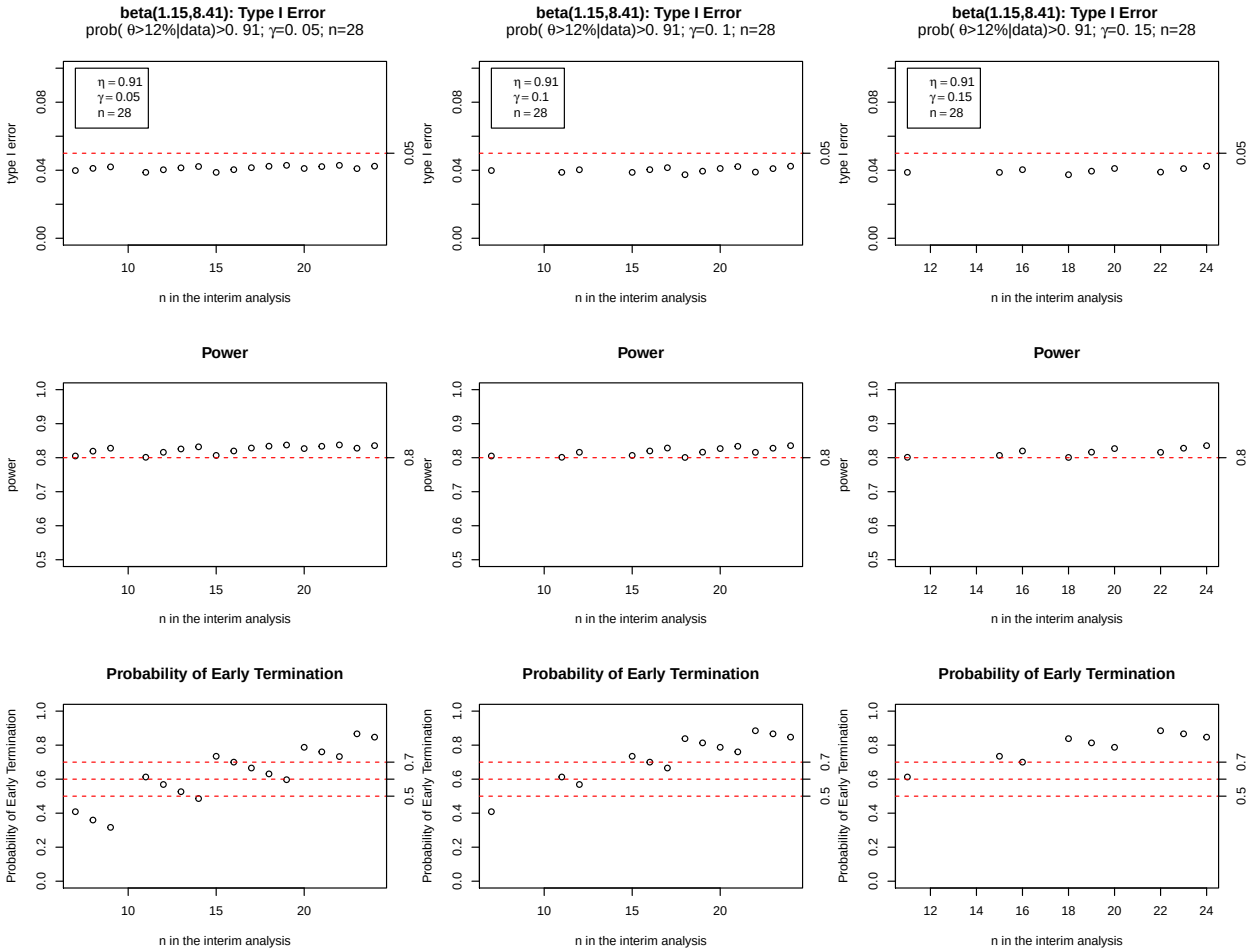
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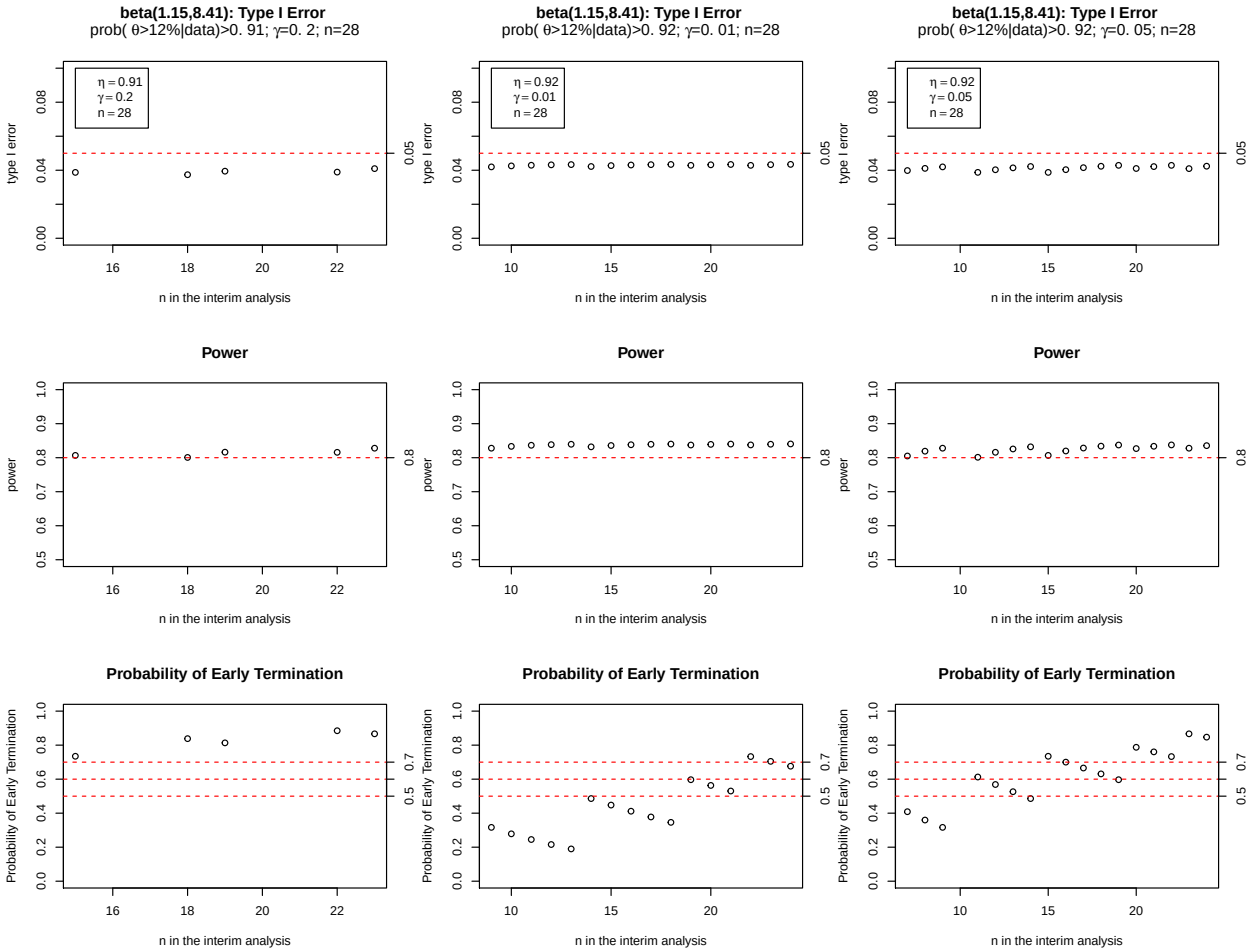
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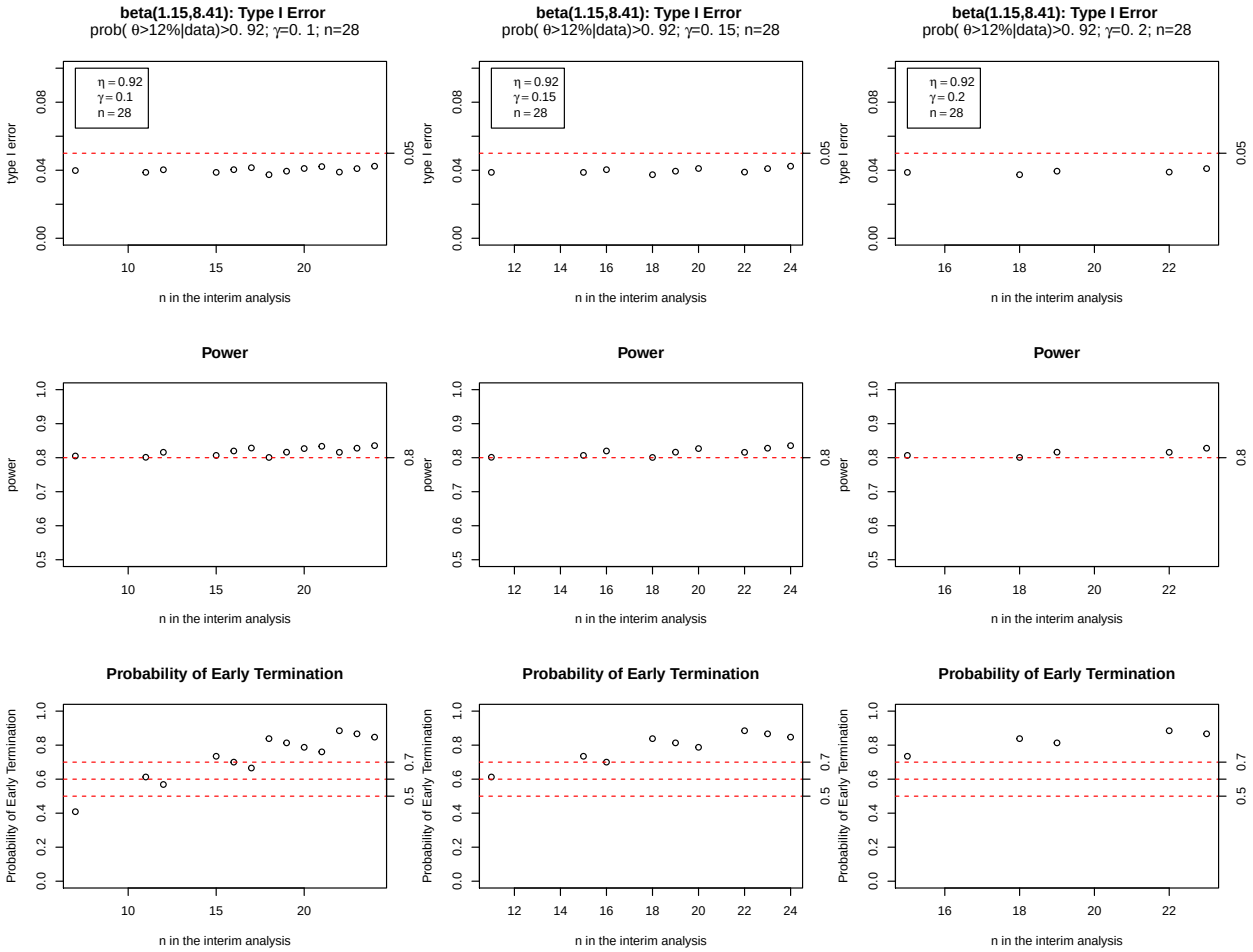
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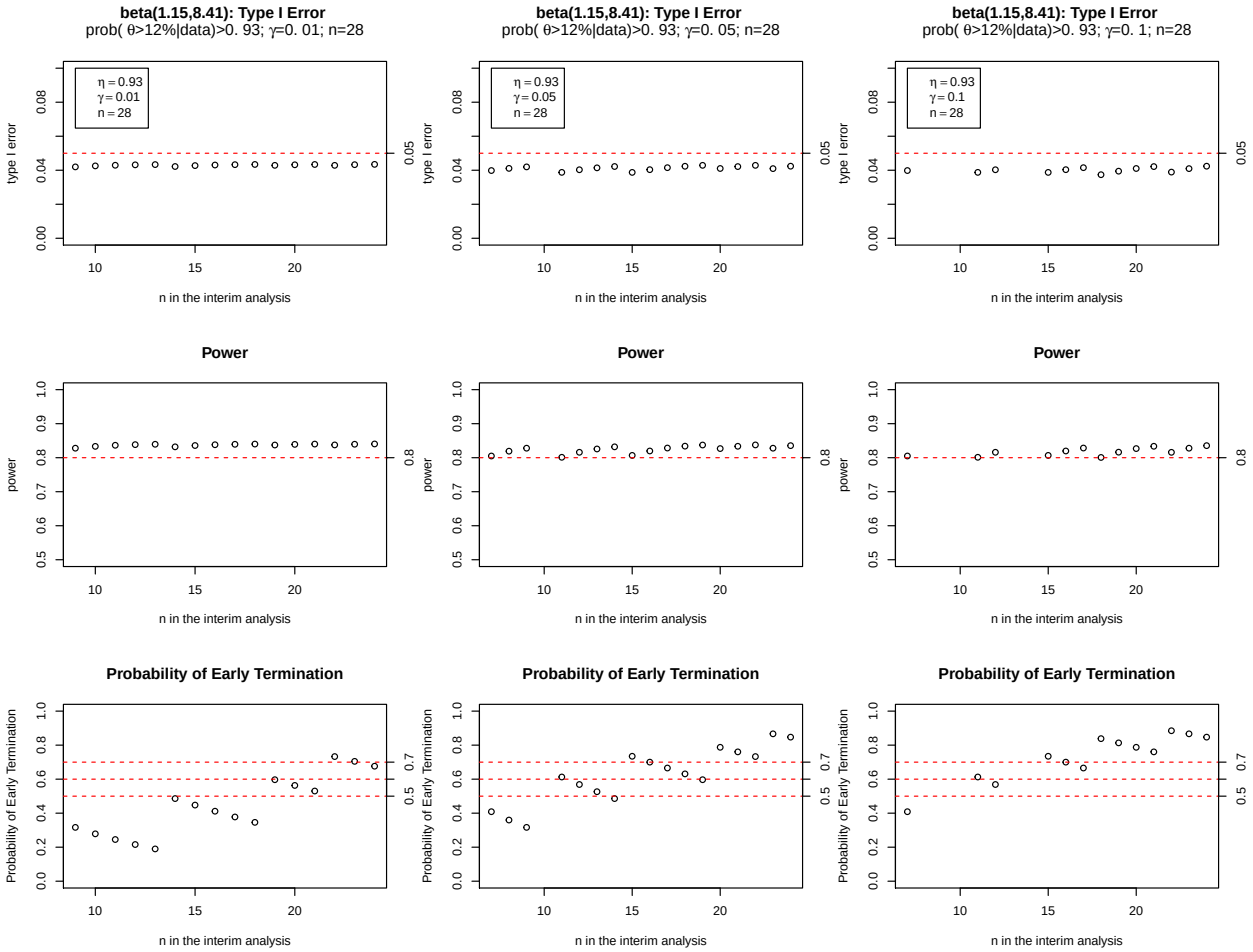
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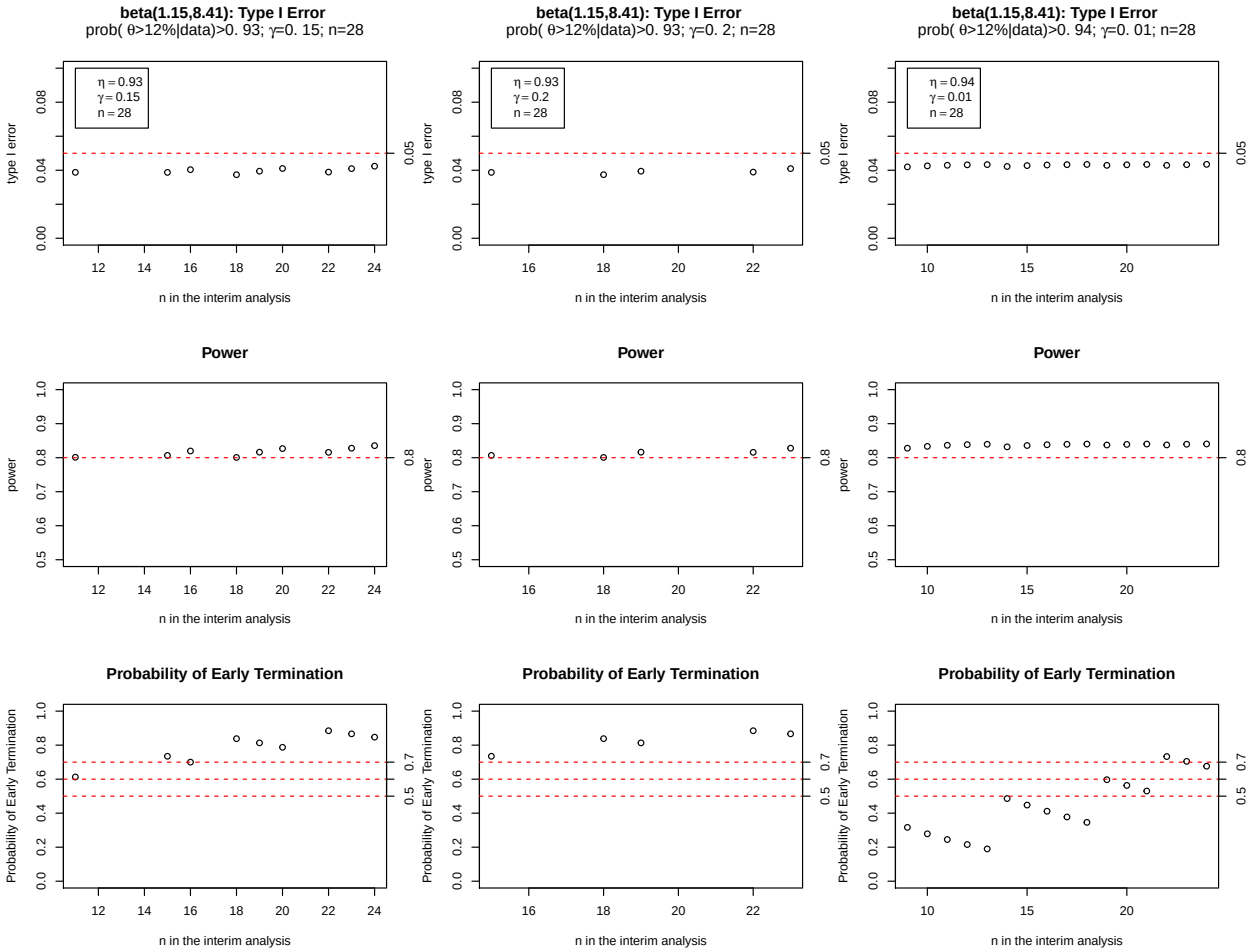
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beta(1.15,8.41): Type I Error
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γ = 0.2
n = 28
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 94; γ=0. 01; n=28
η = 0.94
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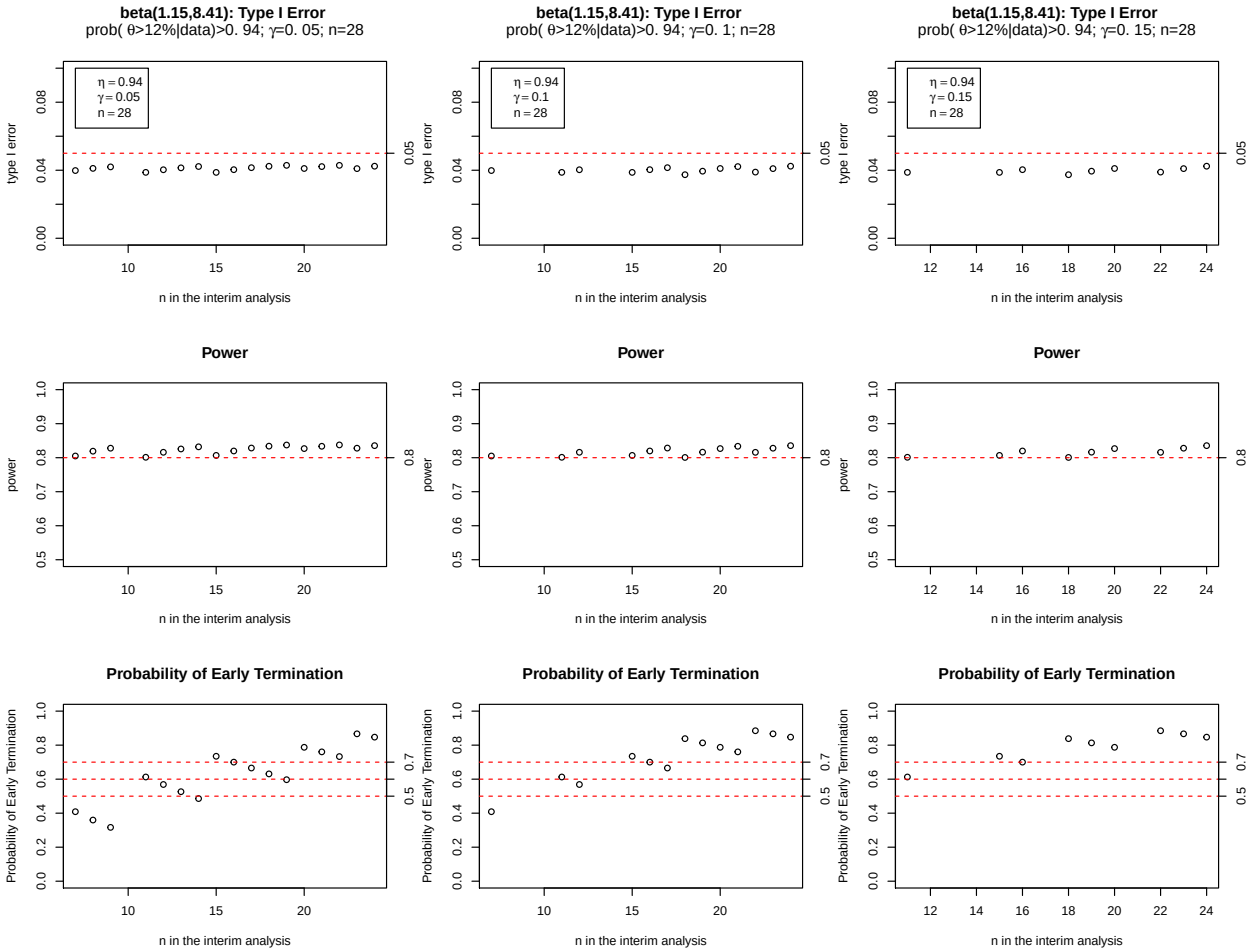
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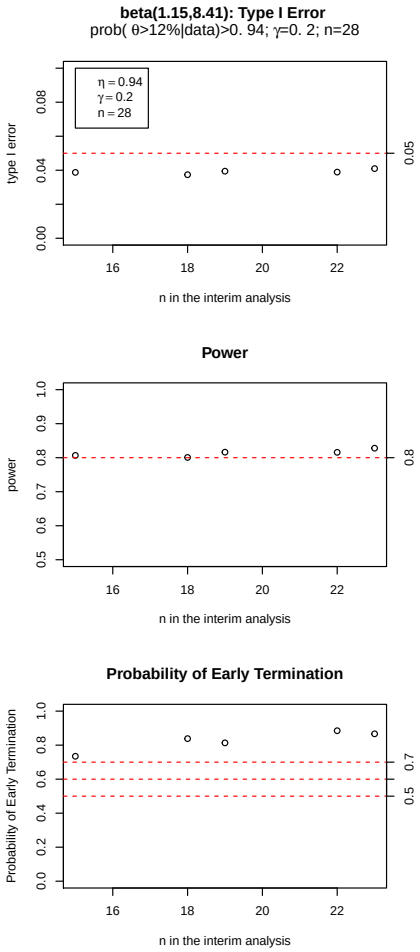
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Probability of Early Termination
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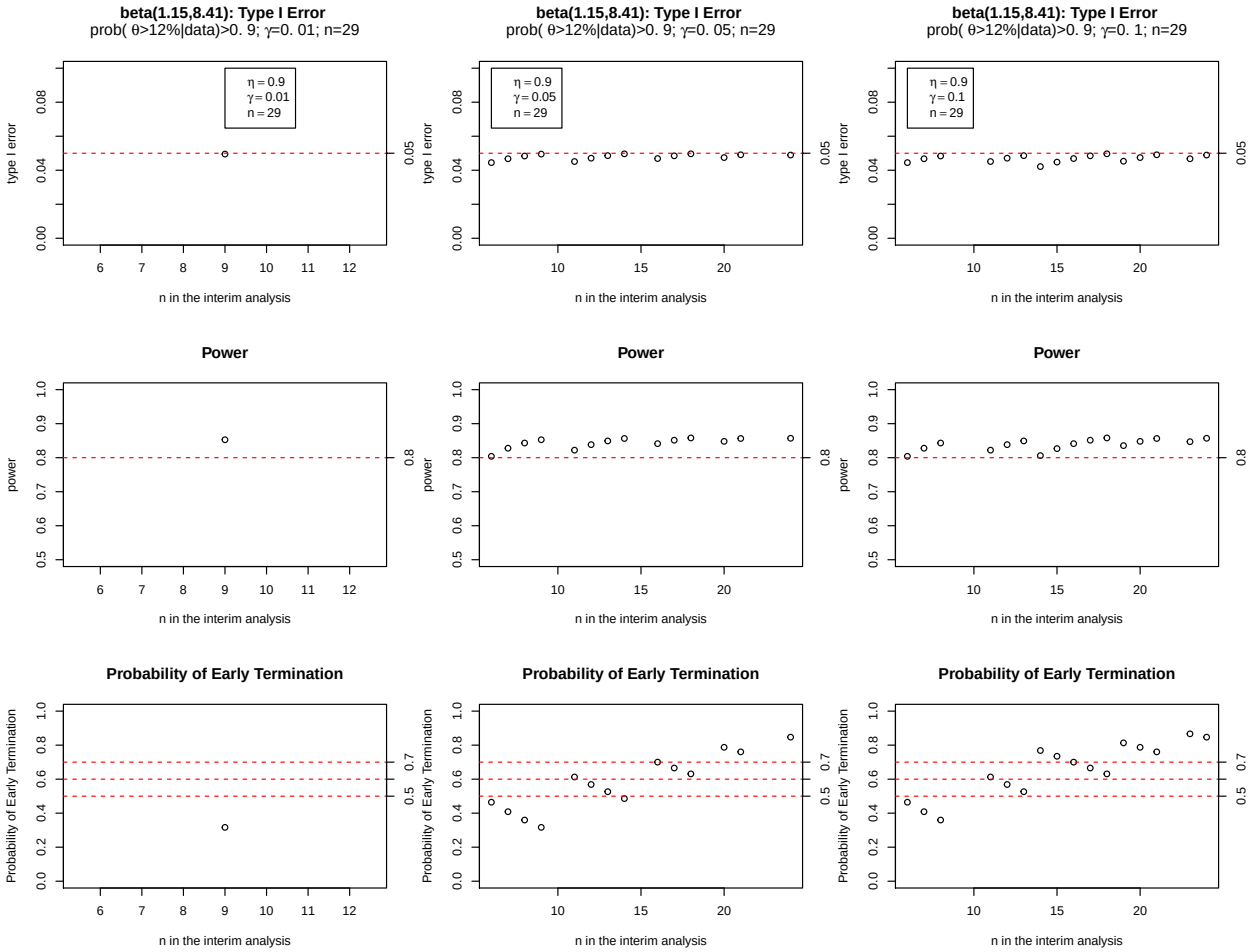
n in the interim analysis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type I error
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beta(1.15,8.41): Type I Error
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γ = 0.05
n = 29
type I error
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beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 1; n=29
η = 0.9
γ = 0.1
n = 29
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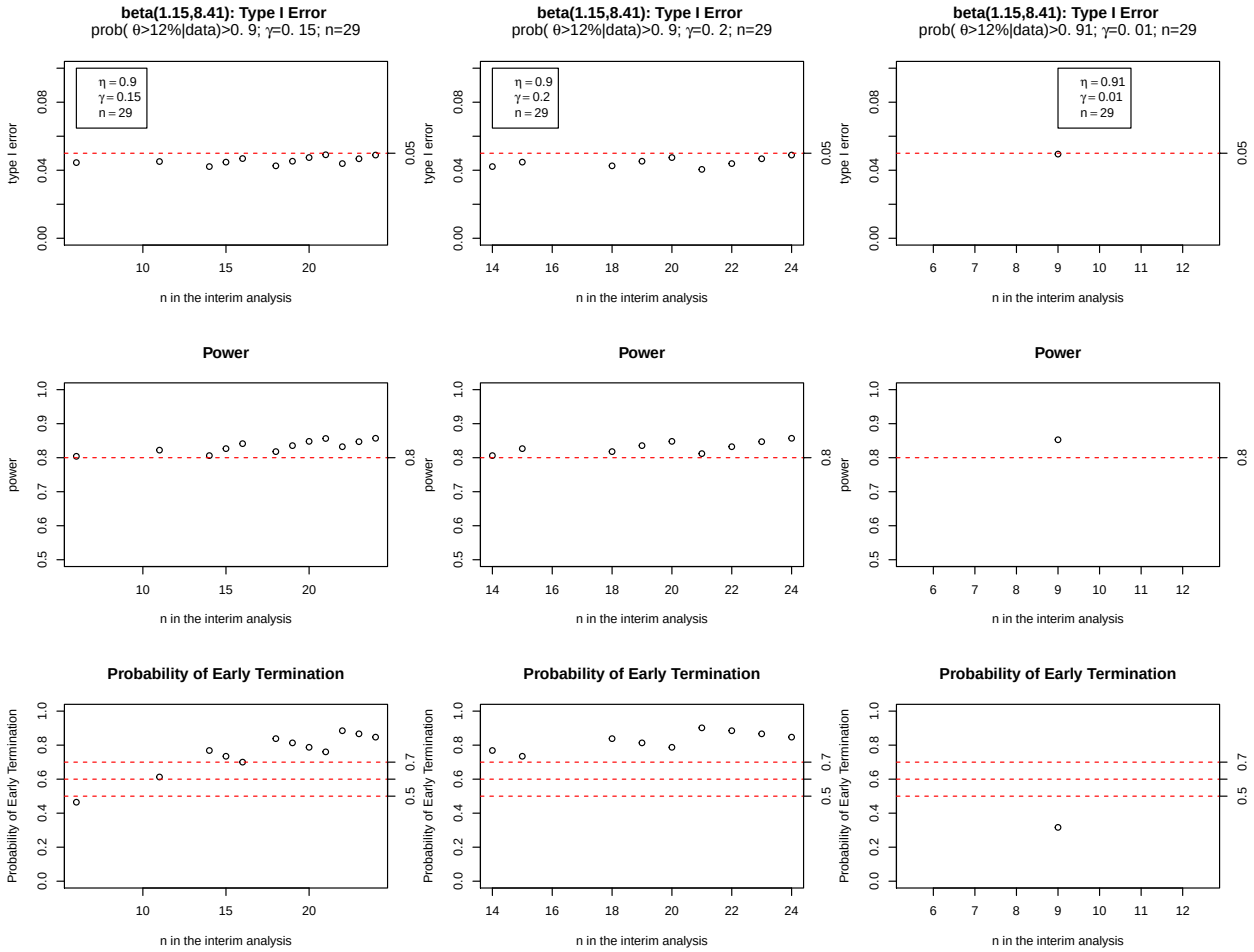
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type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 9; γ=0. 2; n=29
η = 0.9
γ = 0.2
n = 29
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 91; γ=0. 01; n=29
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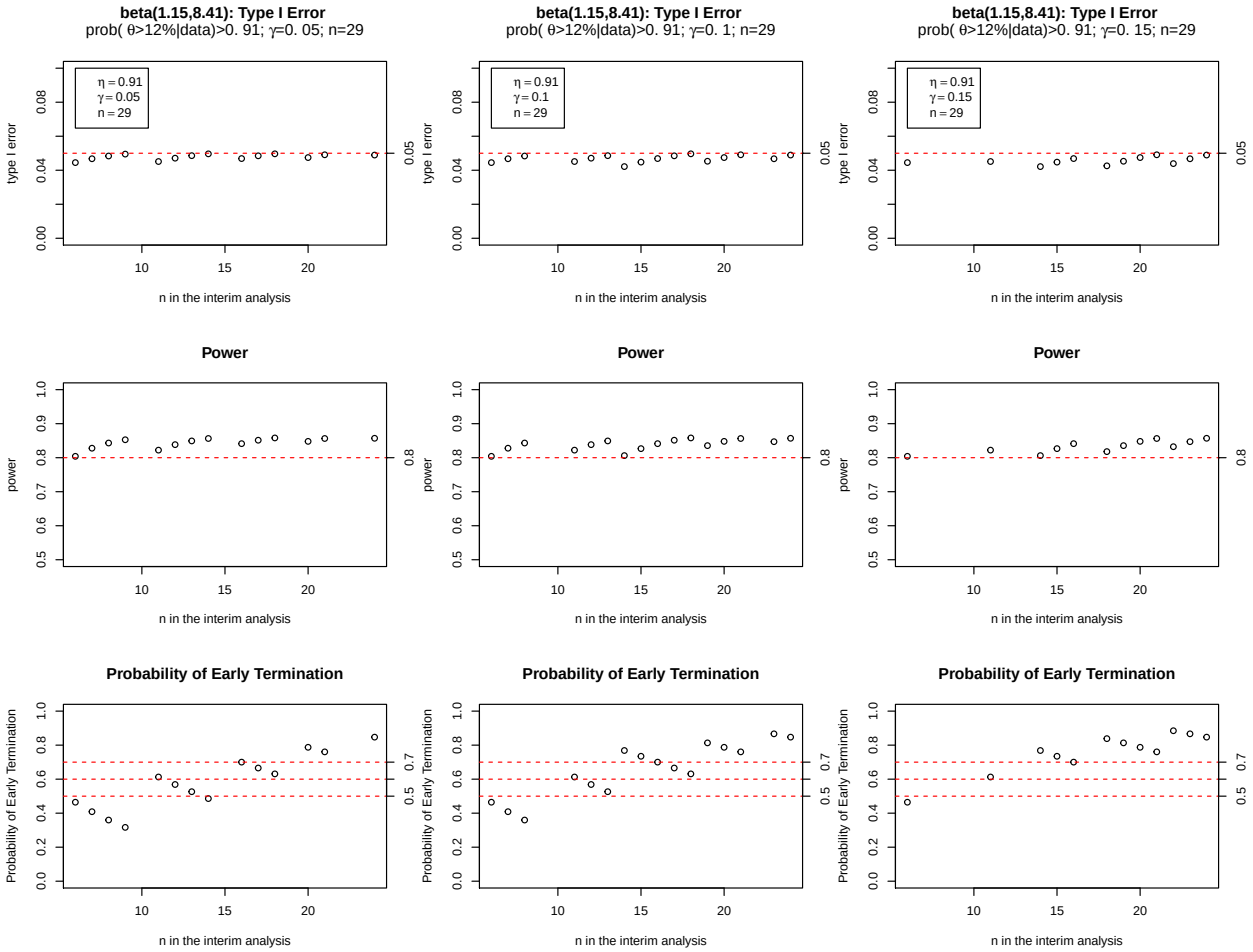
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Probability of Early Termination
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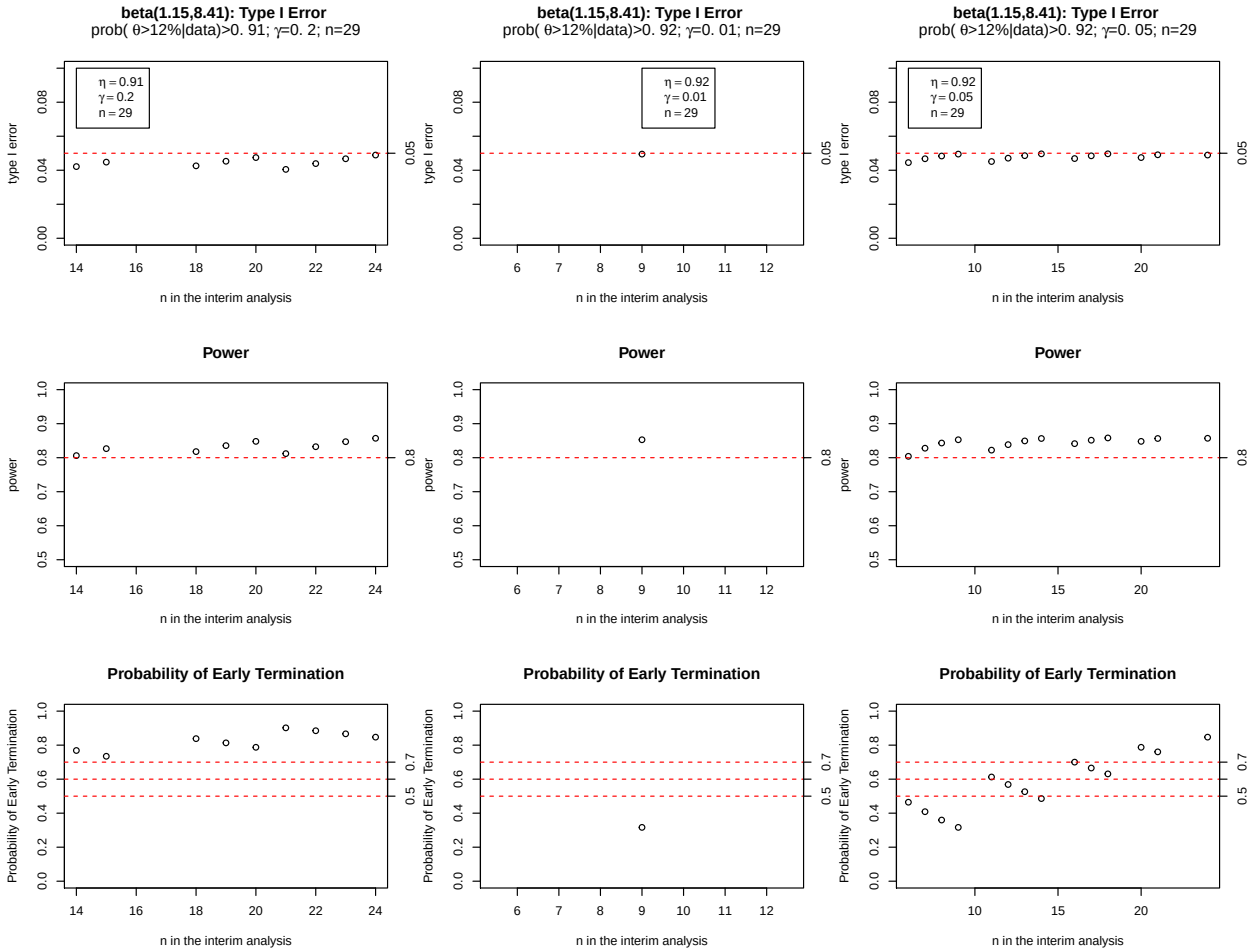
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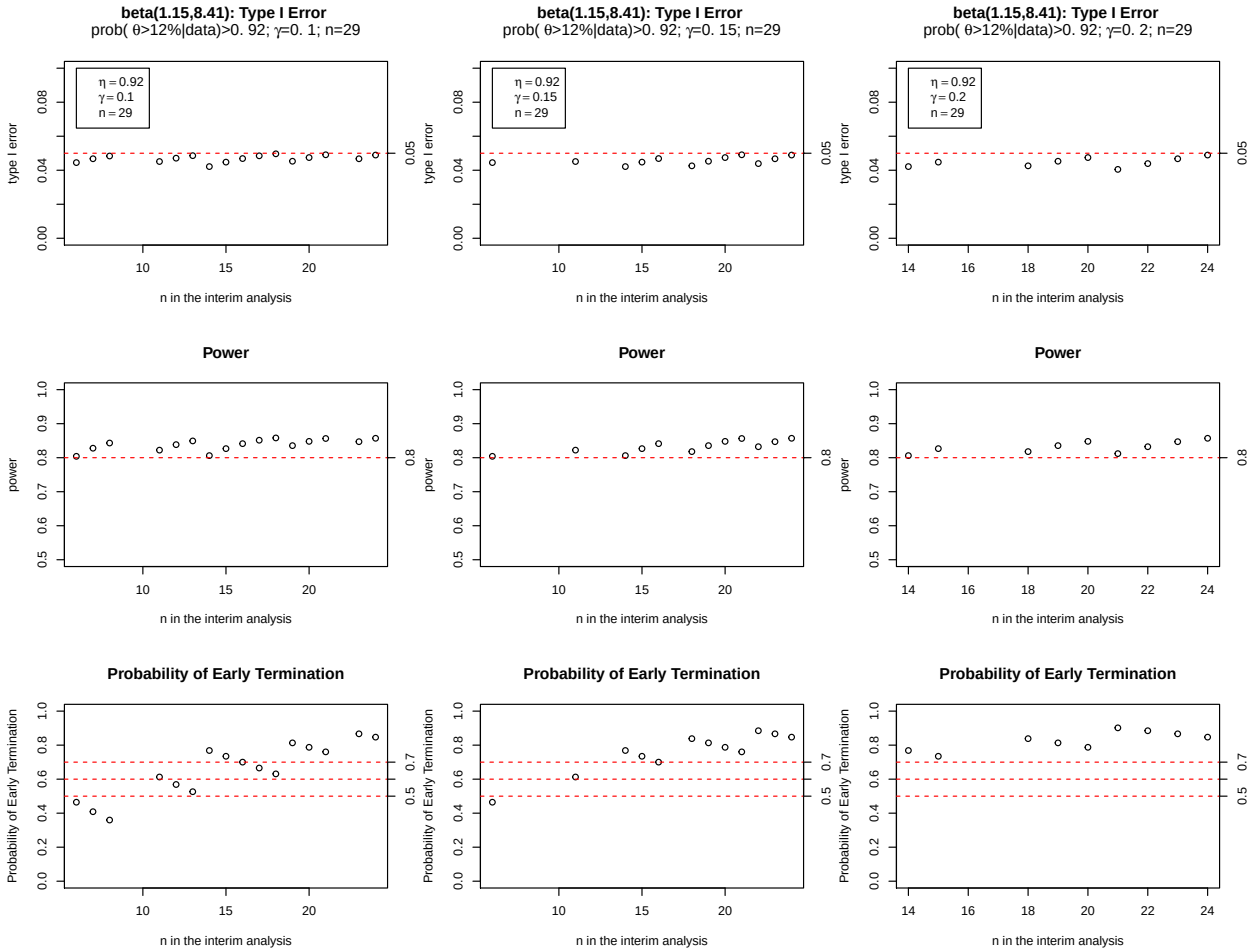
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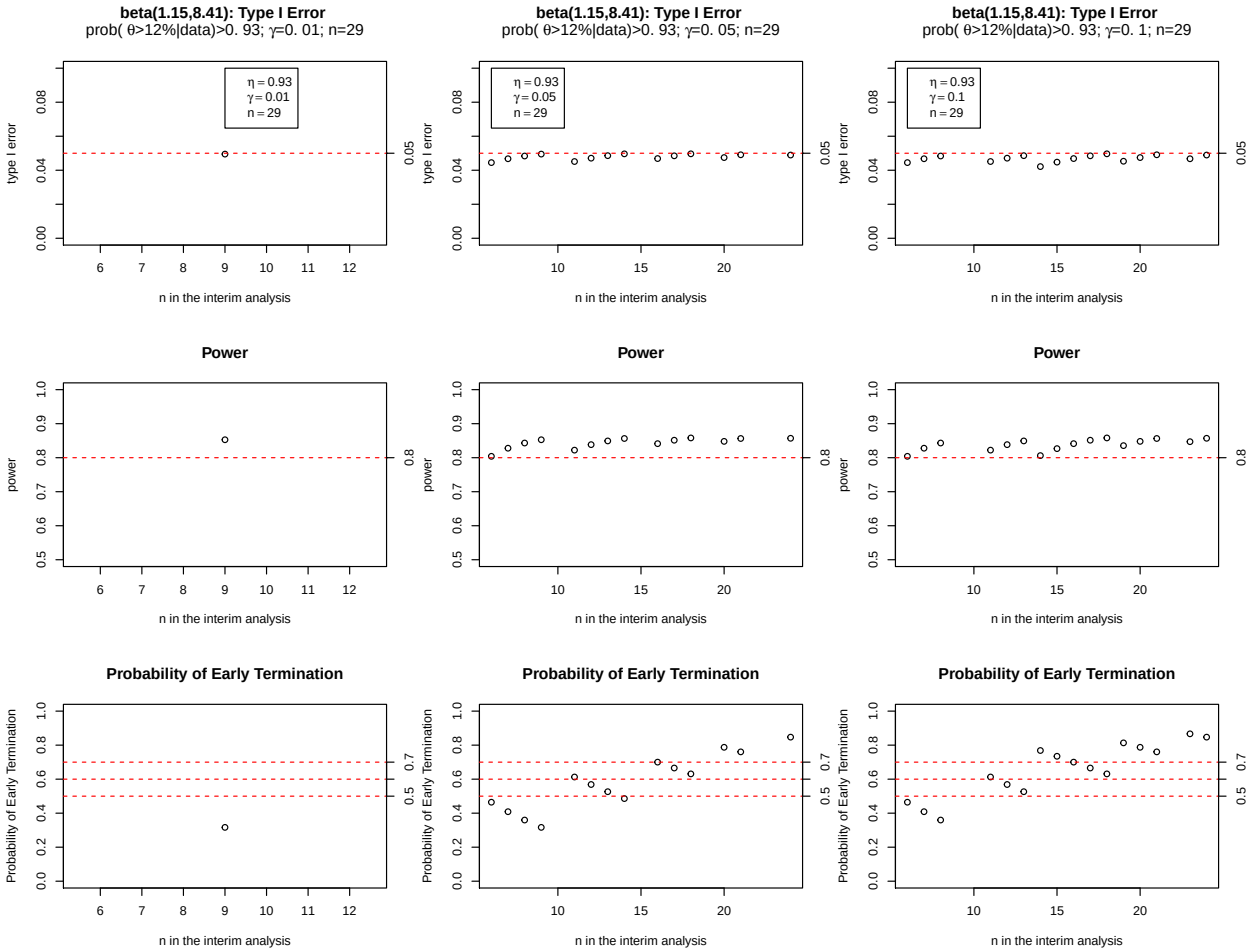
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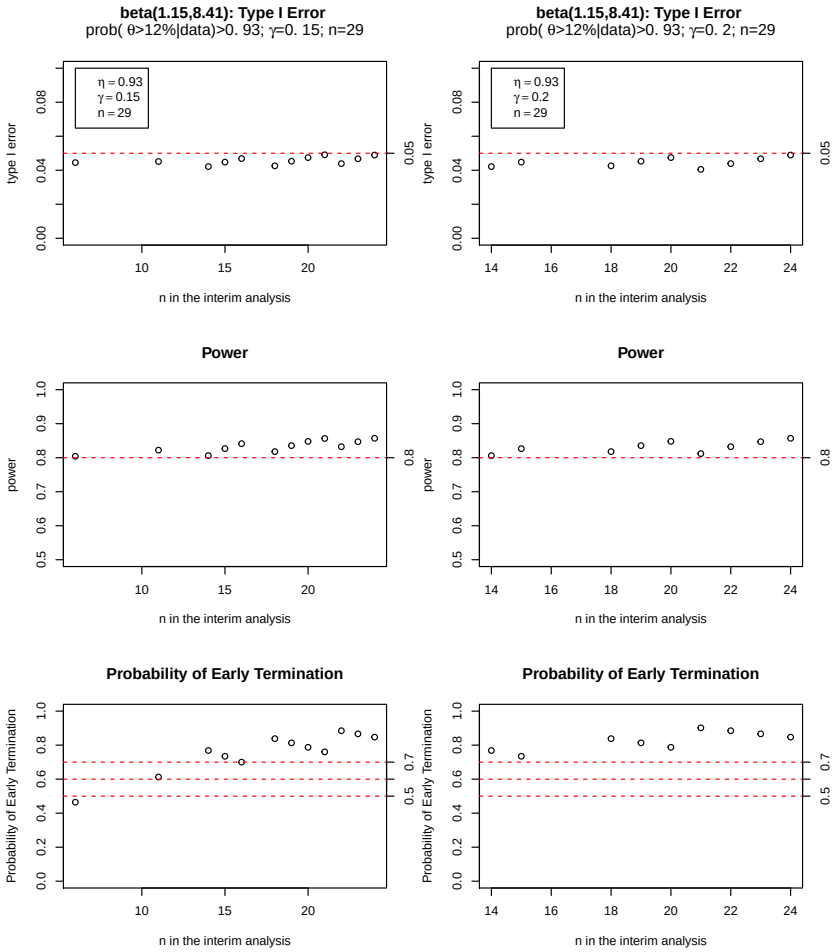
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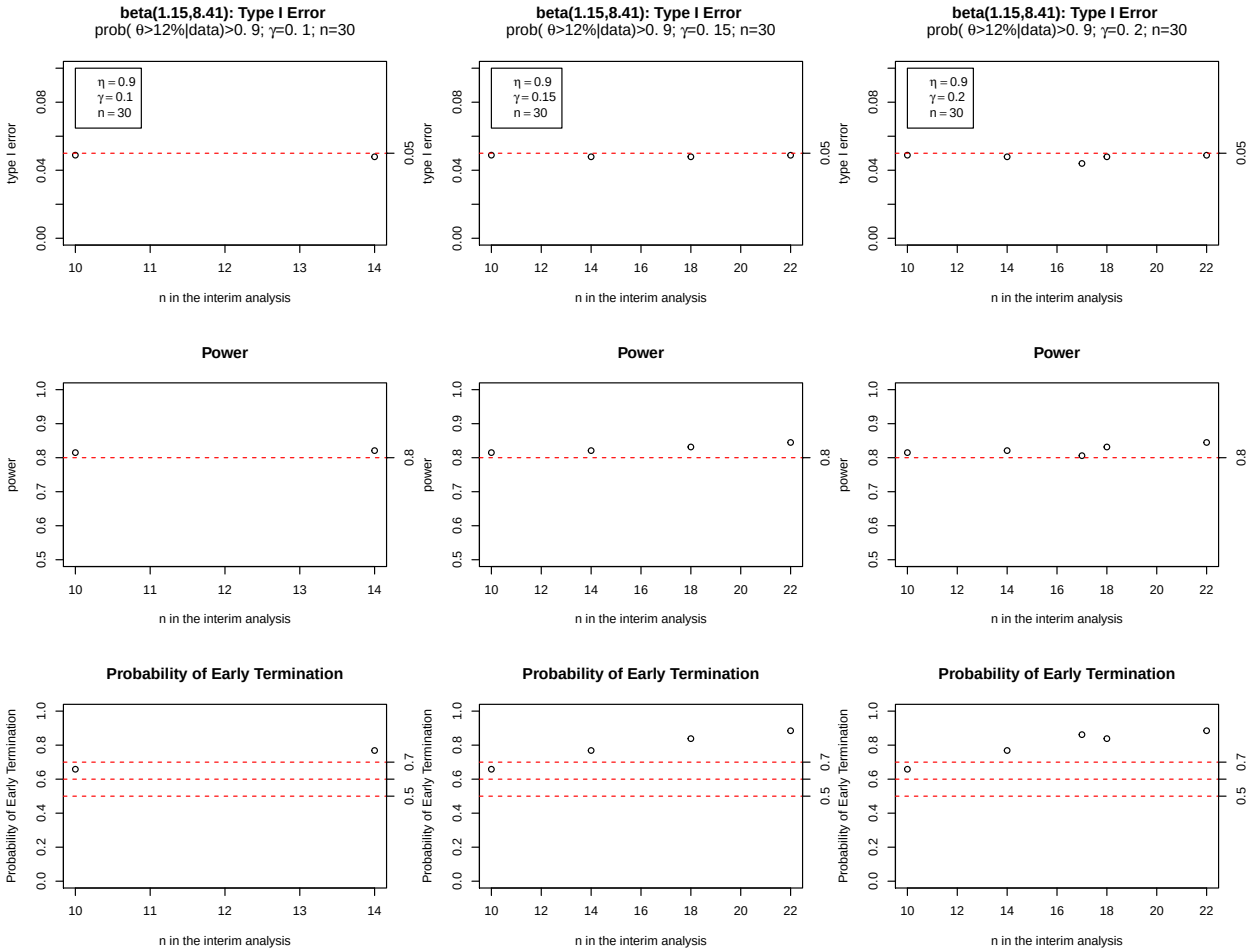
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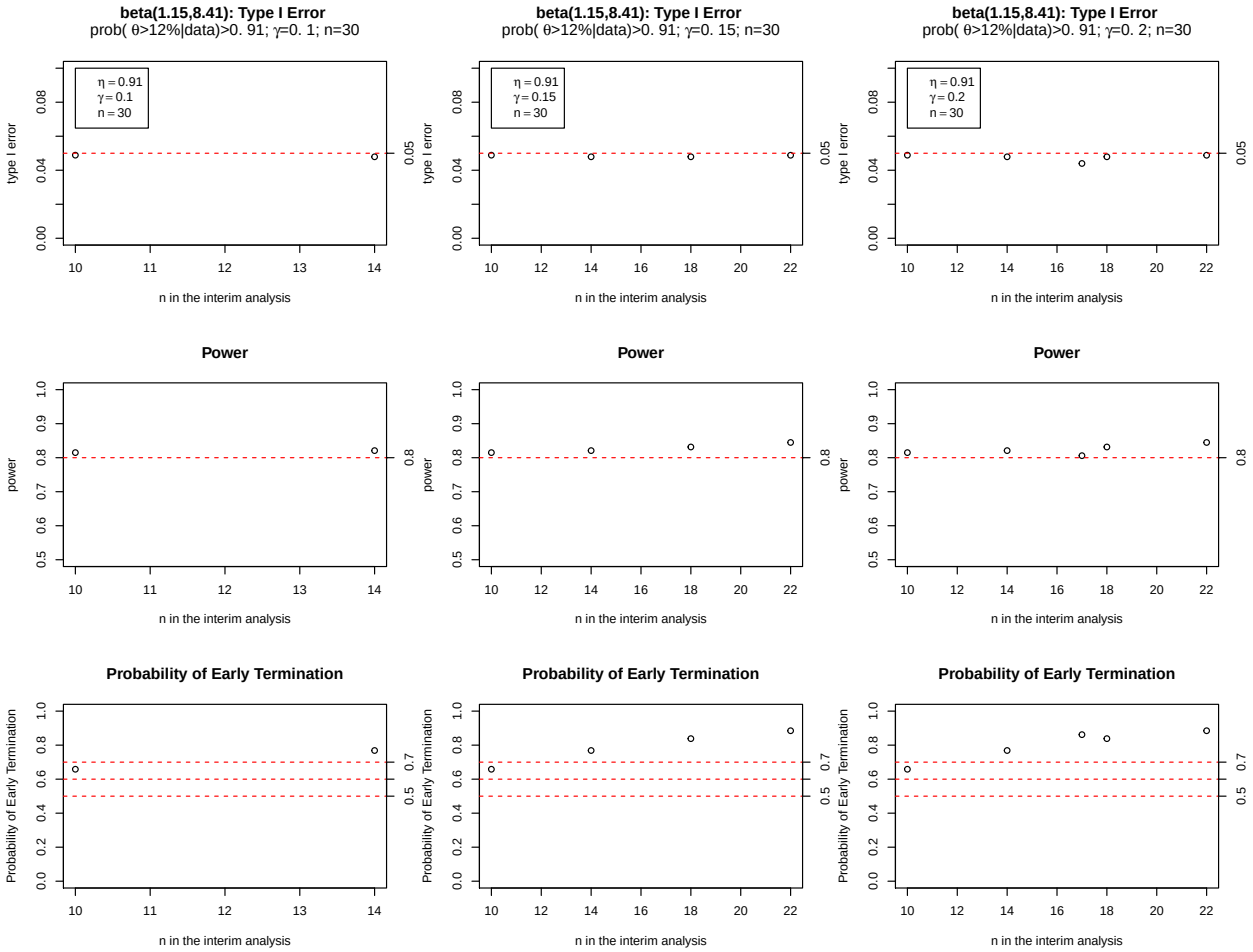
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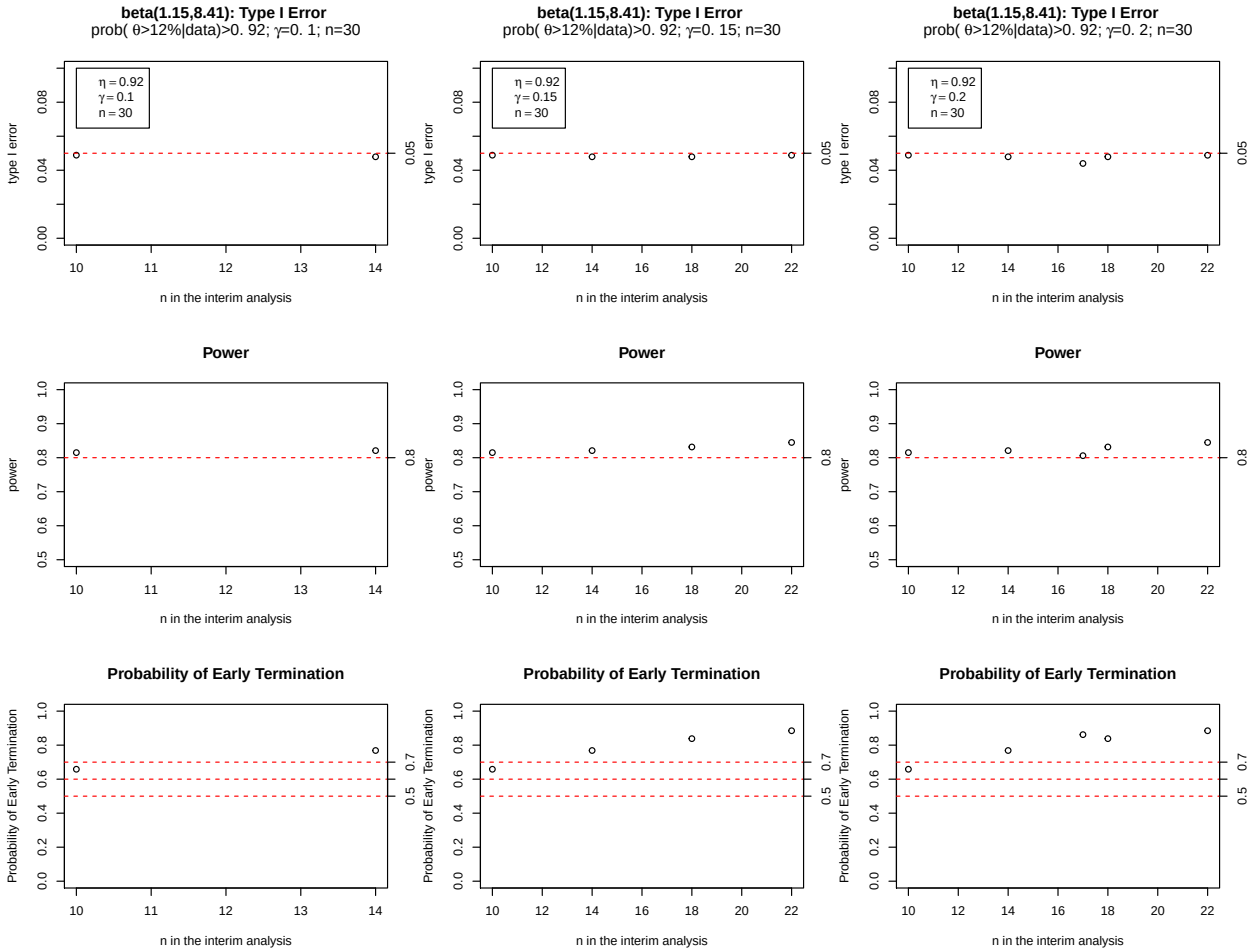
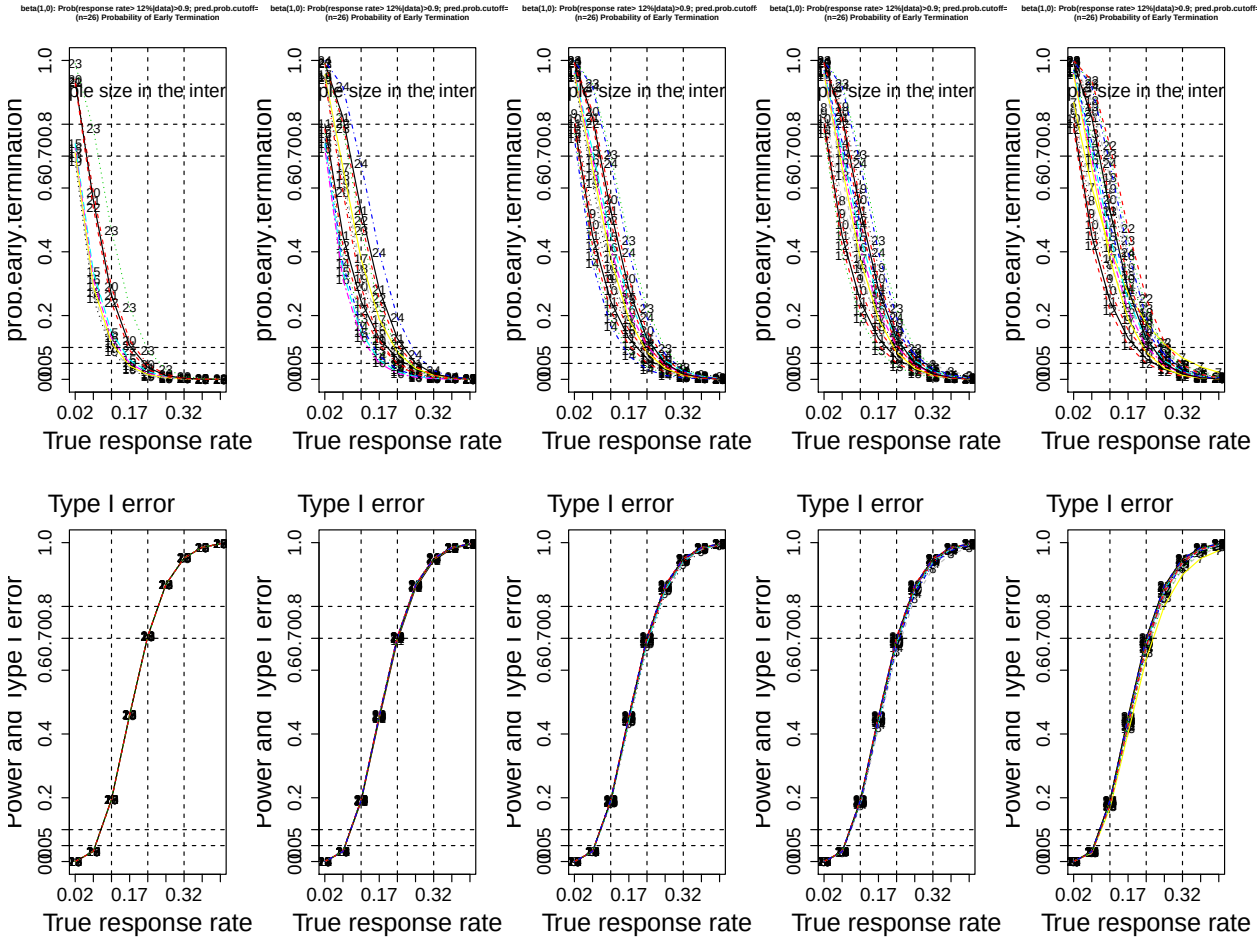
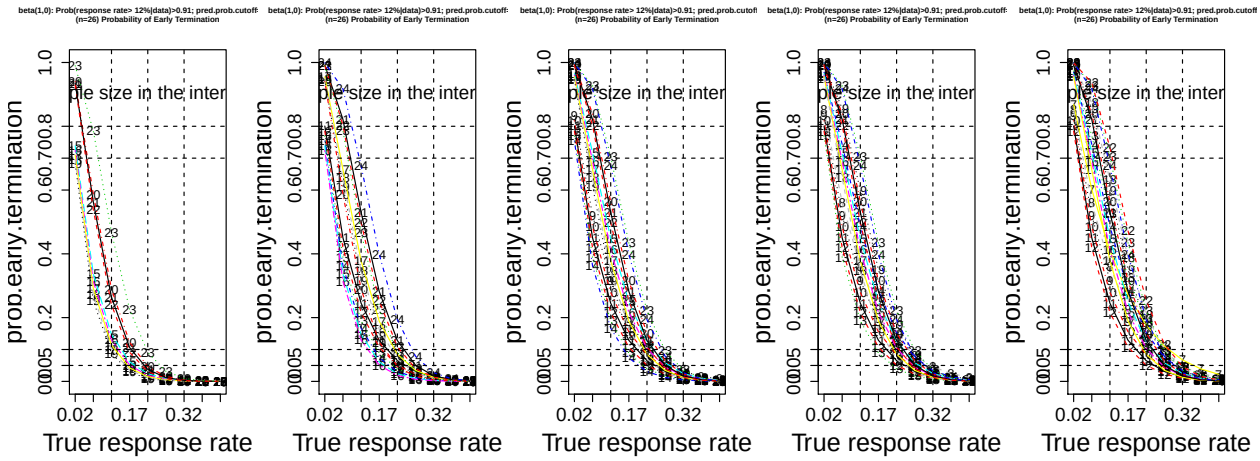
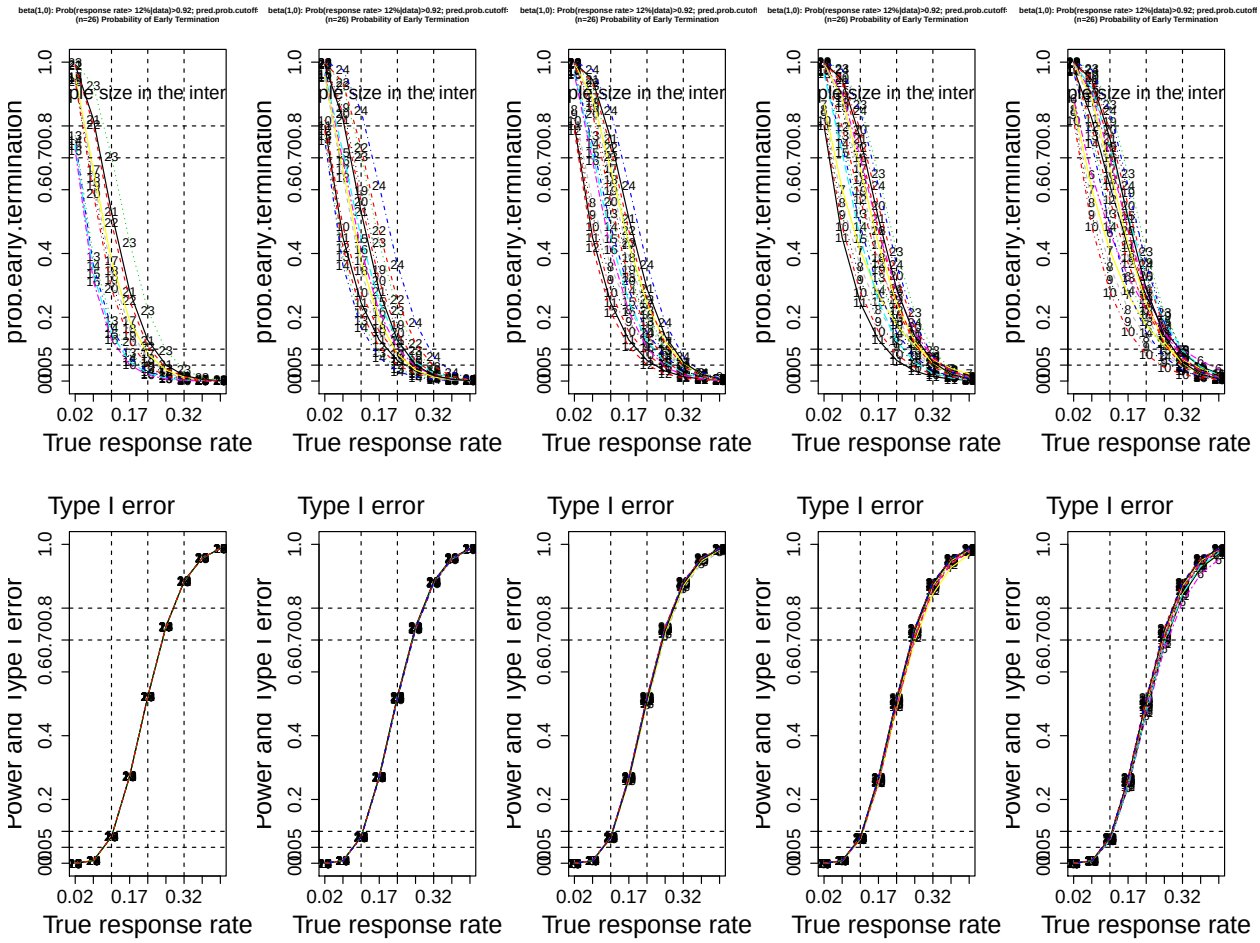
Probability of Early Termination
n in the interim analysis

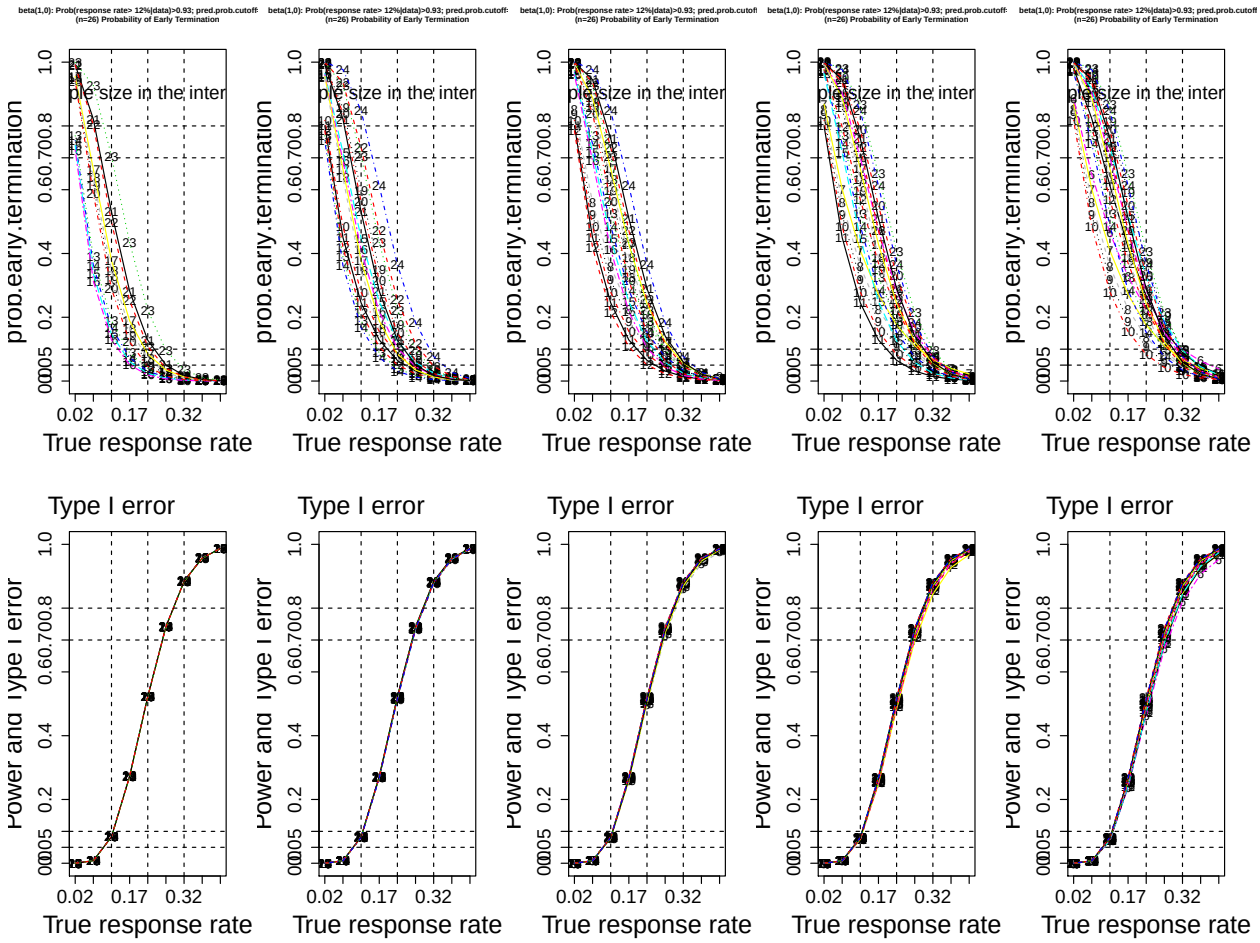

beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 1; n=30
η = 0.92
γ = 0.1
n = 30
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 15; n=30
η = 0.92
γ = 0.15
n = 30
type I error
n in the interim analysis
beta(1.15,8.41): Type I Error
prob(θ>12%|data)>0. 92; γ=0. 2; n=30
η = 0.92
γ = 0.2
n = 30
type I error
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis

Prior Distribution: beta(1,0)






beta(1,0): Prob(response rate> 12%|data)>0.92; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
0.17
0.32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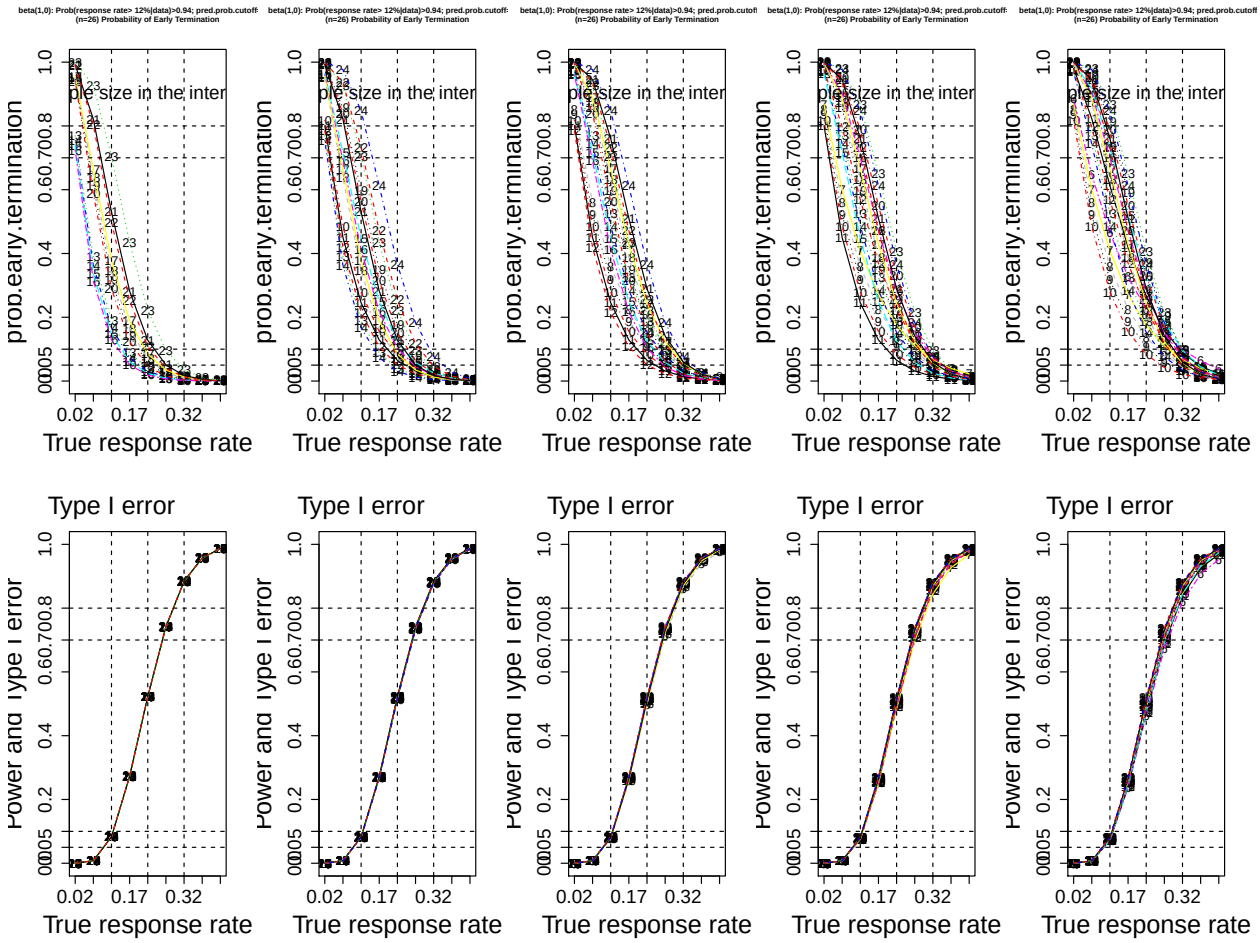
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True response rate
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Power and Type I error
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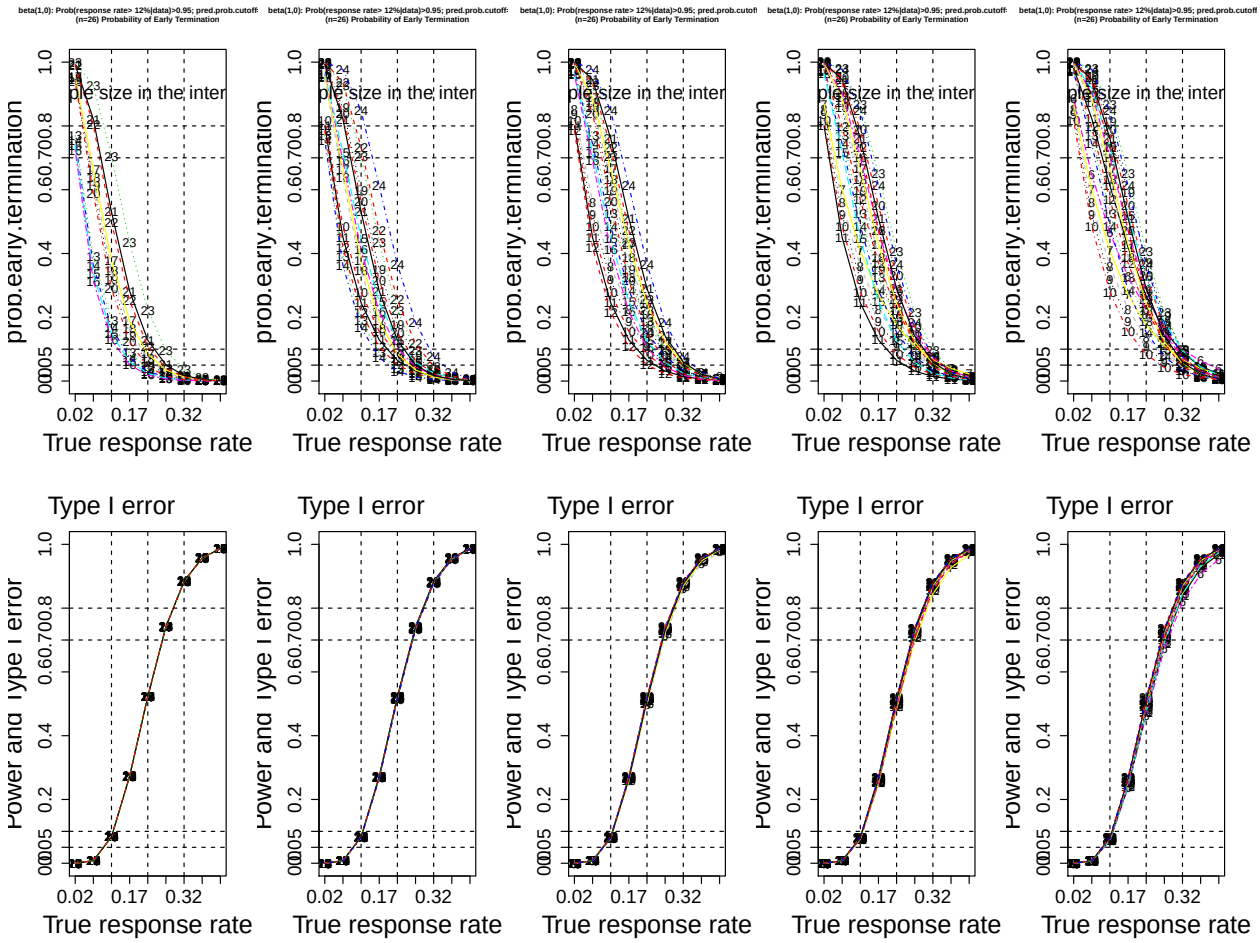
0.0 0.2 0.4 0.6 0.7 0.8 1.0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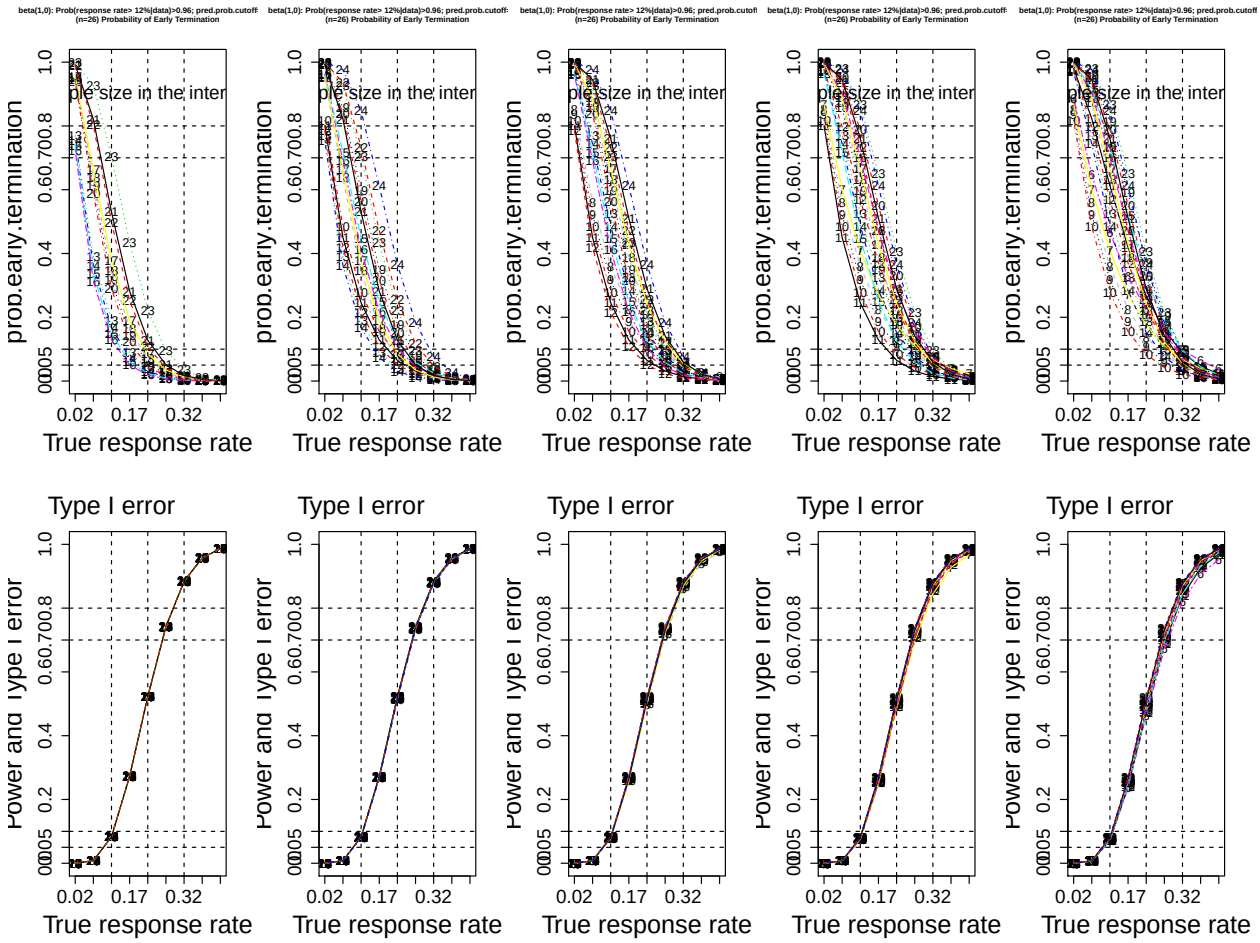
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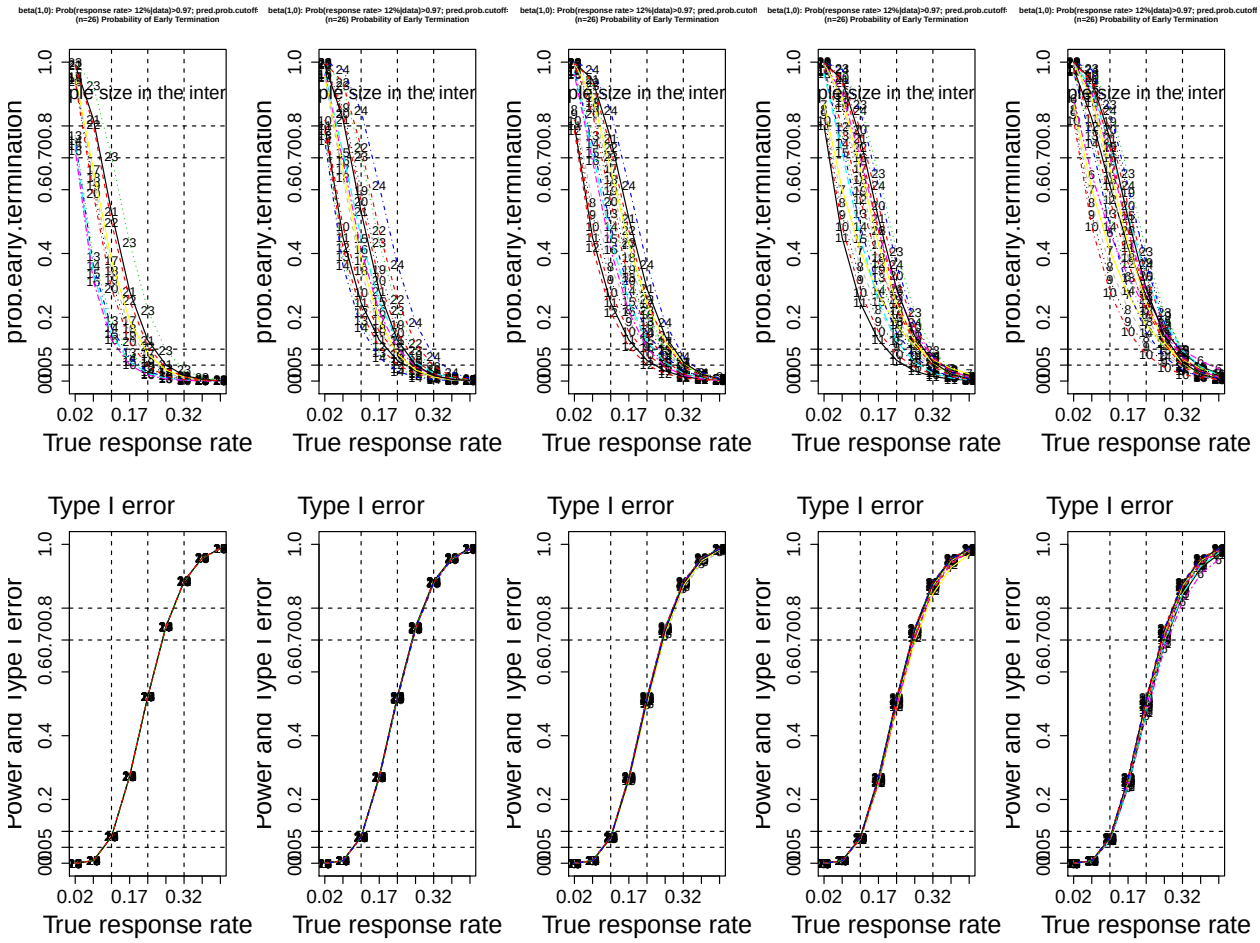
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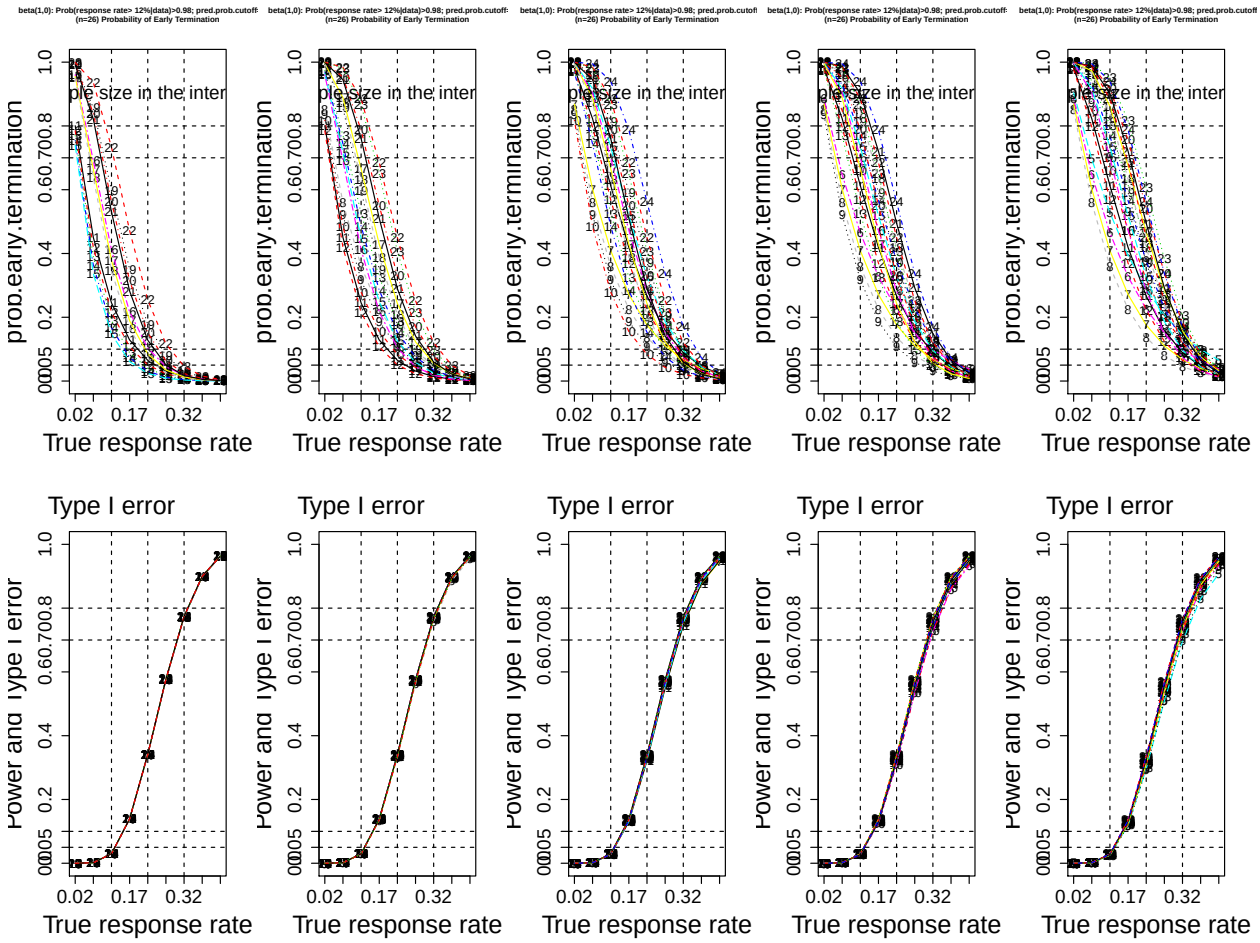
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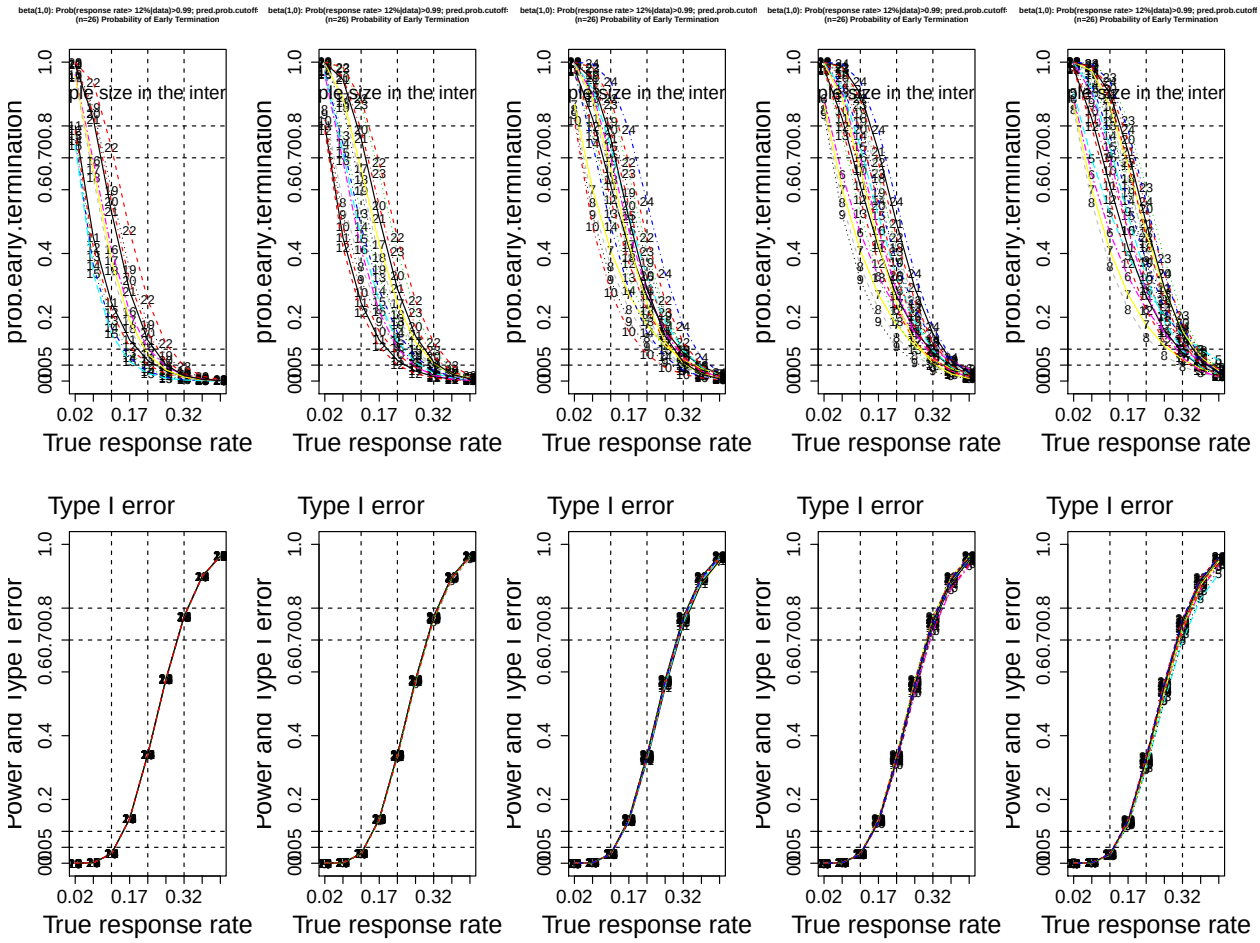
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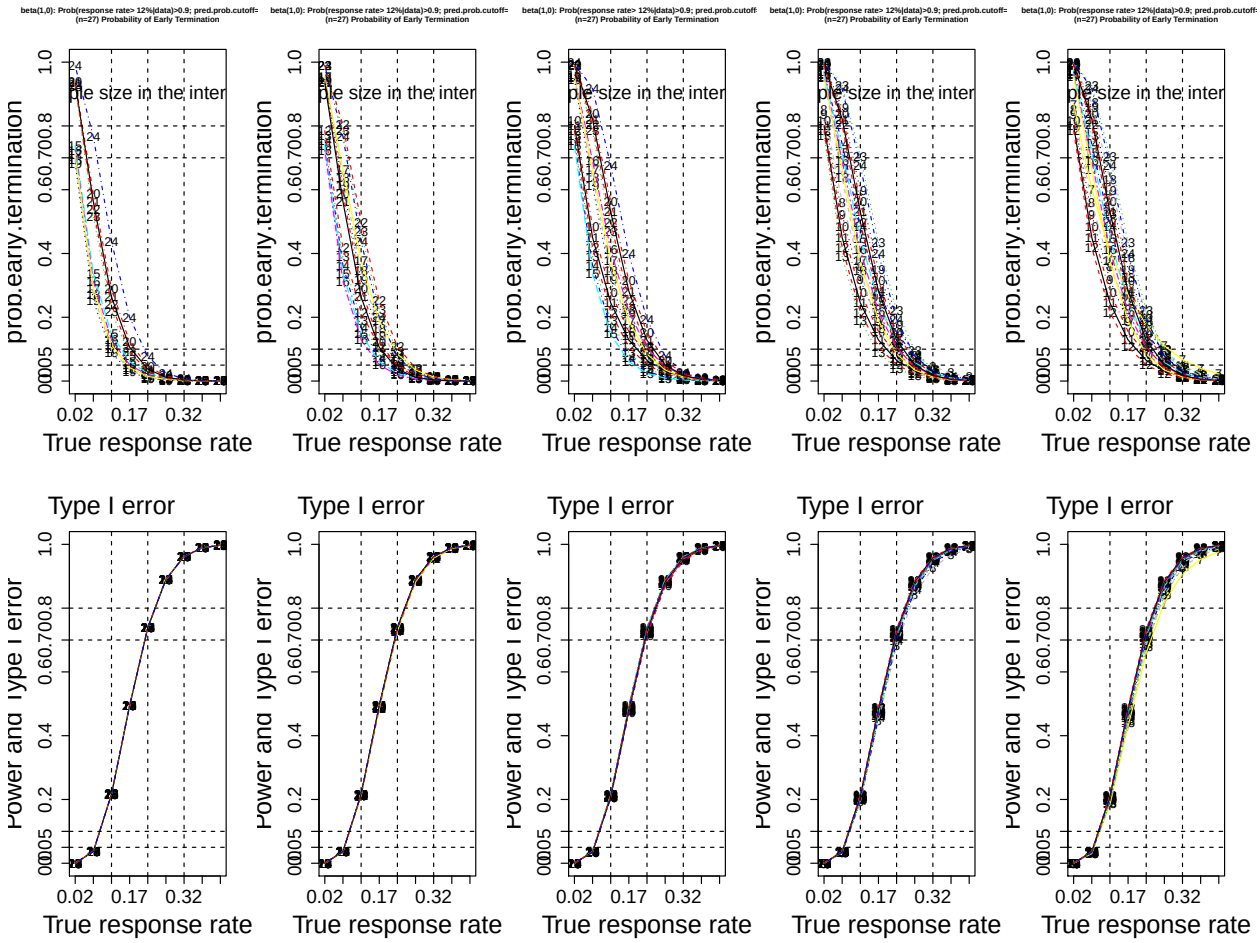
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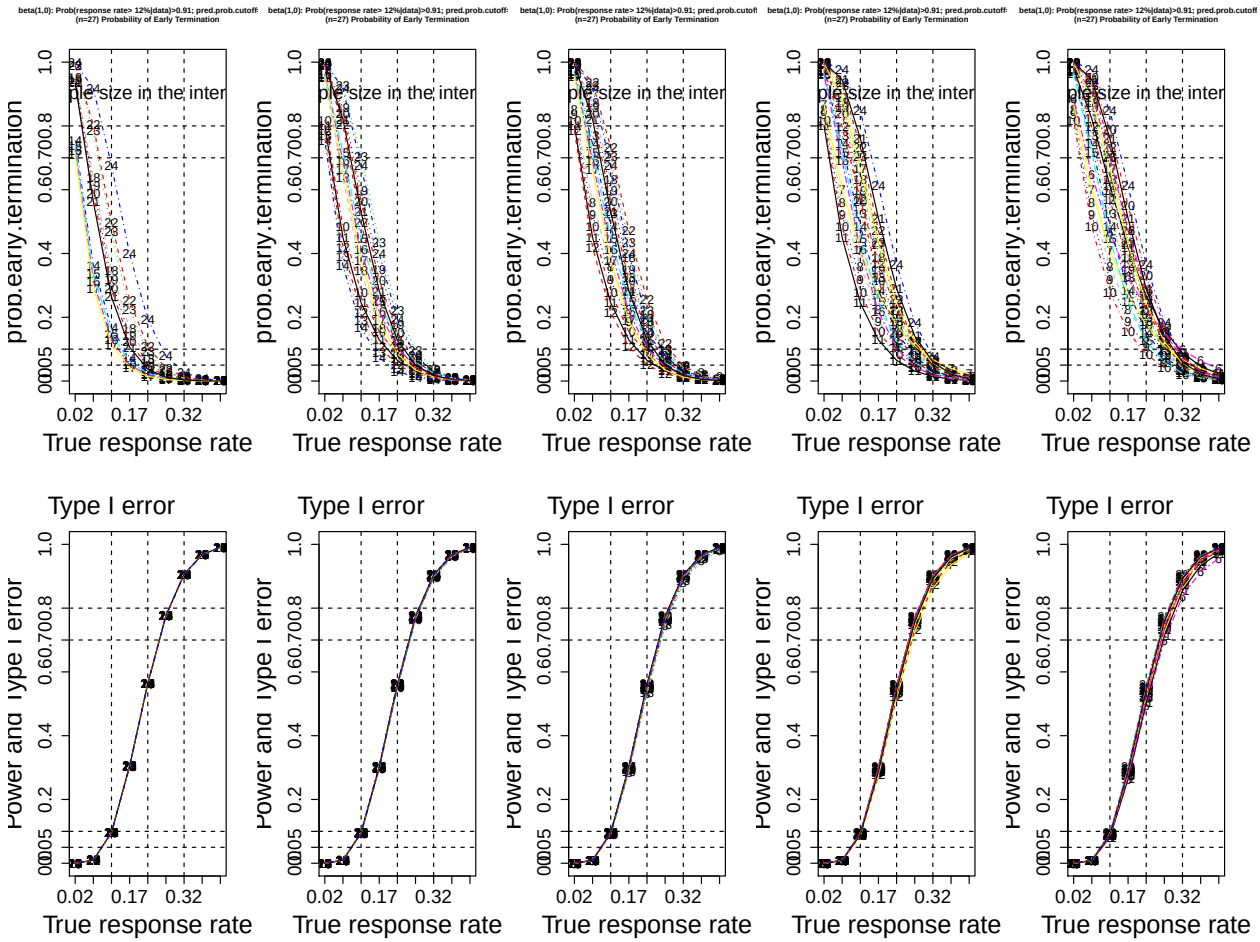
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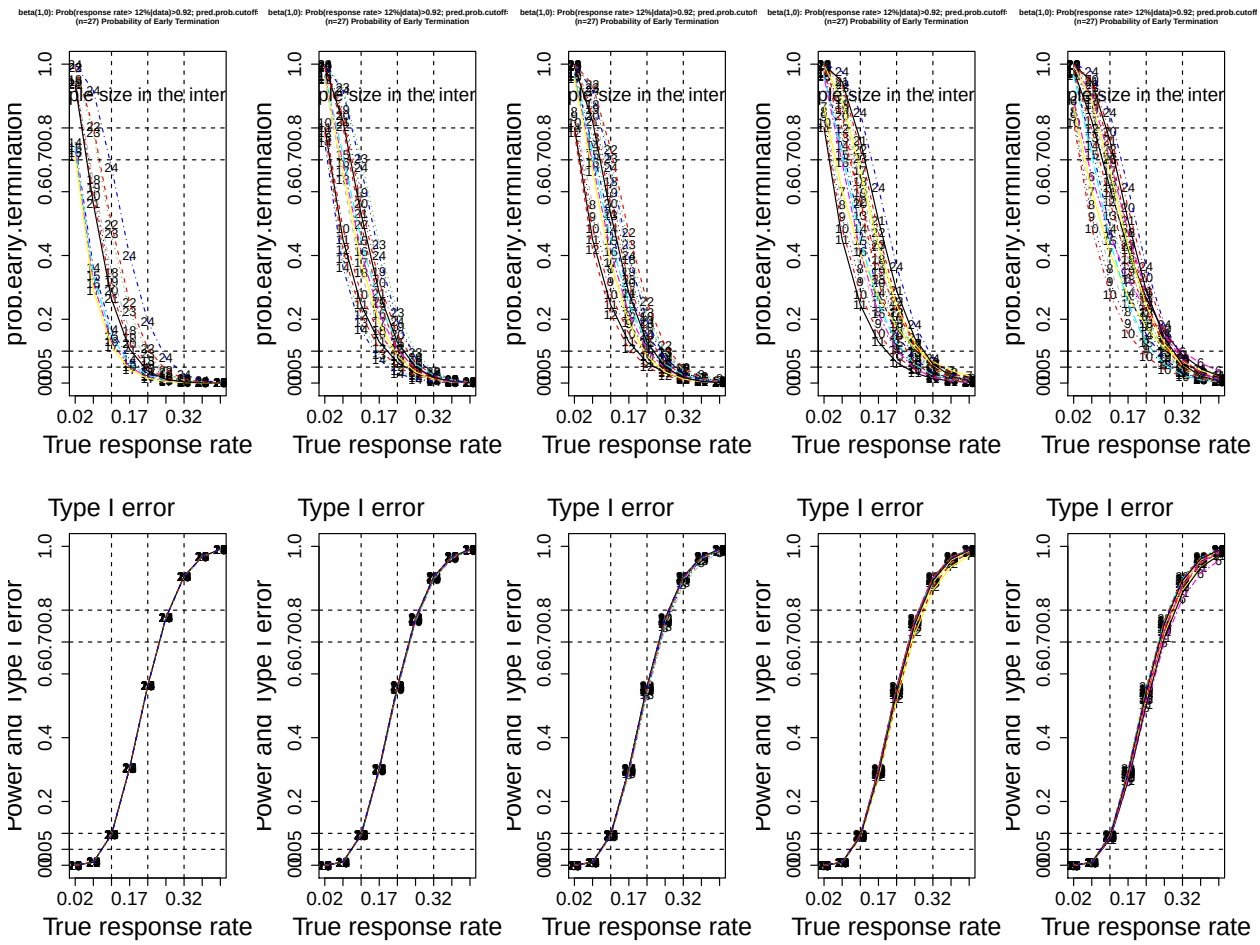
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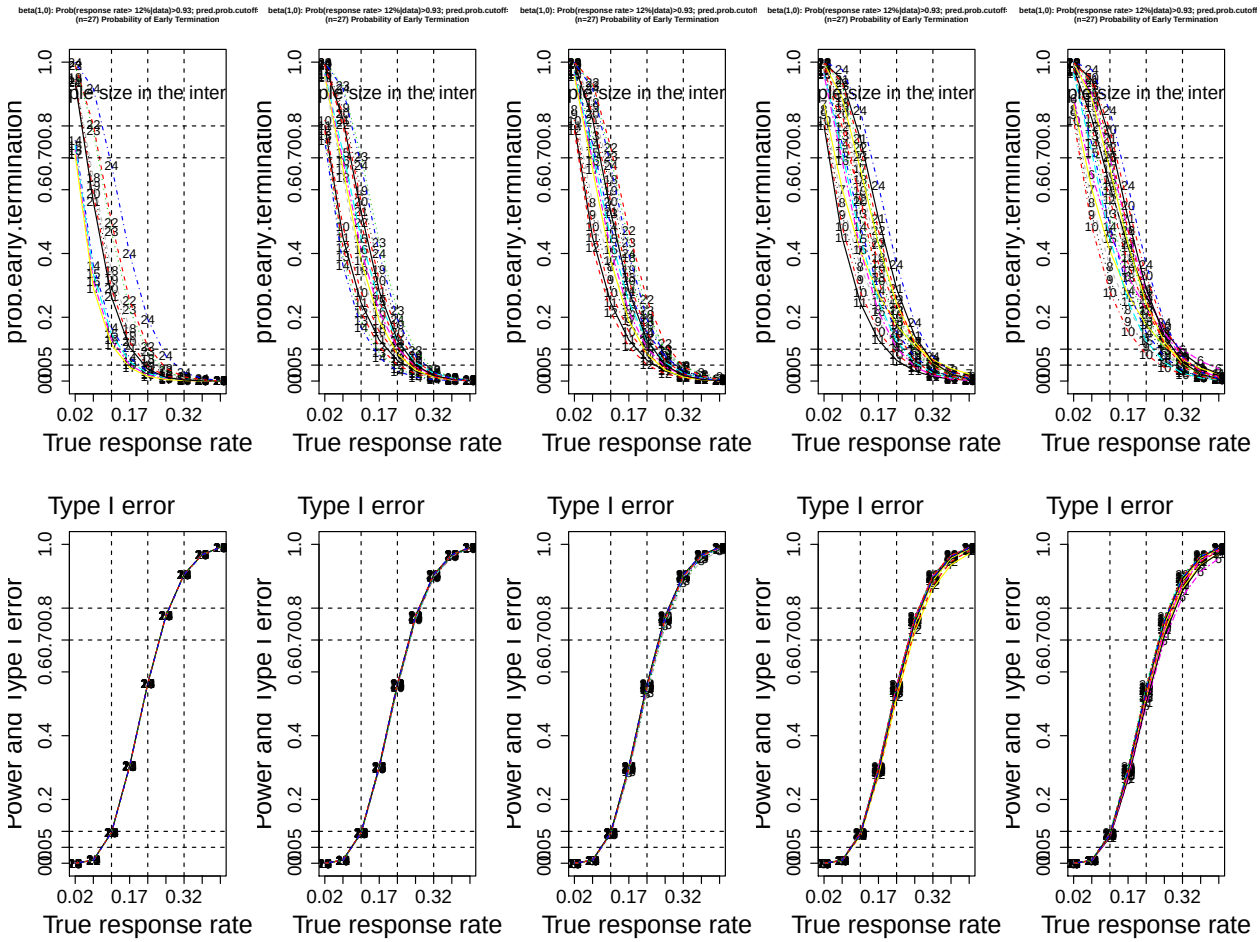
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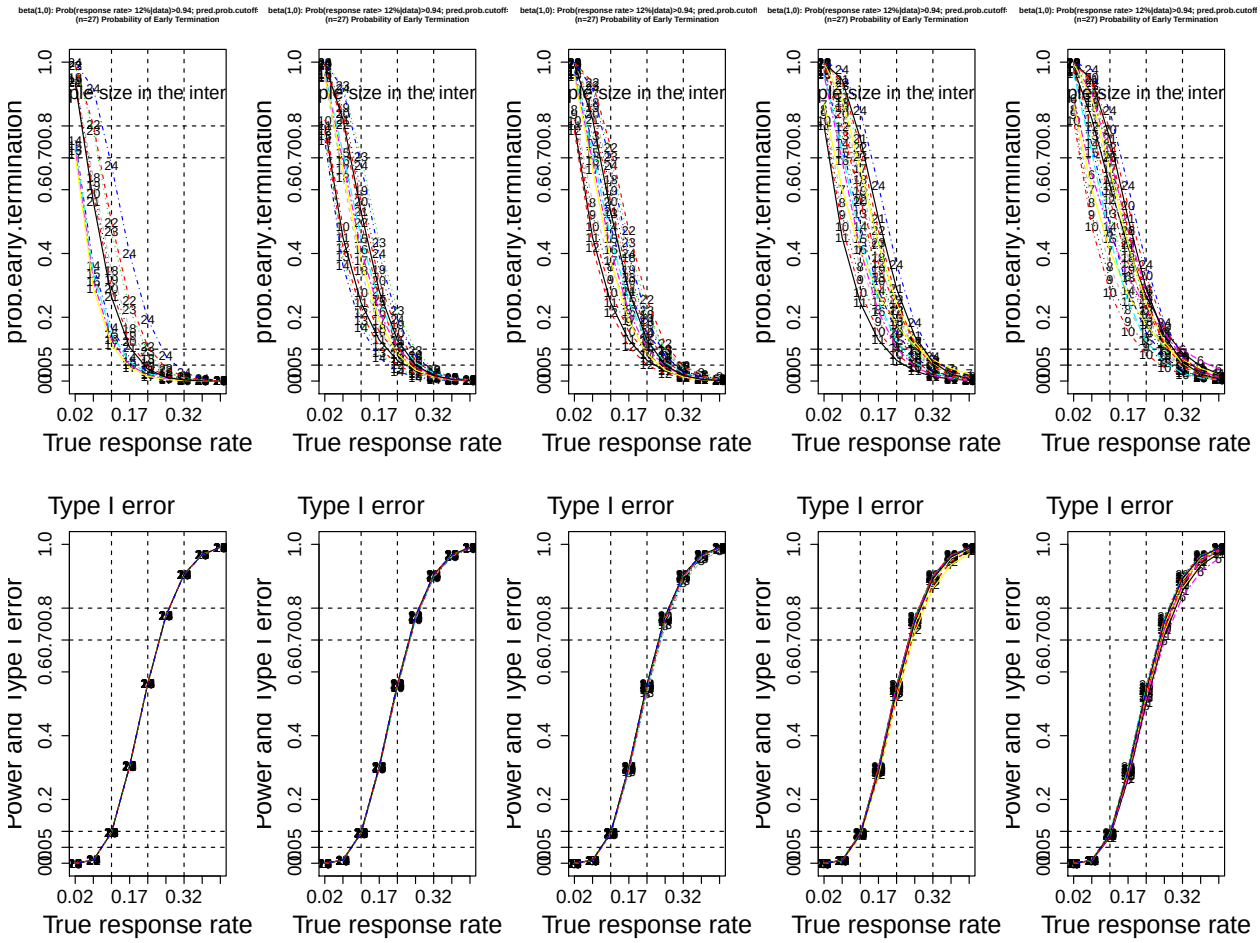
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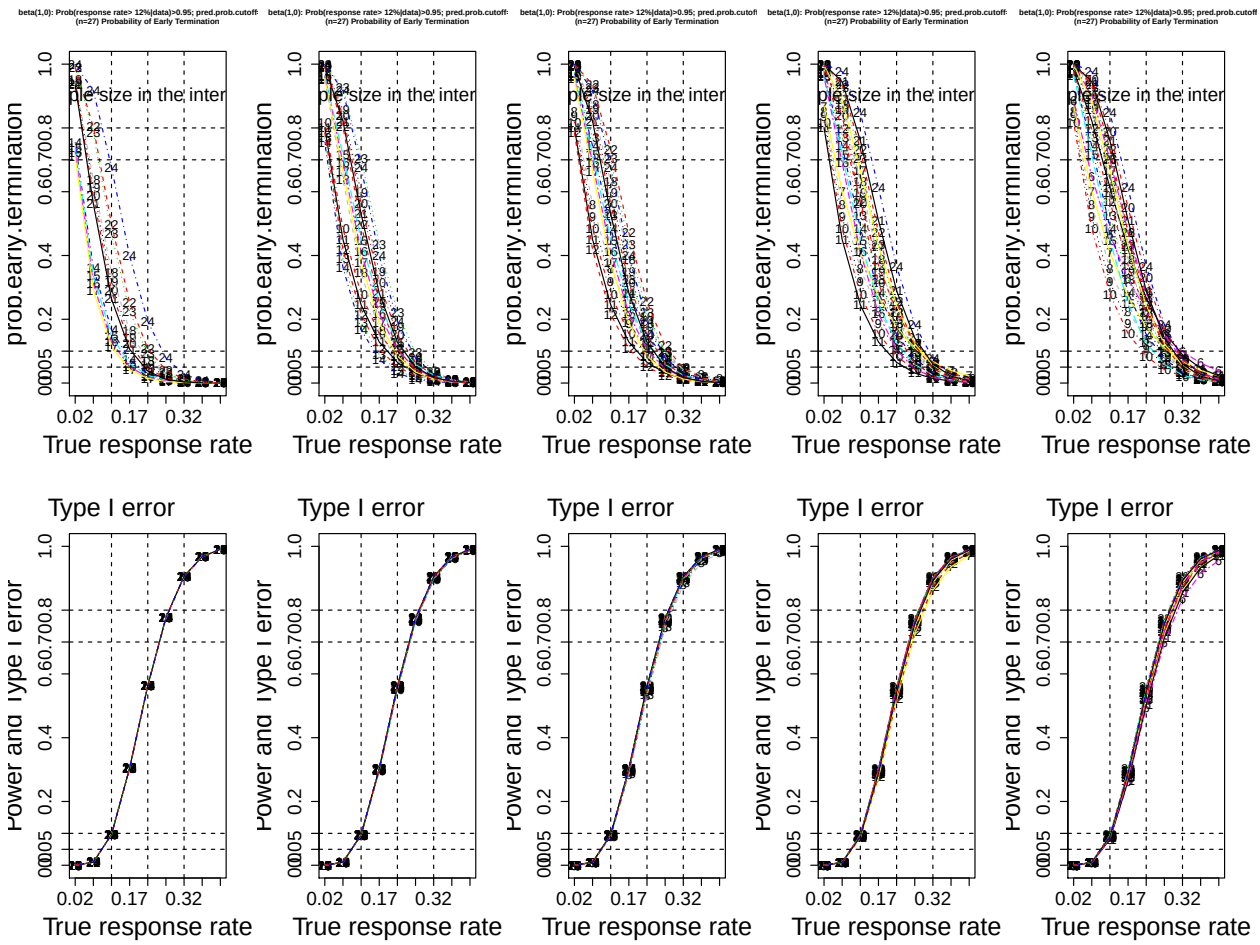
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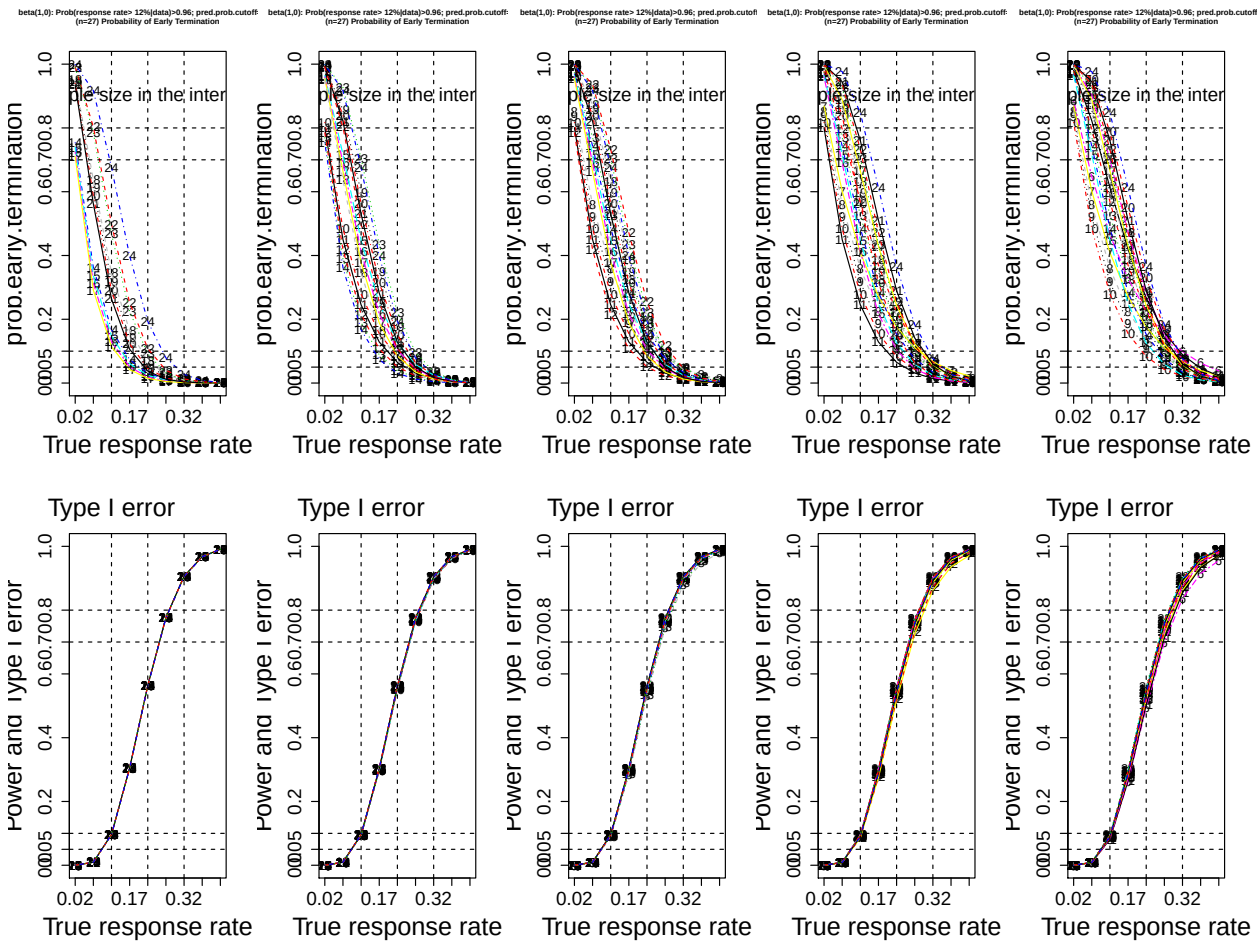
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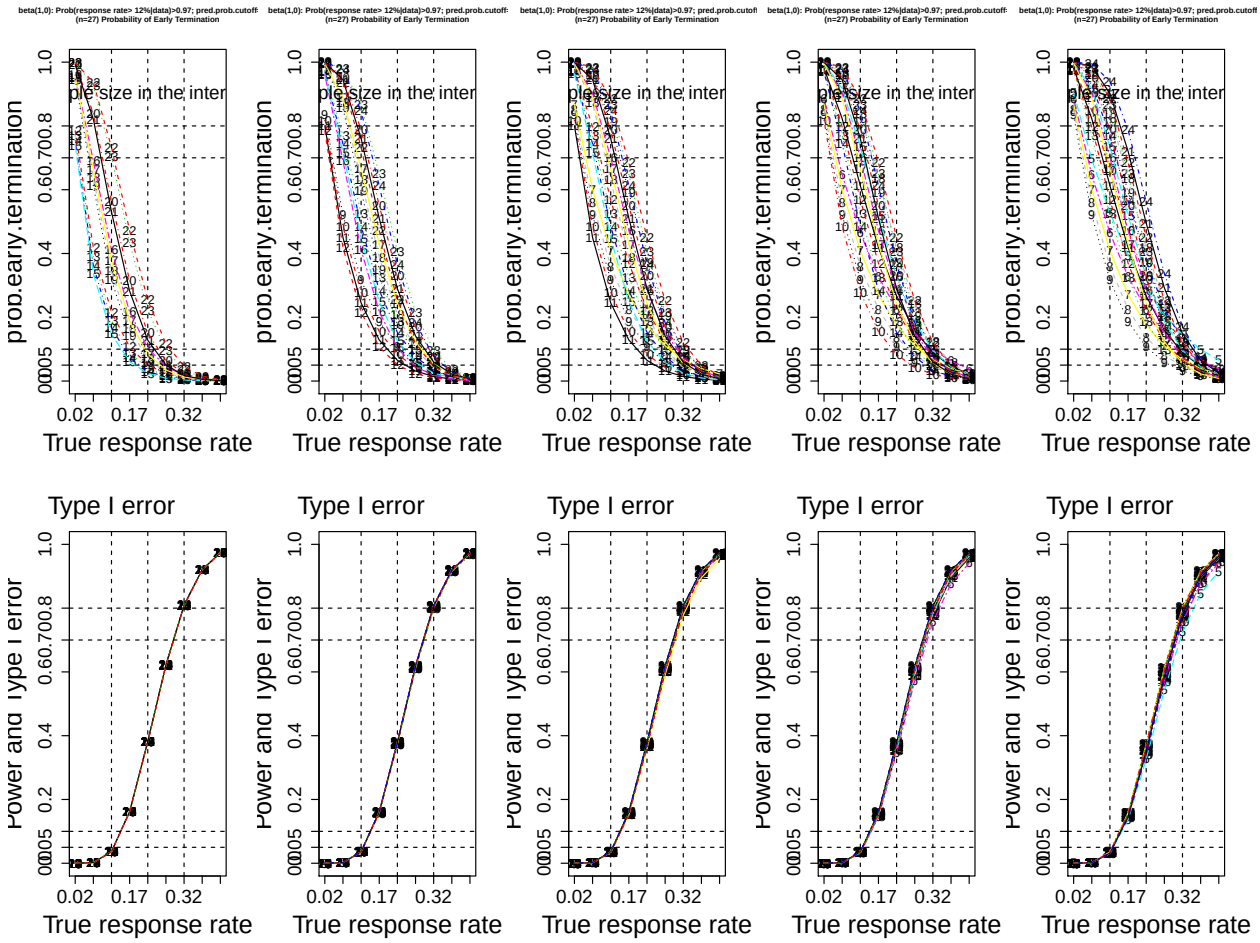
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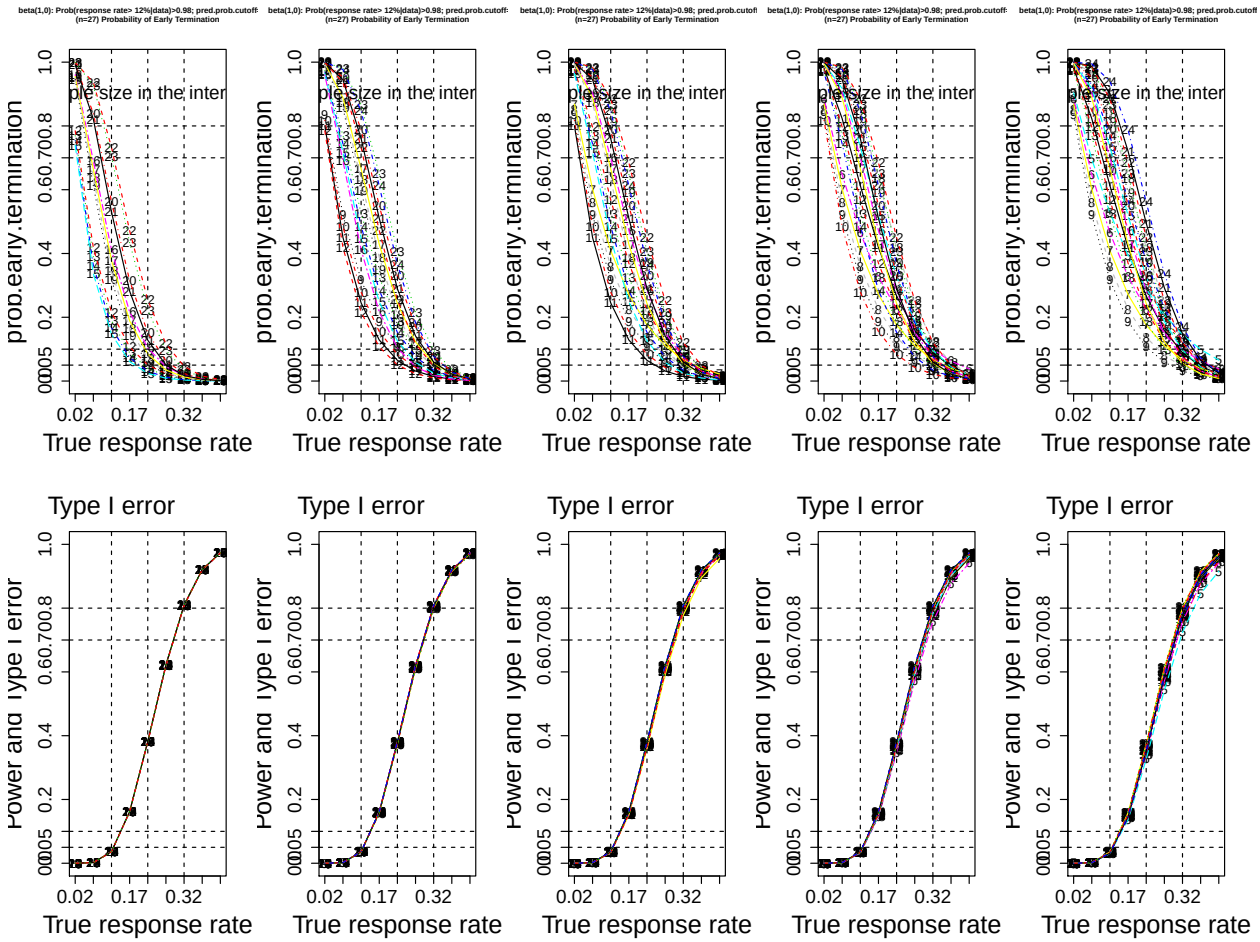
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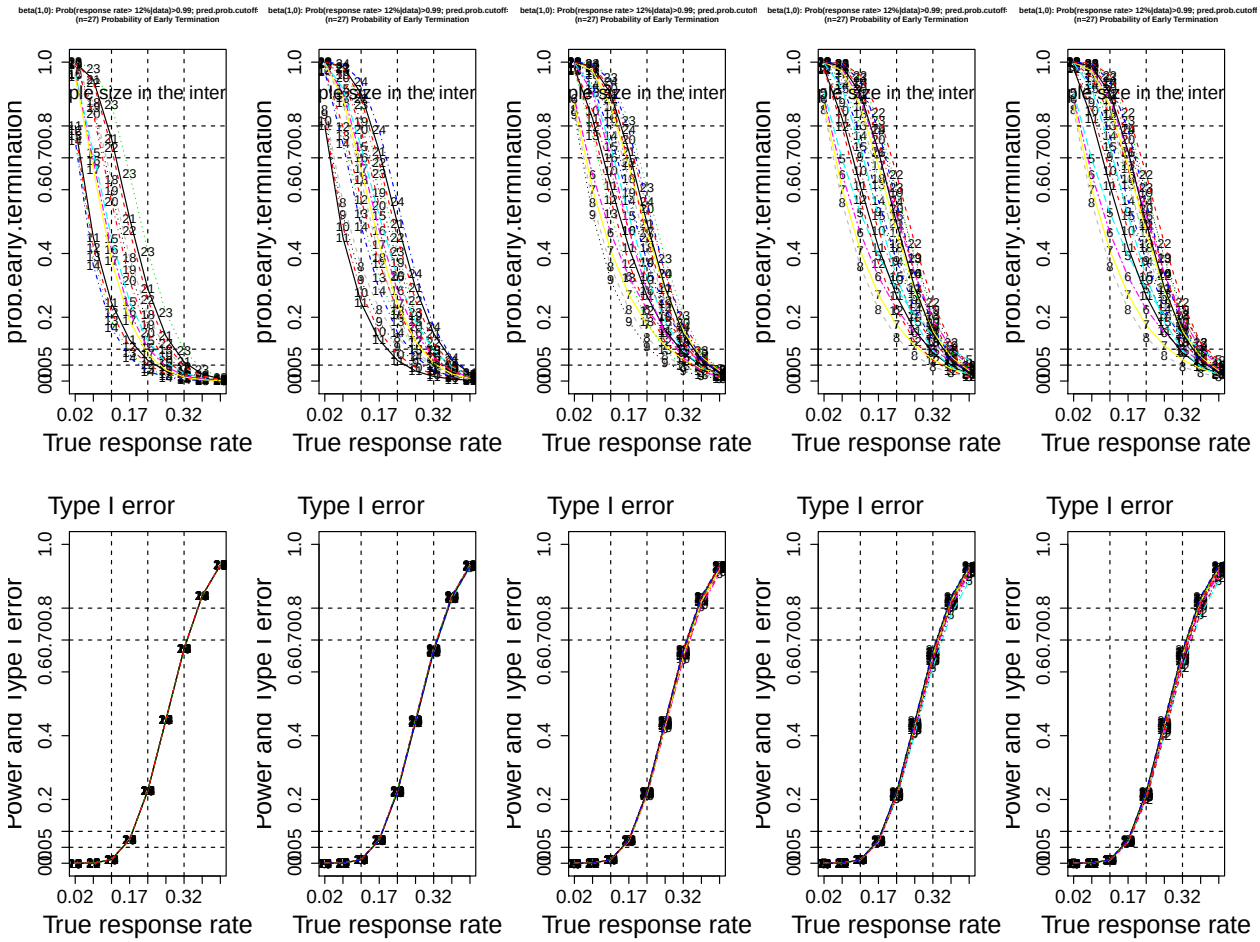
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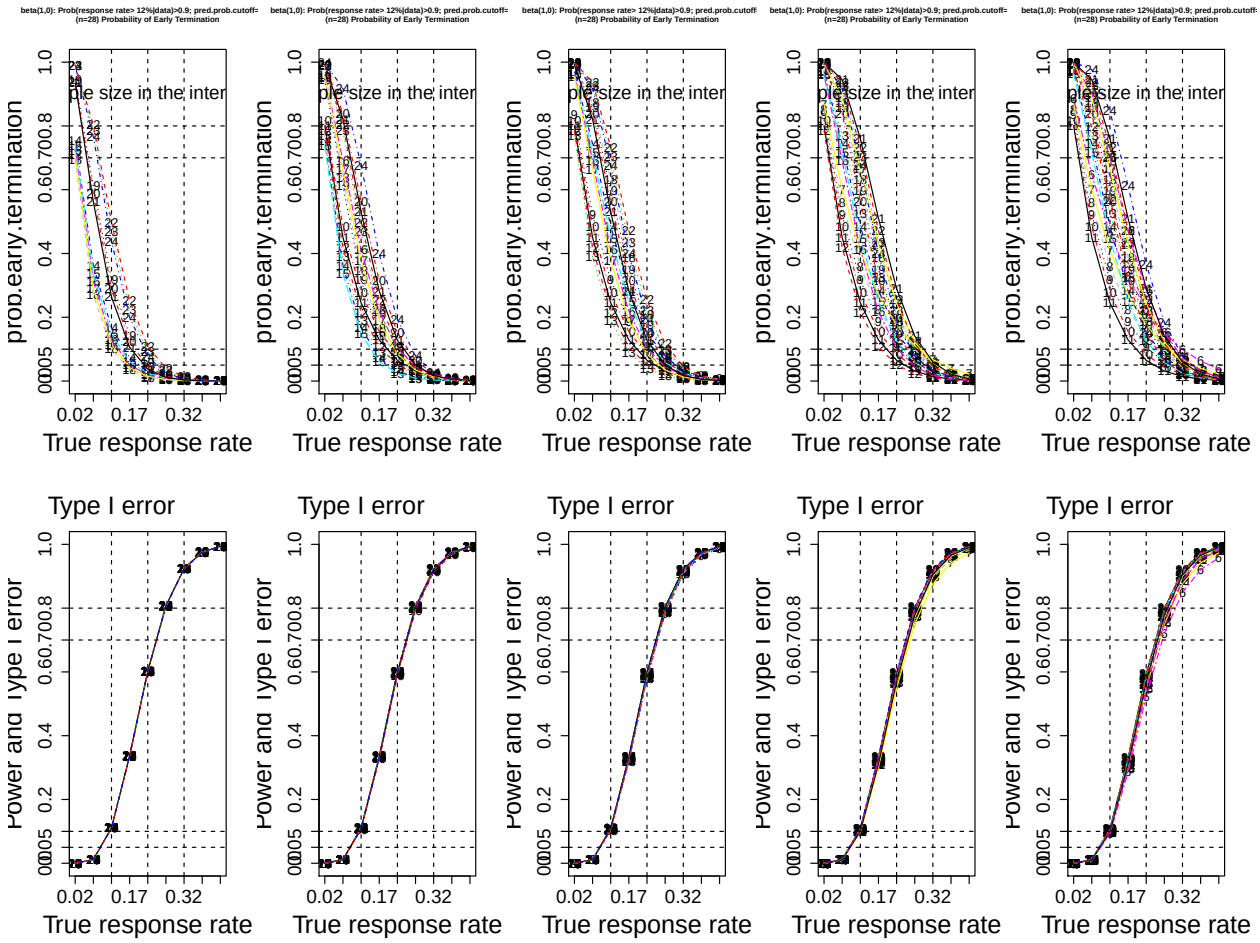
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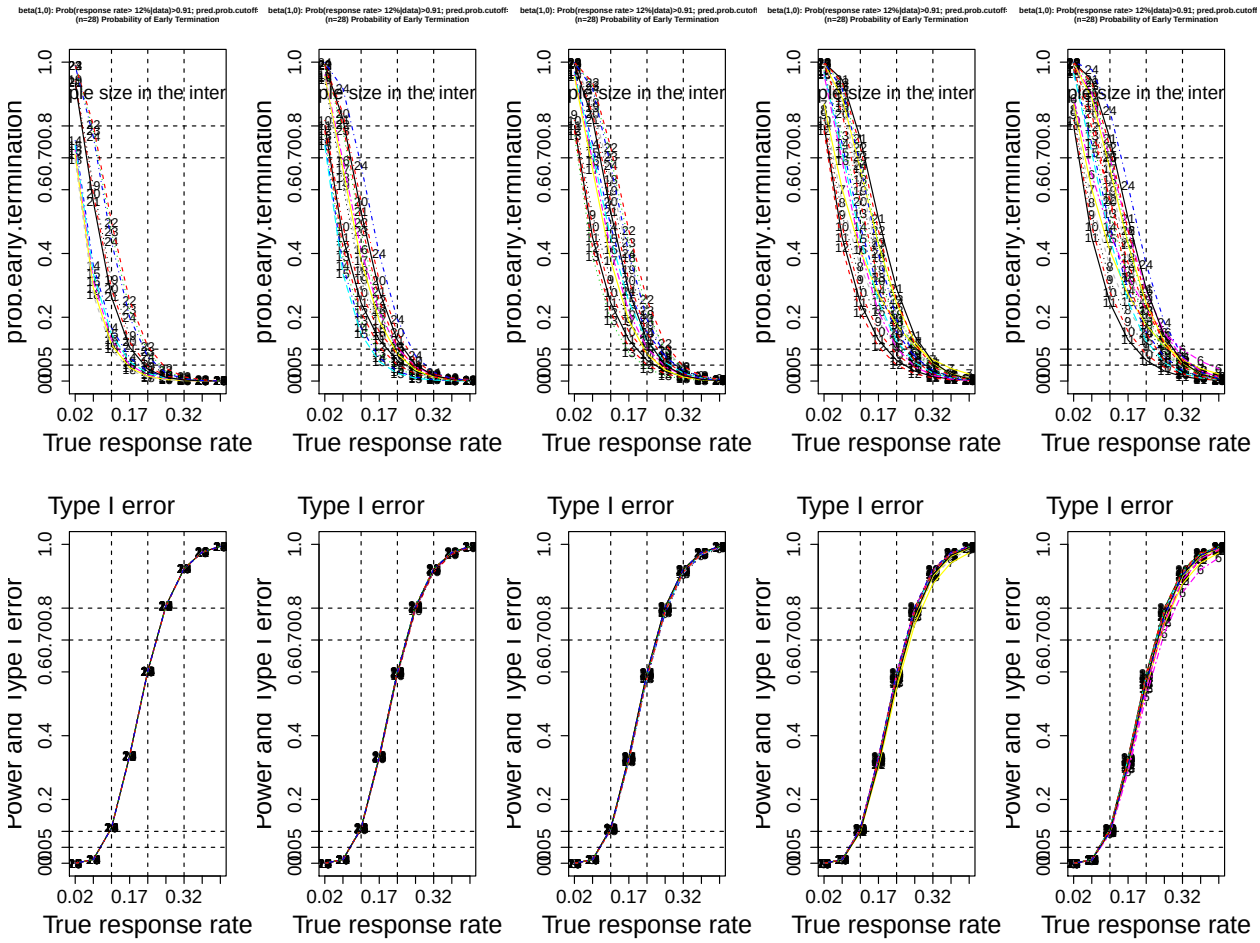
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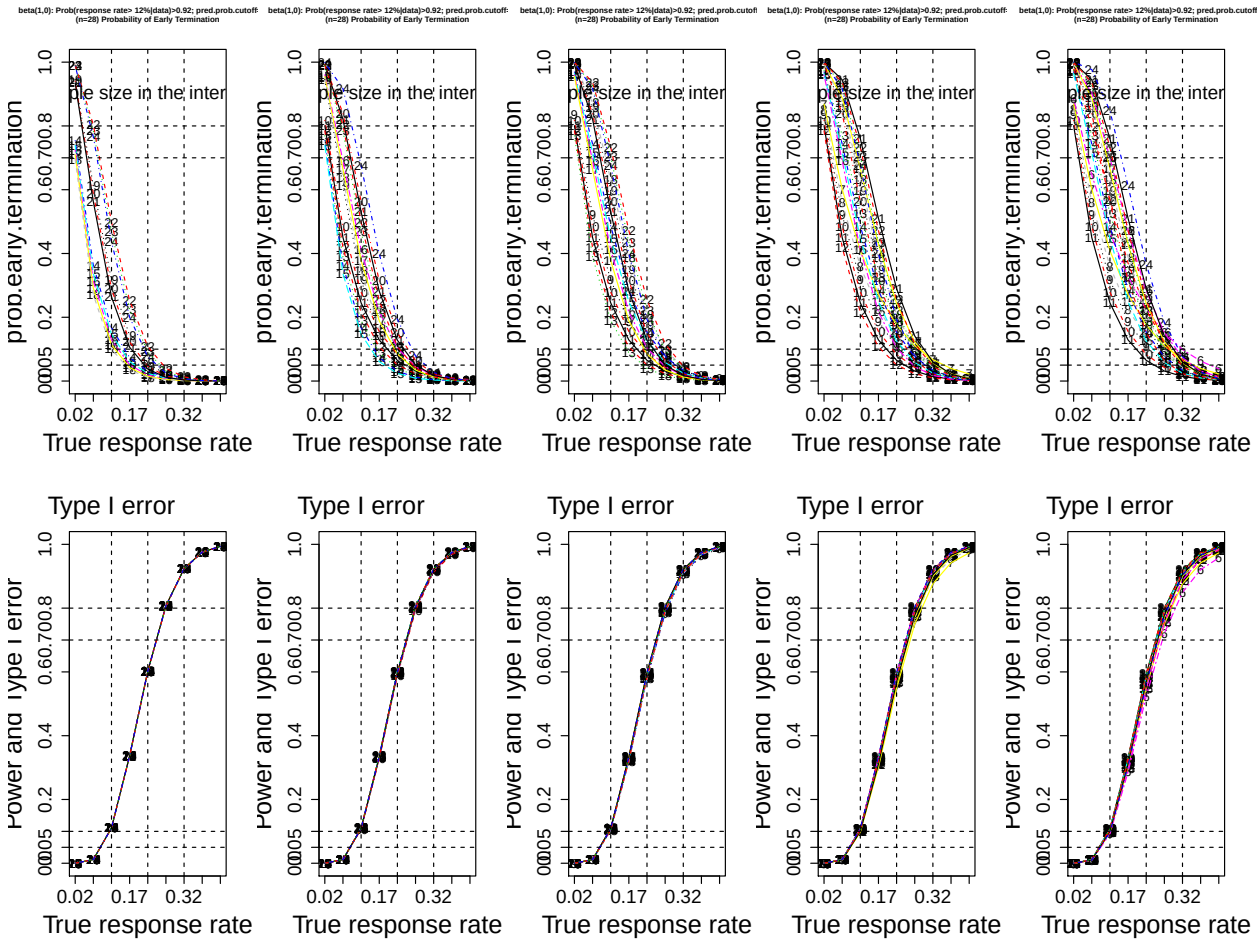
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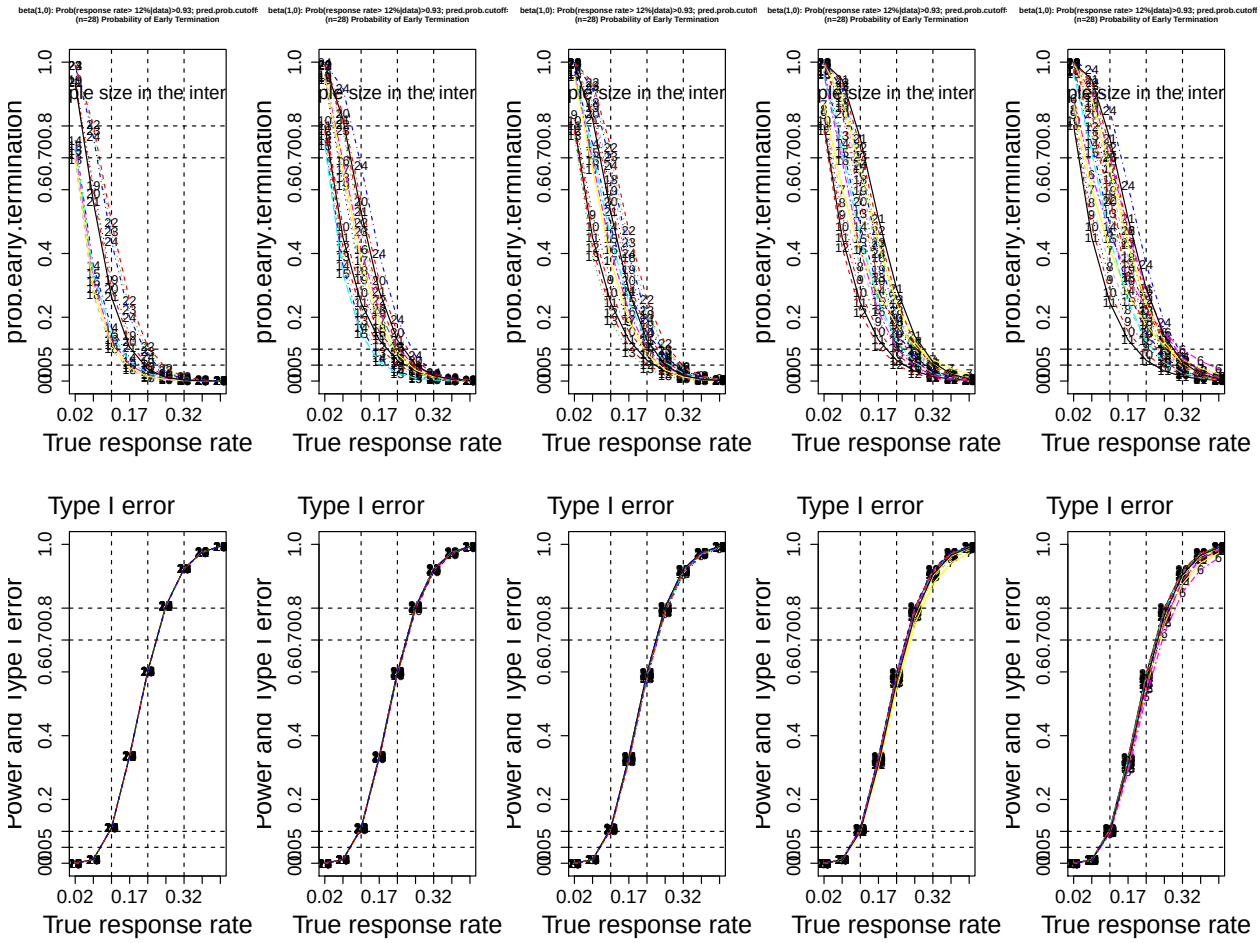
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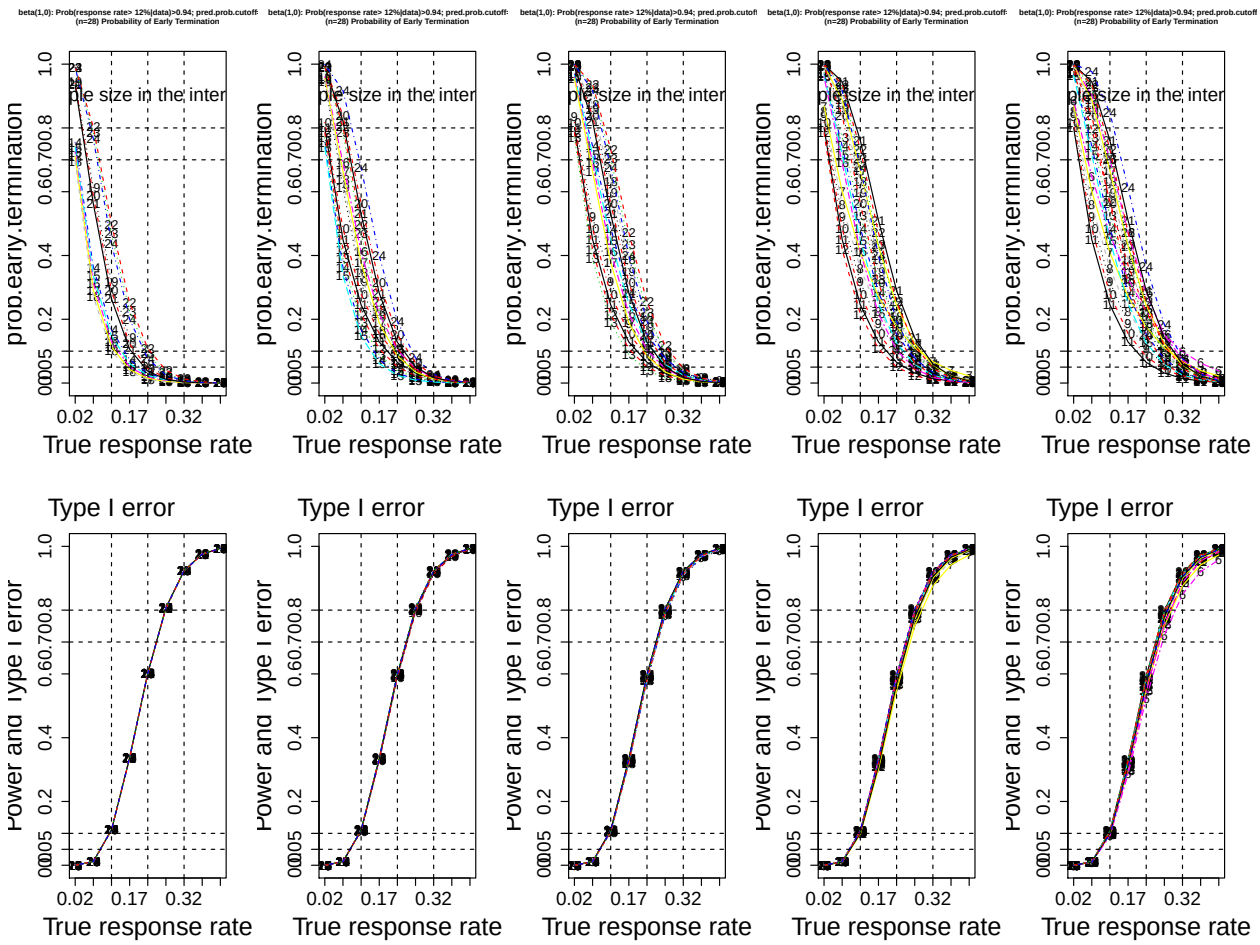
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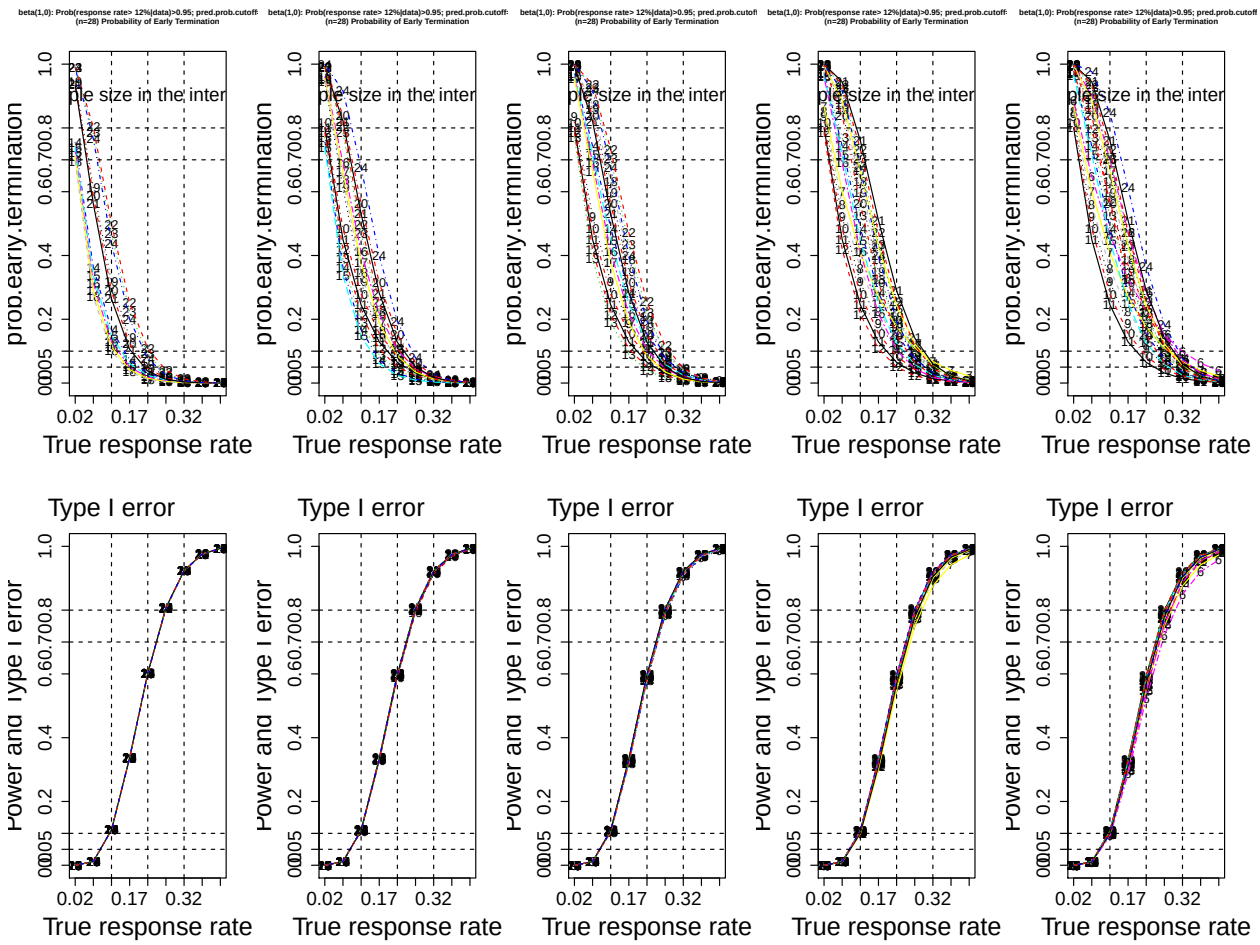
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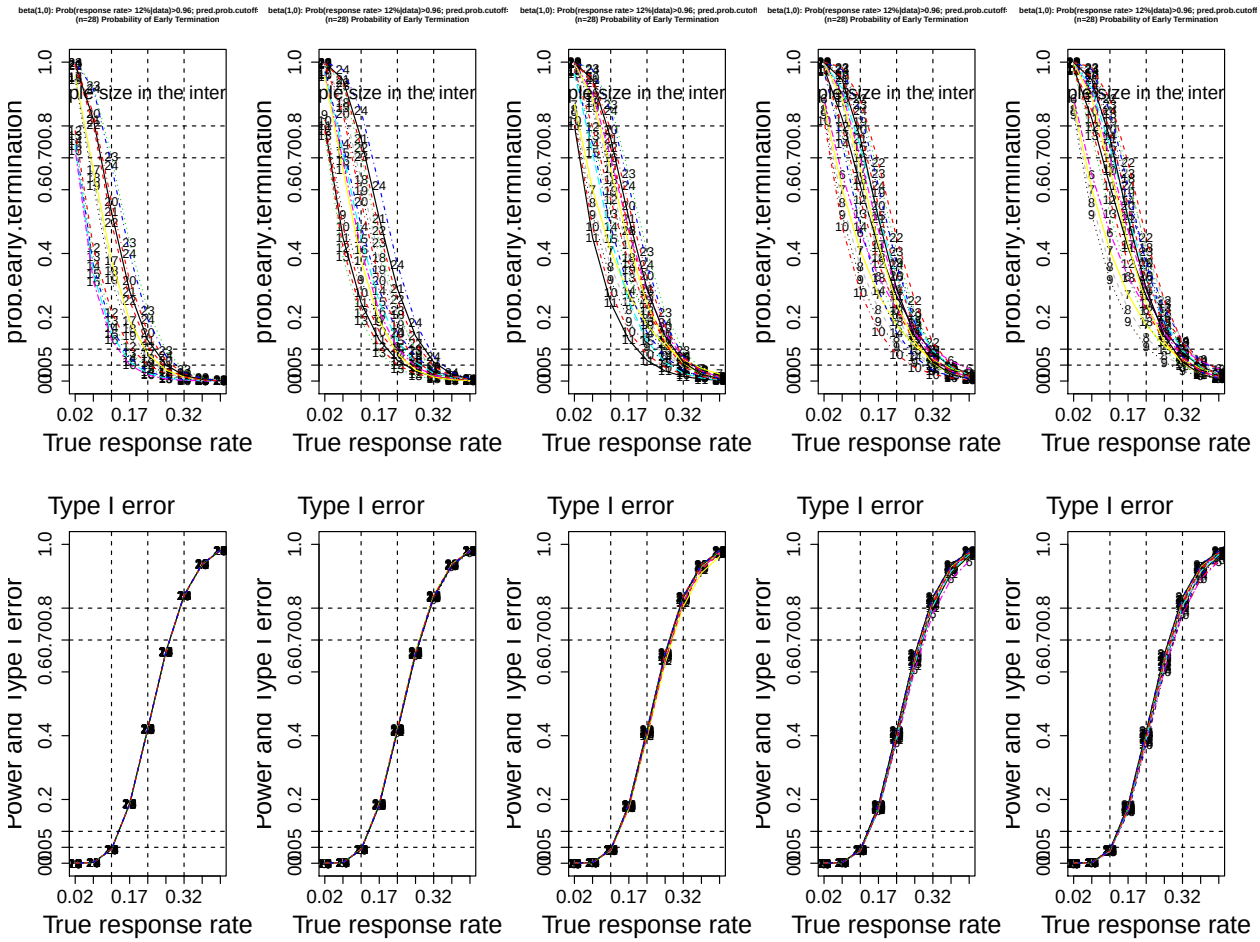
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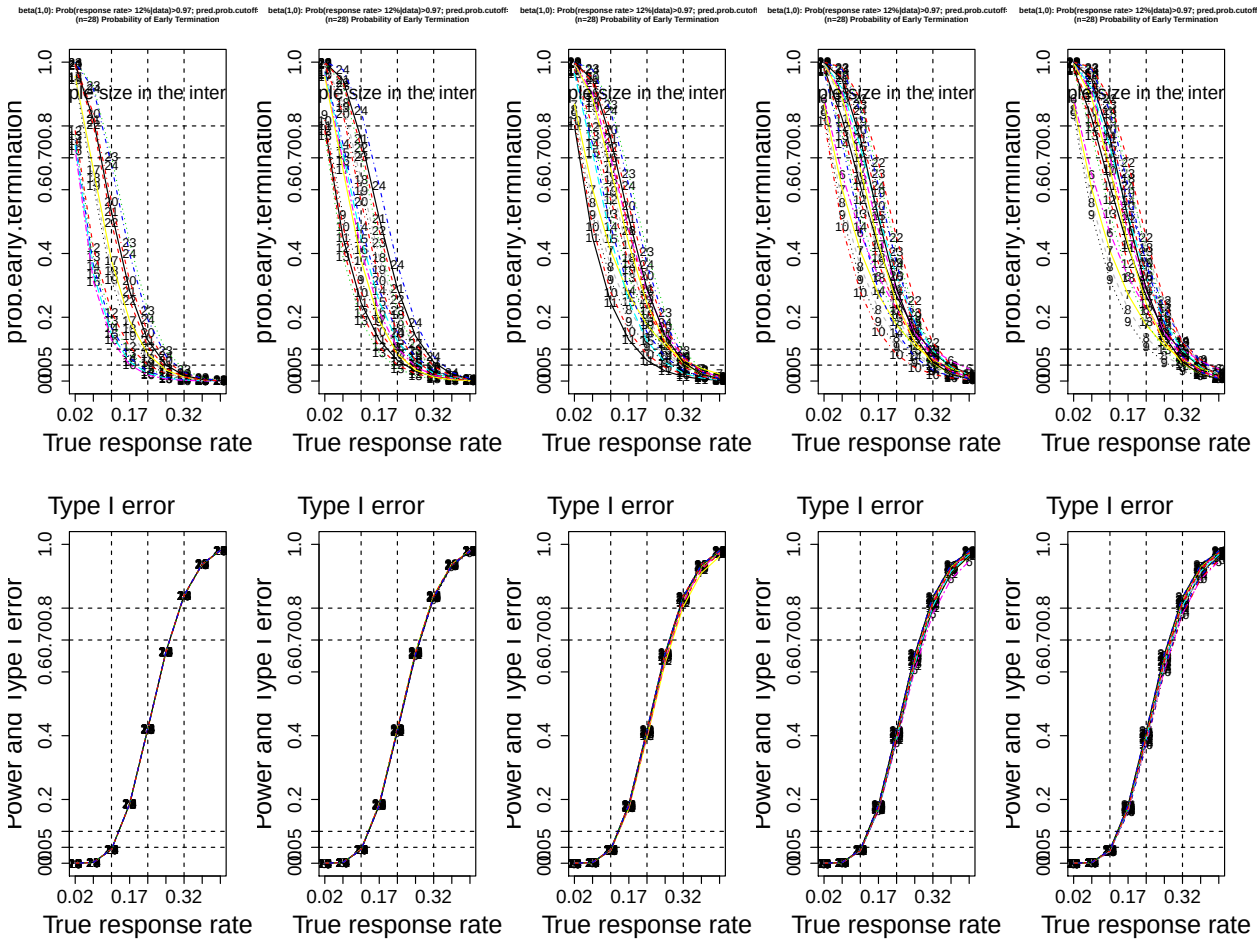
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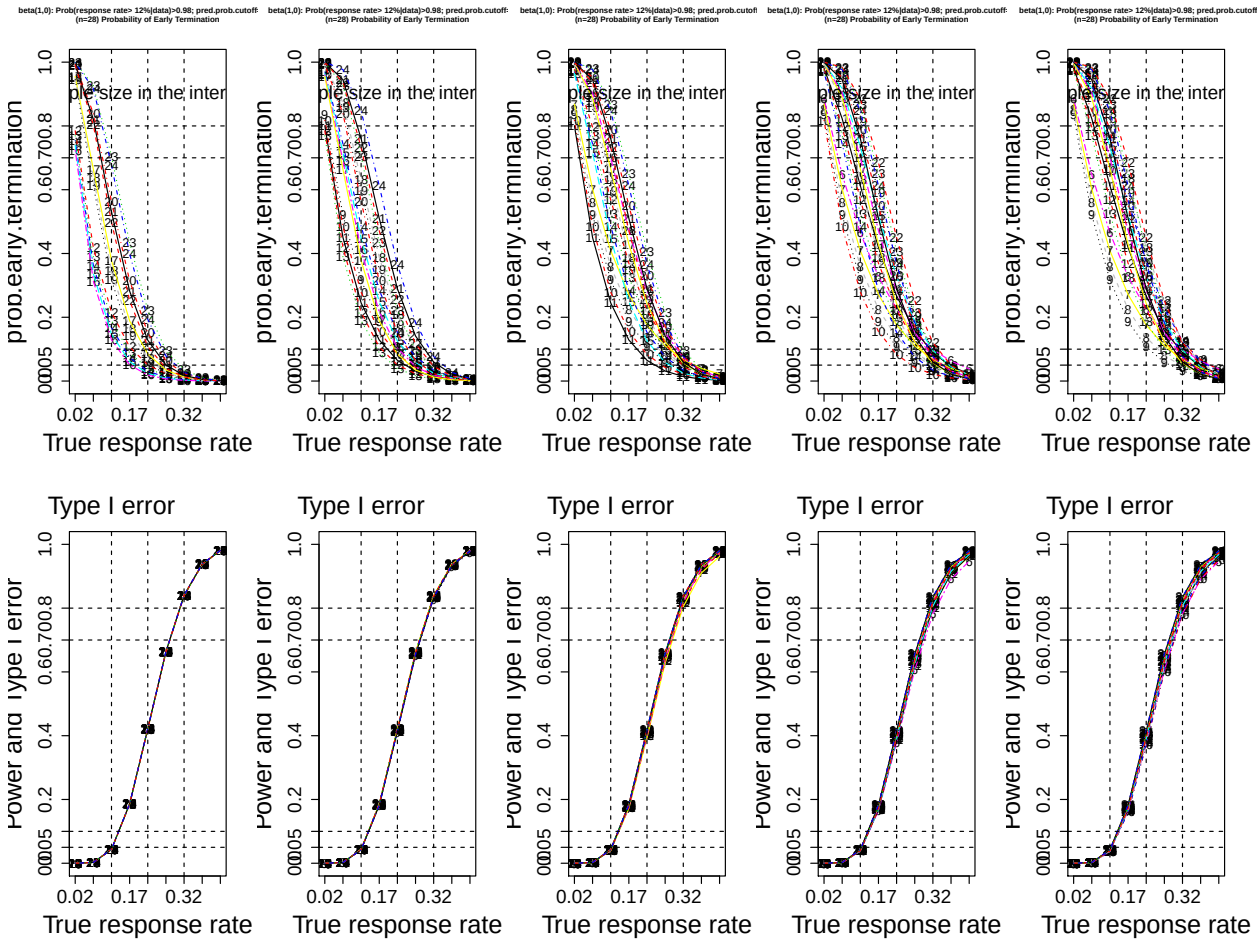
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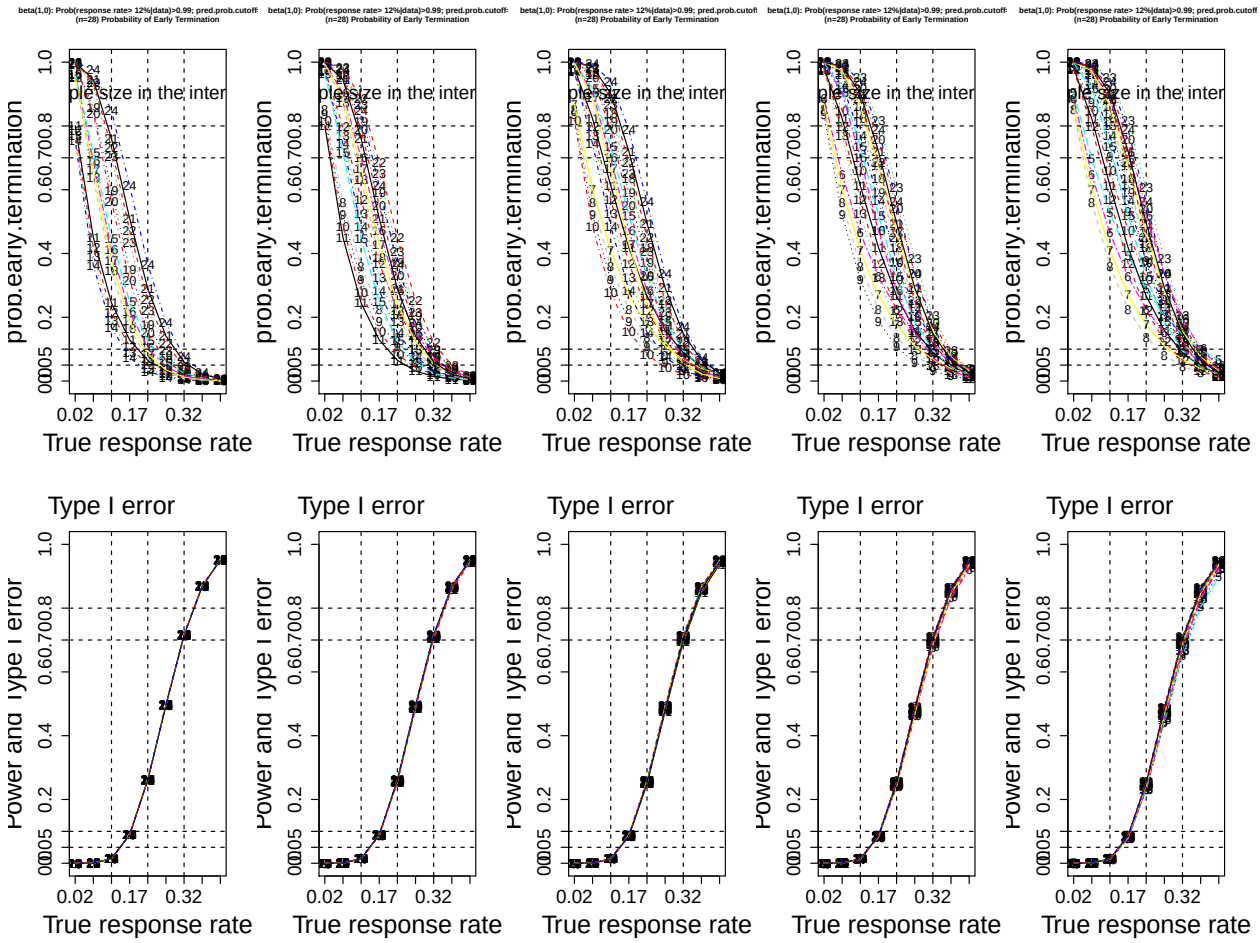
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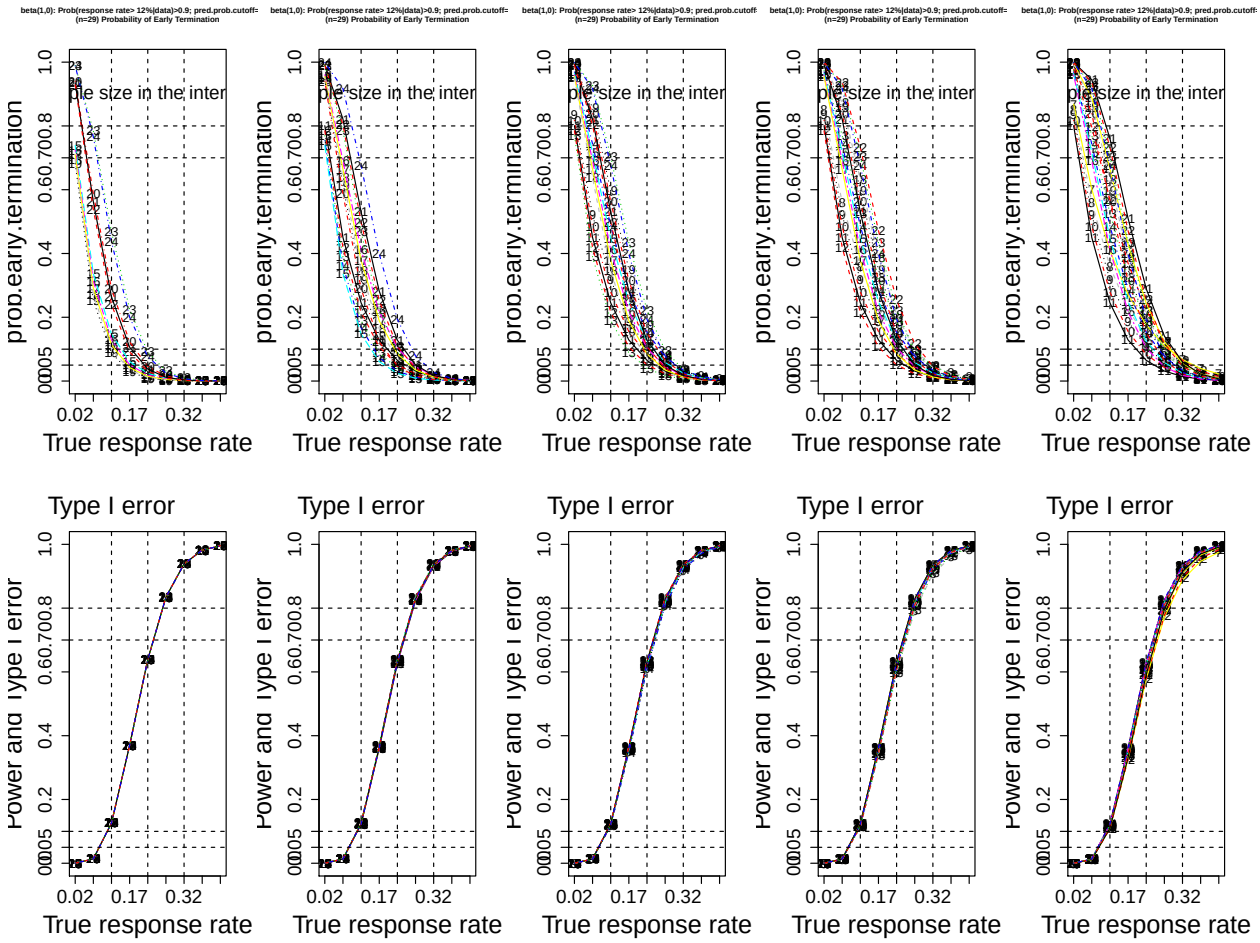
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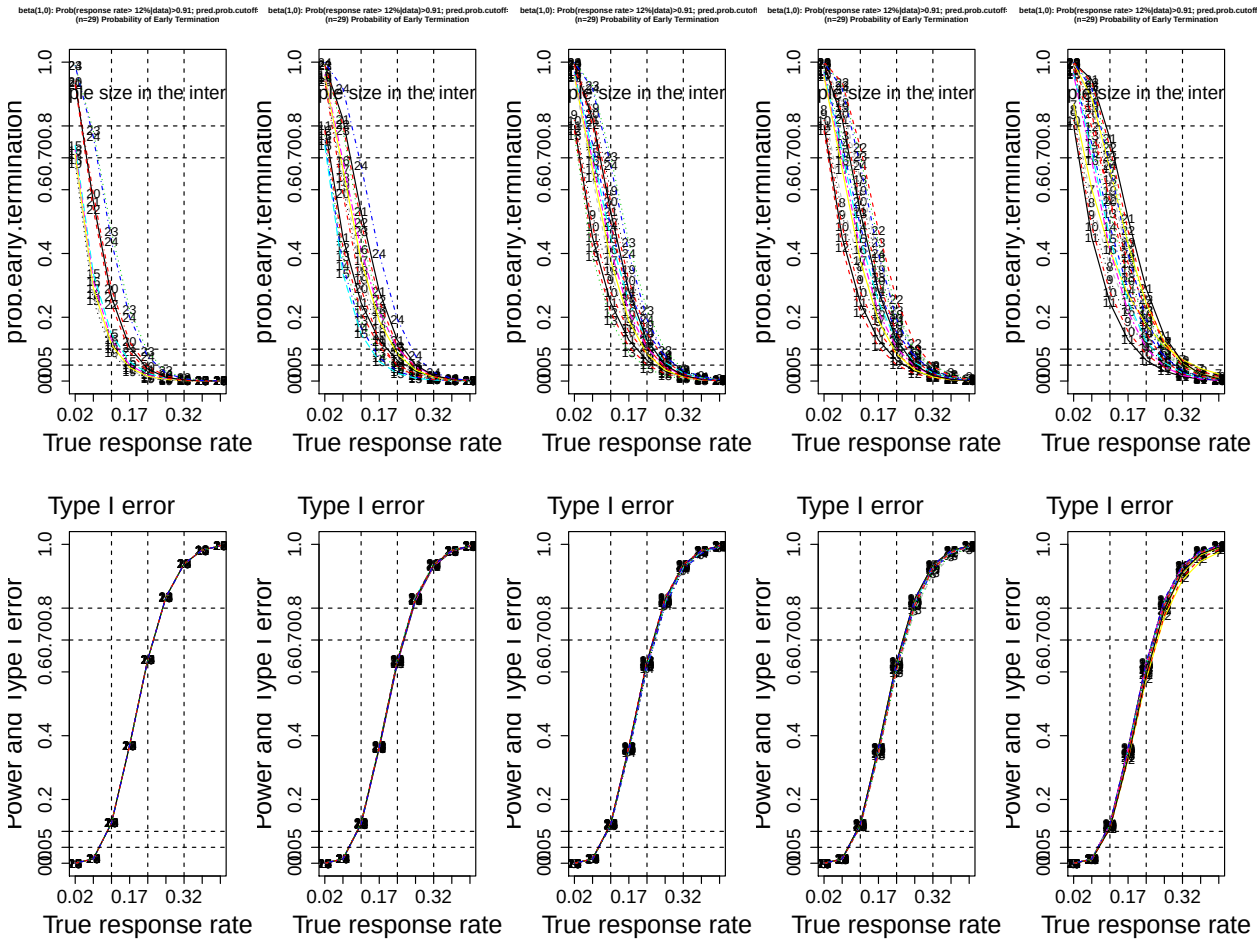
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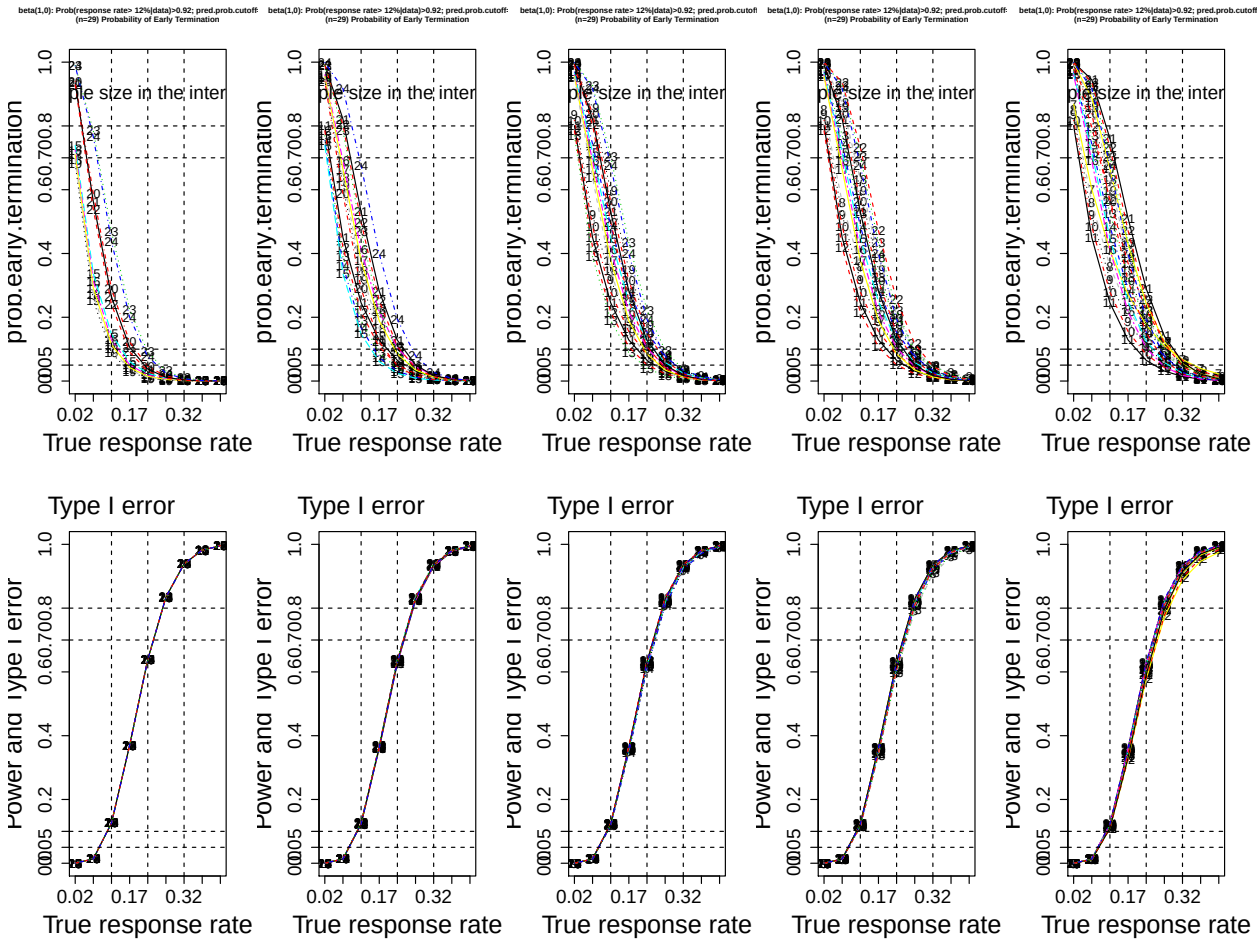
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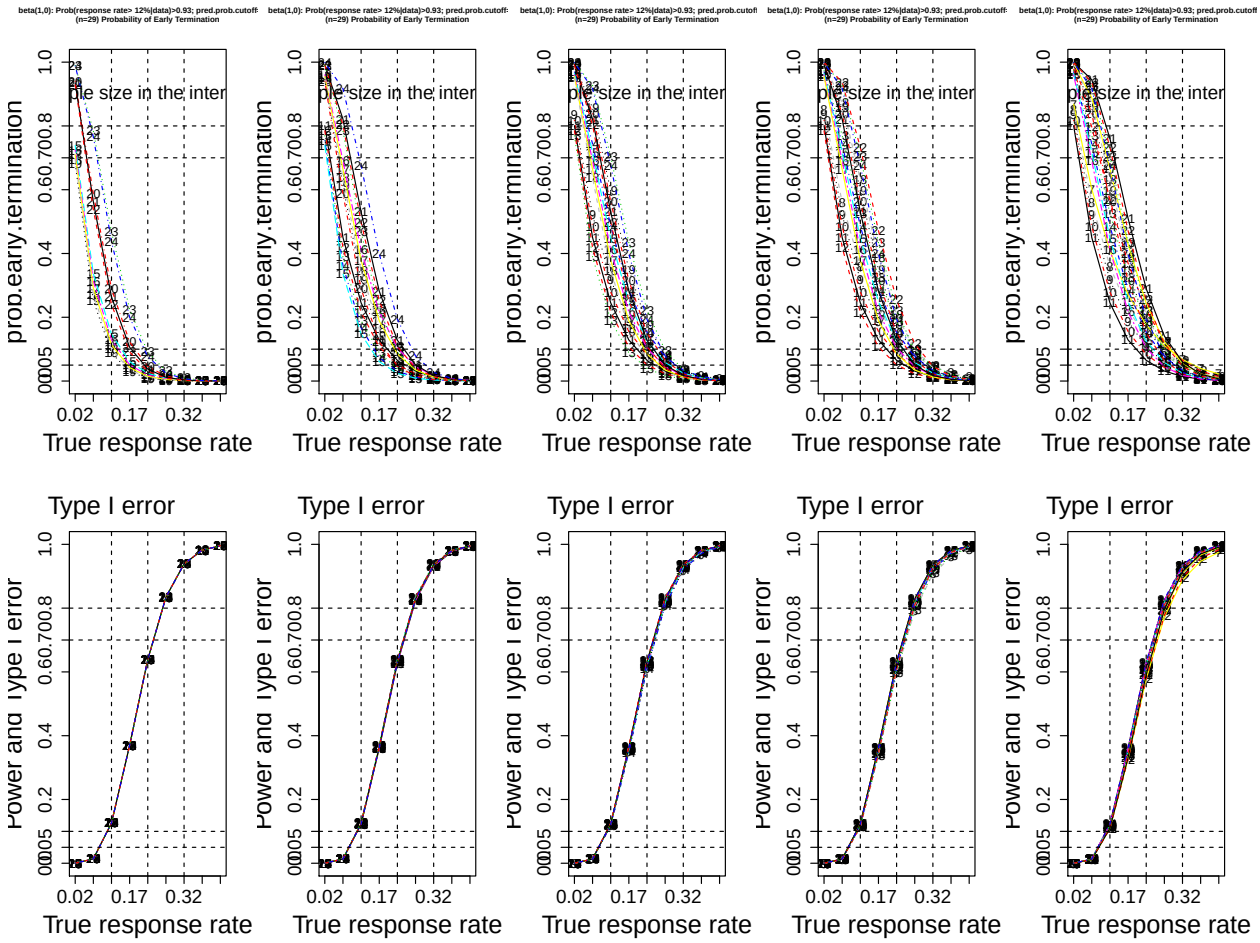
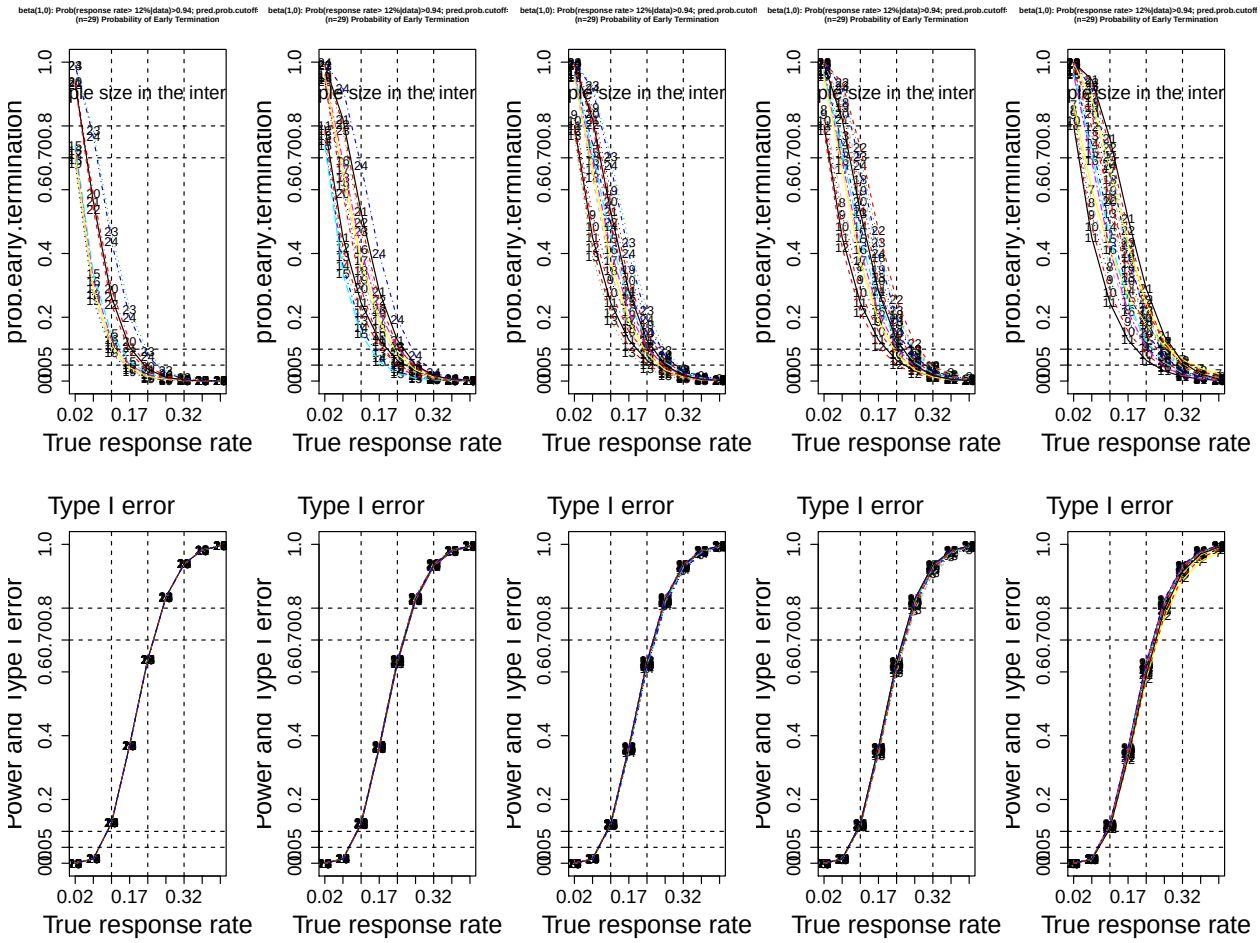
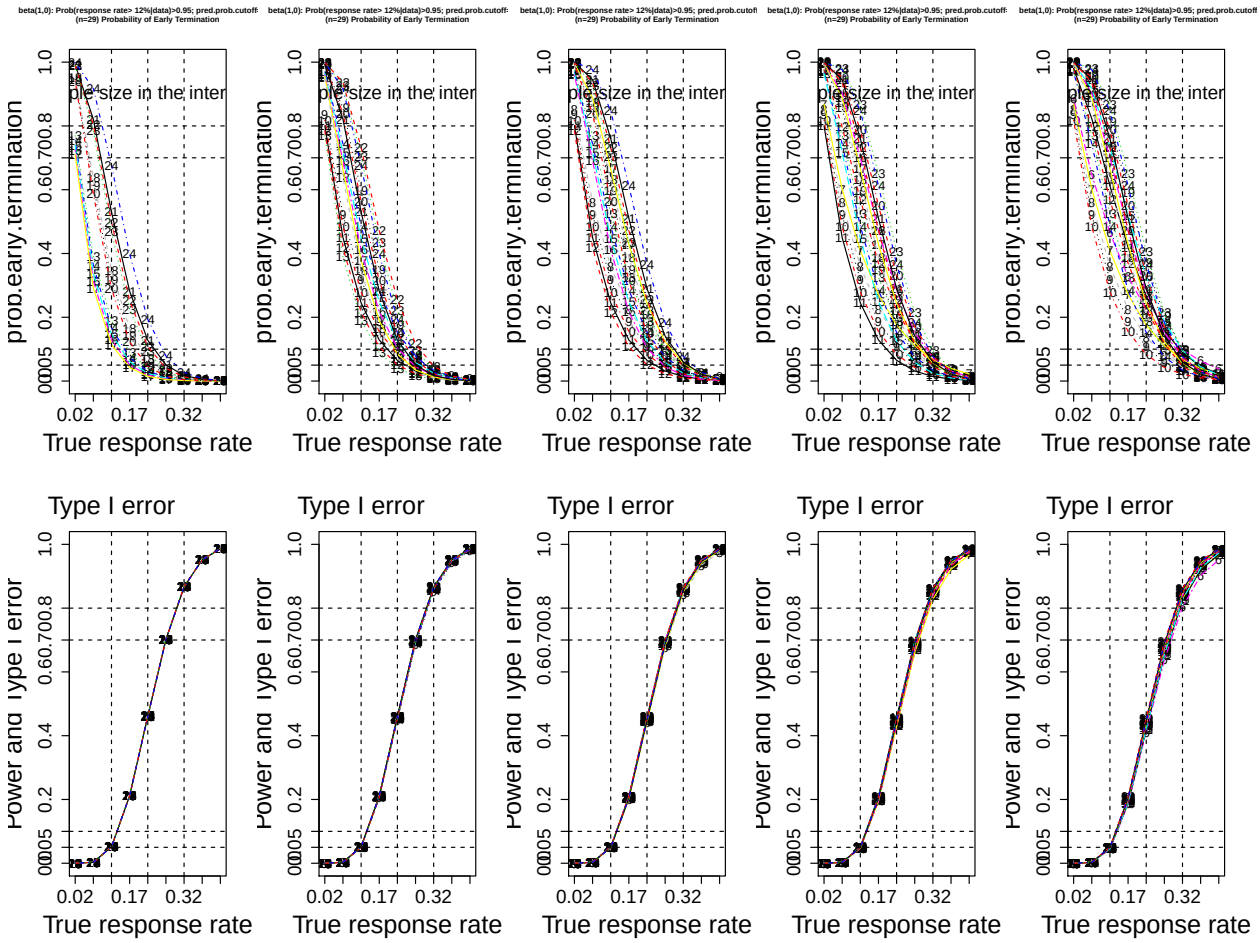
1.0


beta(1,0): Prob(response rate> 12%|data)>0.93; pred.prob.cutoff
(n=29) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
0.32
0.0
0.2
0.4
0.6
0.8
1.0


beta(1,0): Prob(response rate> 12%|data)>0.94; pred.prob.cutoff
(n=29) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
0.32
0.0
0.2
0.4
0.6
0.8
1.0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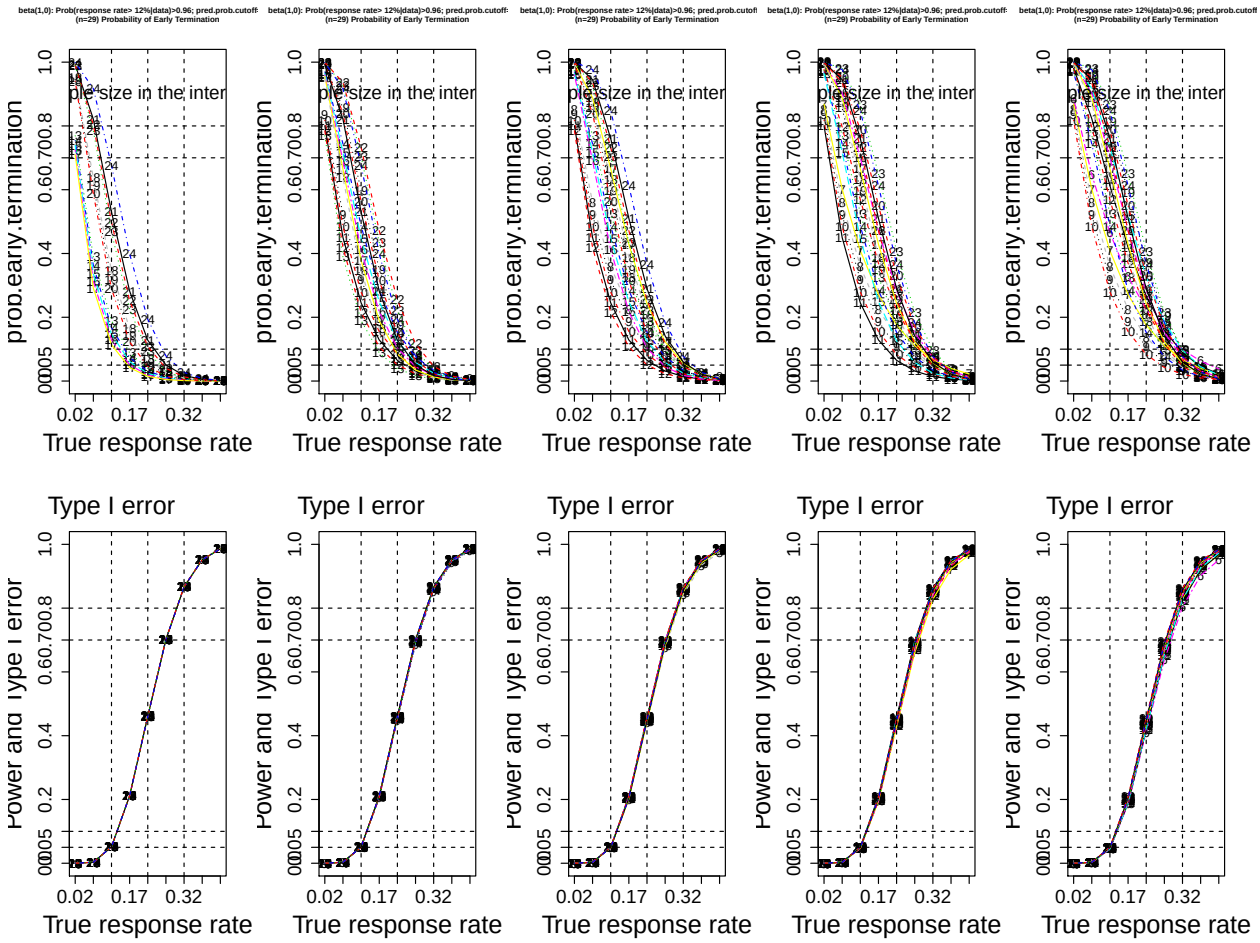
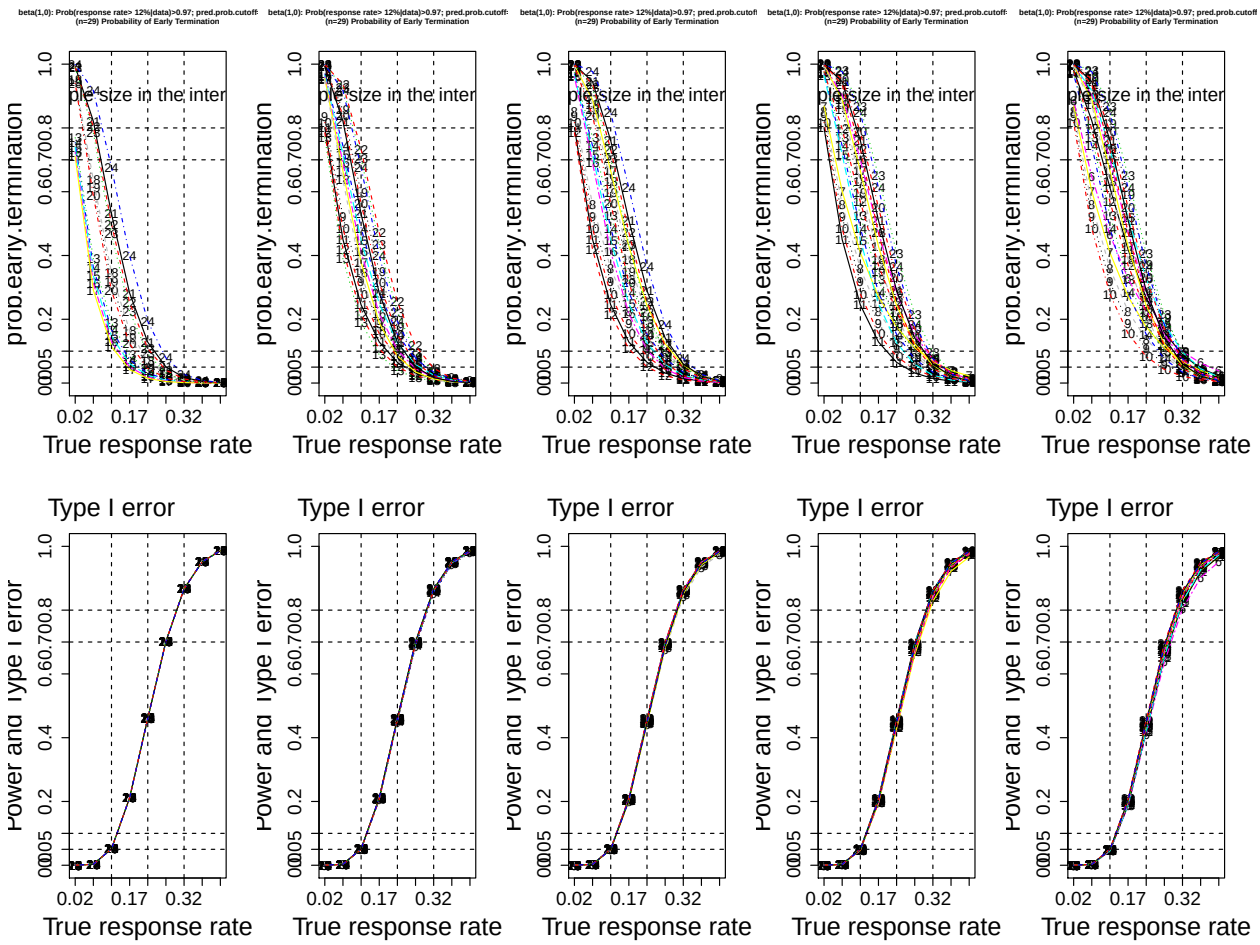
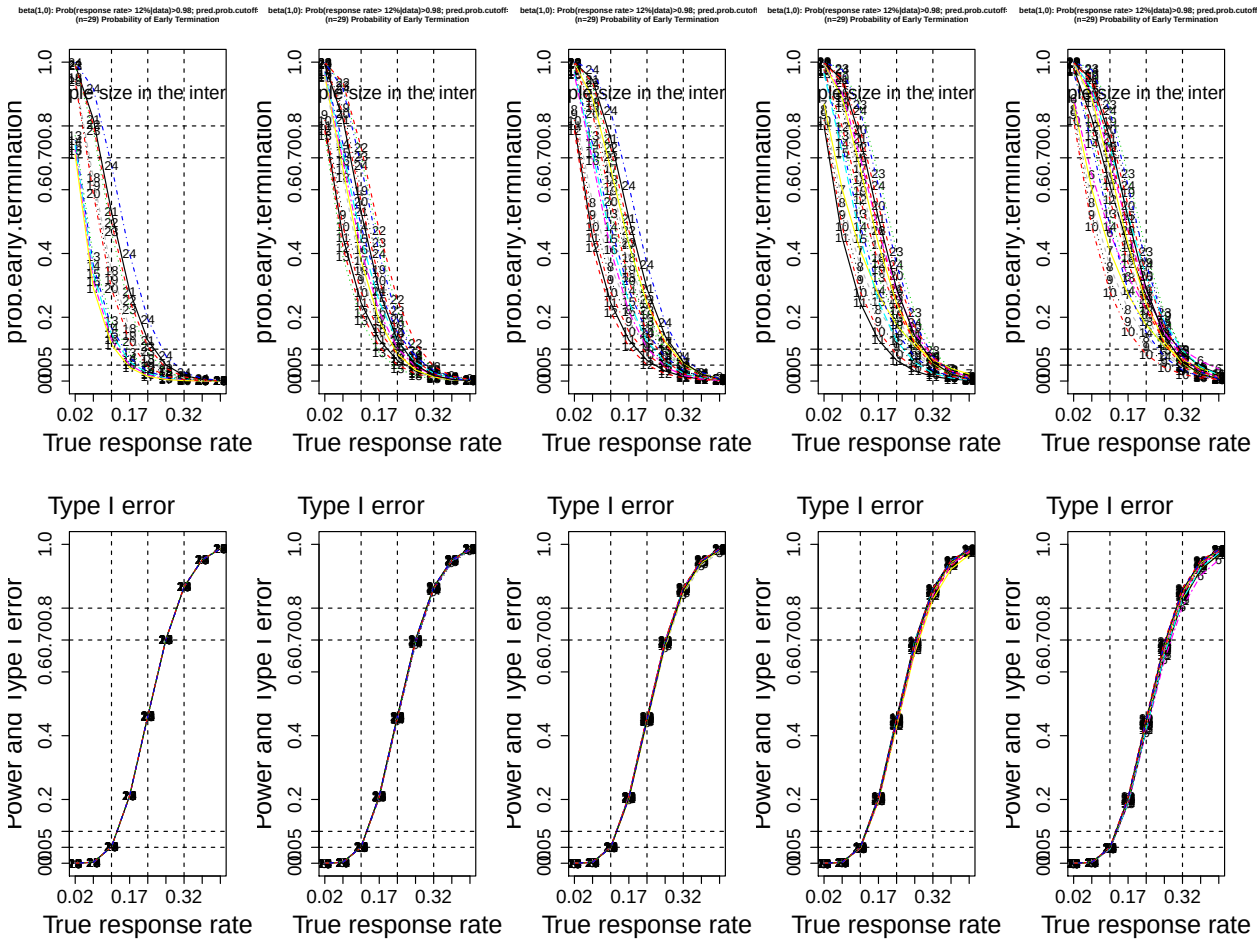
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
0.32


beta(1,0): Prob(response rate> 12%|data)>0.96; pred.prob.cutoff
(n=29) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02 0.17 0.32
0.0 0.2 0.4 0.6 0.7 0.8 1.0


beta(1,0): Prob(response rate> 12%|data)>0.97; pred.prob.cutoff
(n=29) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02 0.17 0.32
0.0 0.2 0.4 0.6 0.7 0.8 1.0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(n=29) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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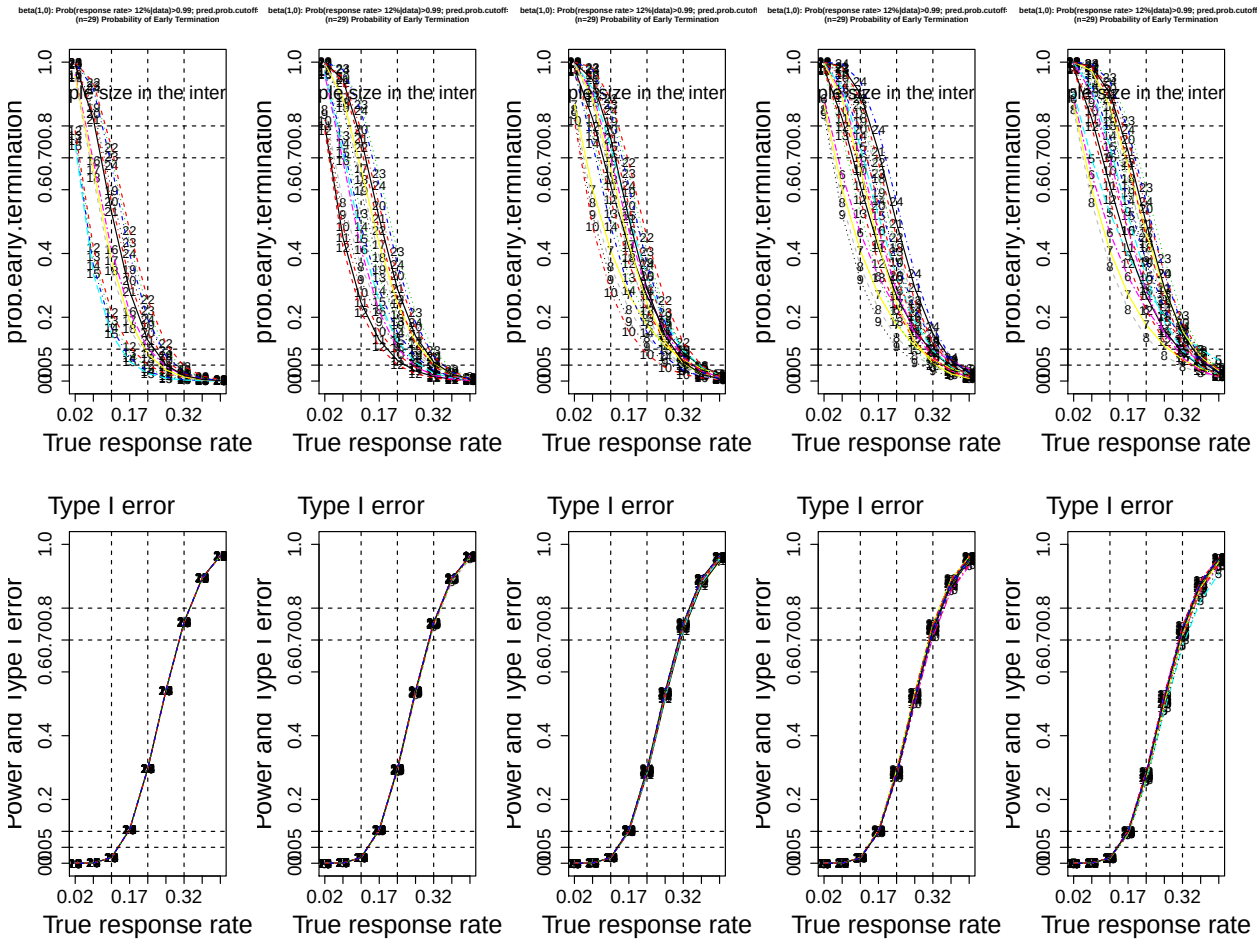
beta(1,0): Prob(response rate> 12%|data)>0.99; pred.prob.cutoff
(n=29) Probability of Early Termination
prob.early.termination
Power and Type I error
True response rate
Type I error
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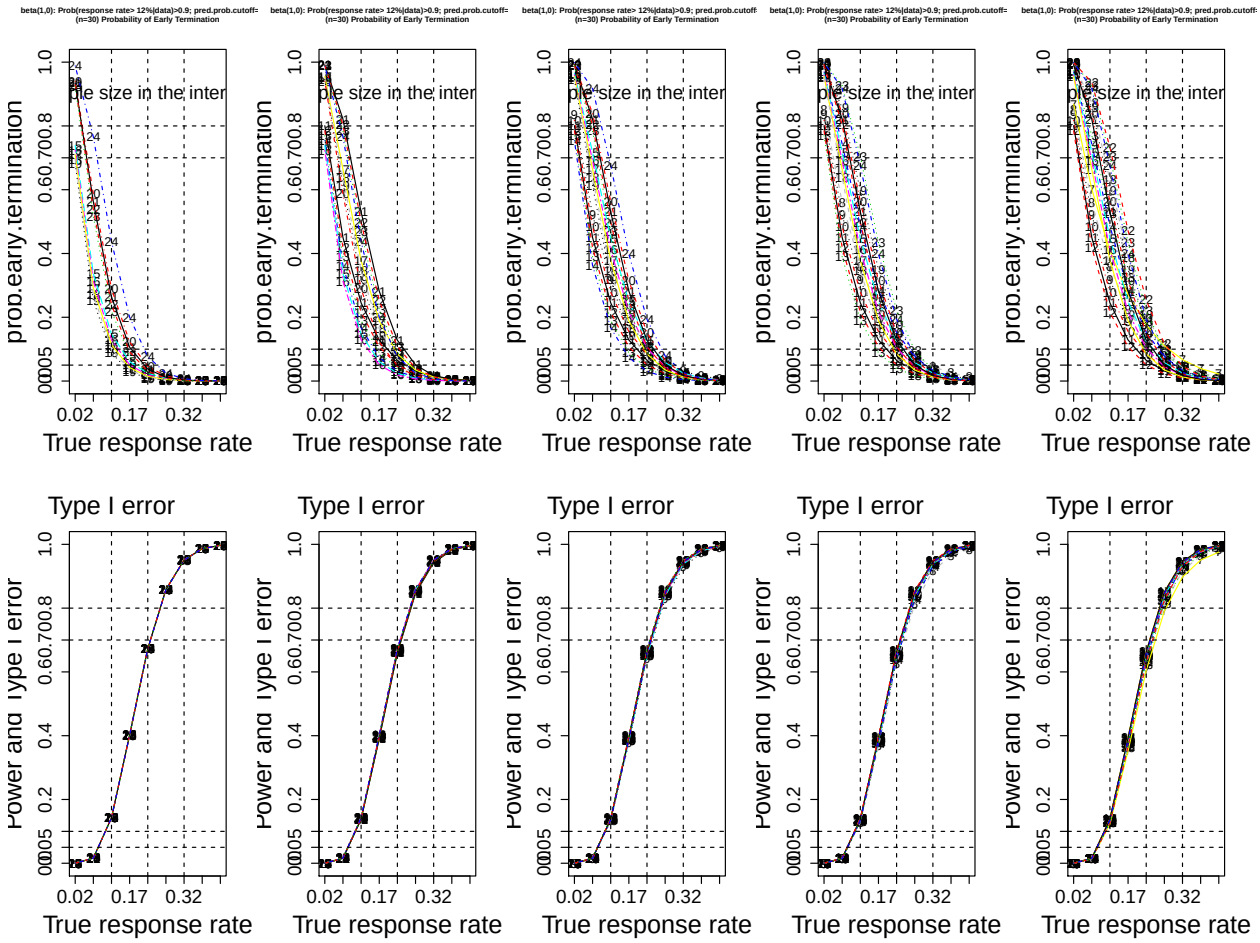
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(n=30) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
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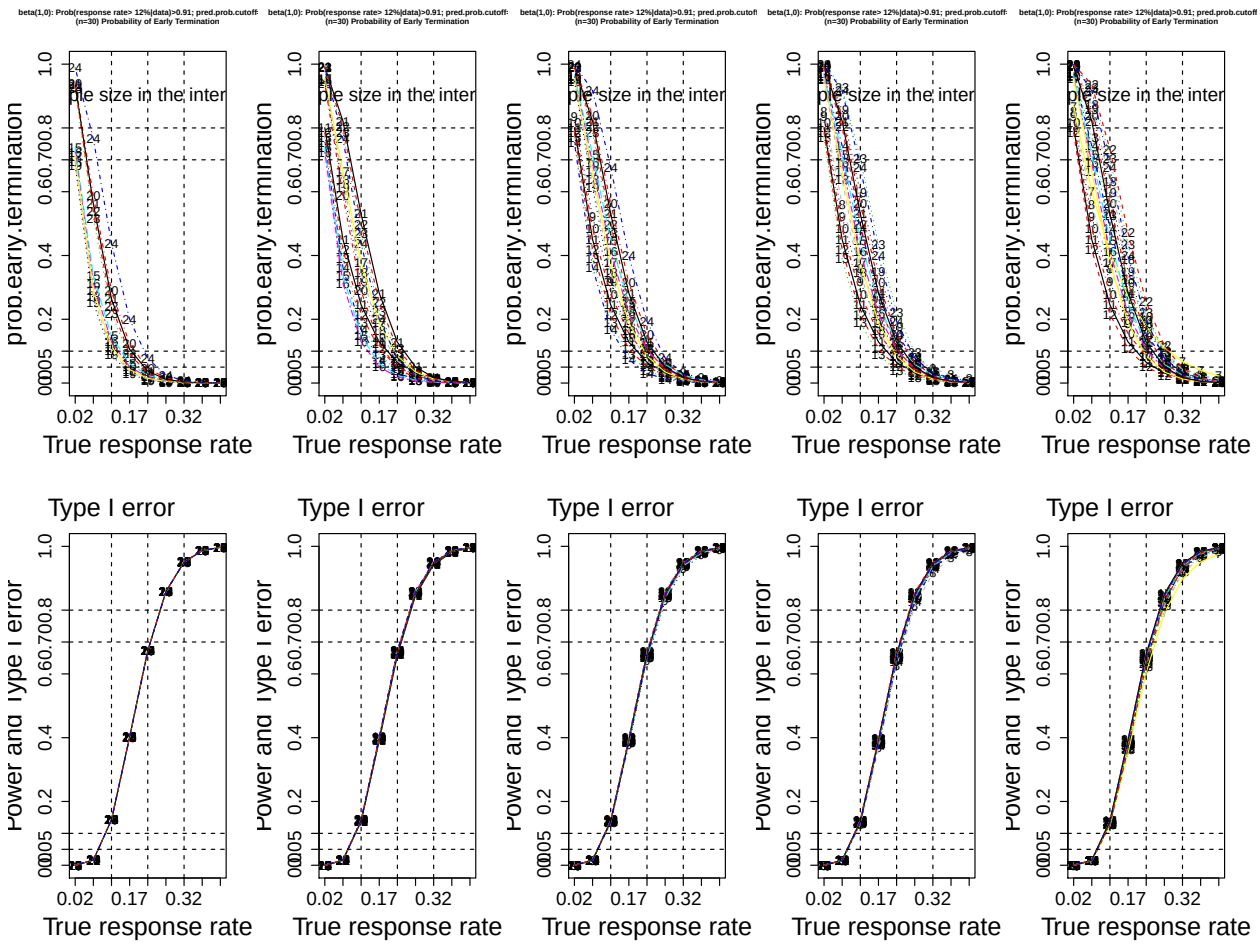
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(n=30) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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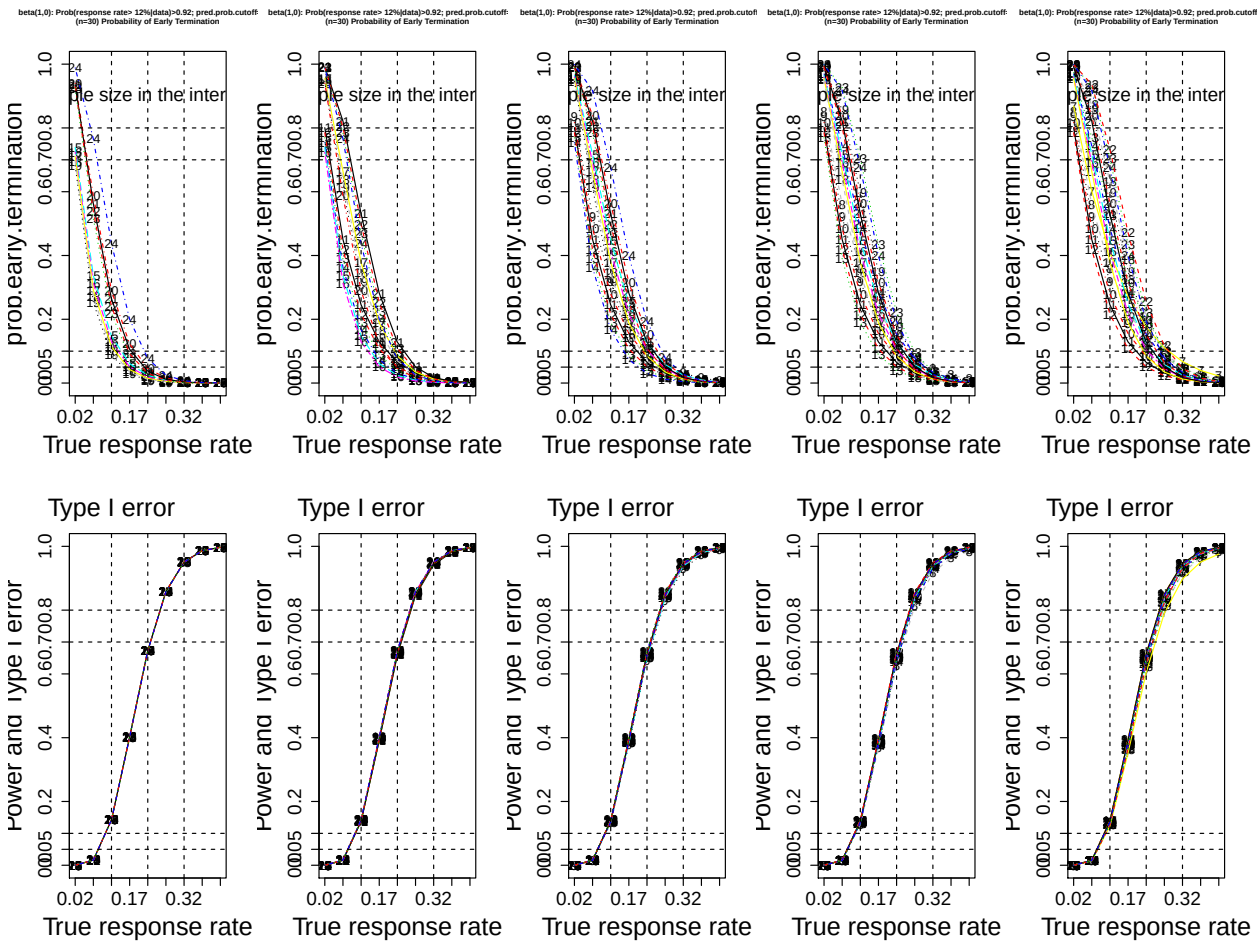
beta(1,0): Prob(response rate> 12%|data)>0.92; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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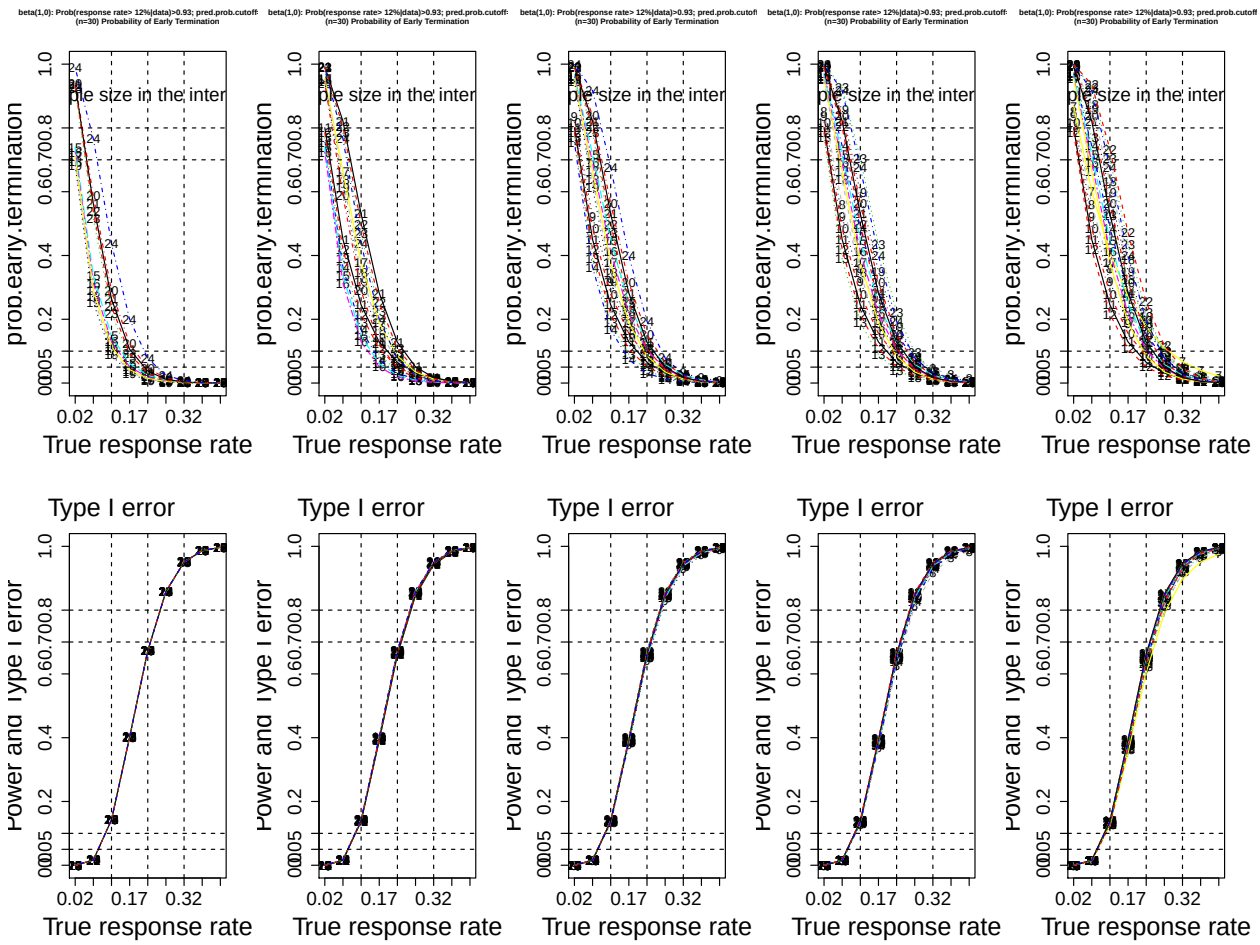
beta(1,0): Prob(response rate> 12%|data)>0.93; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
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Power and Type I error
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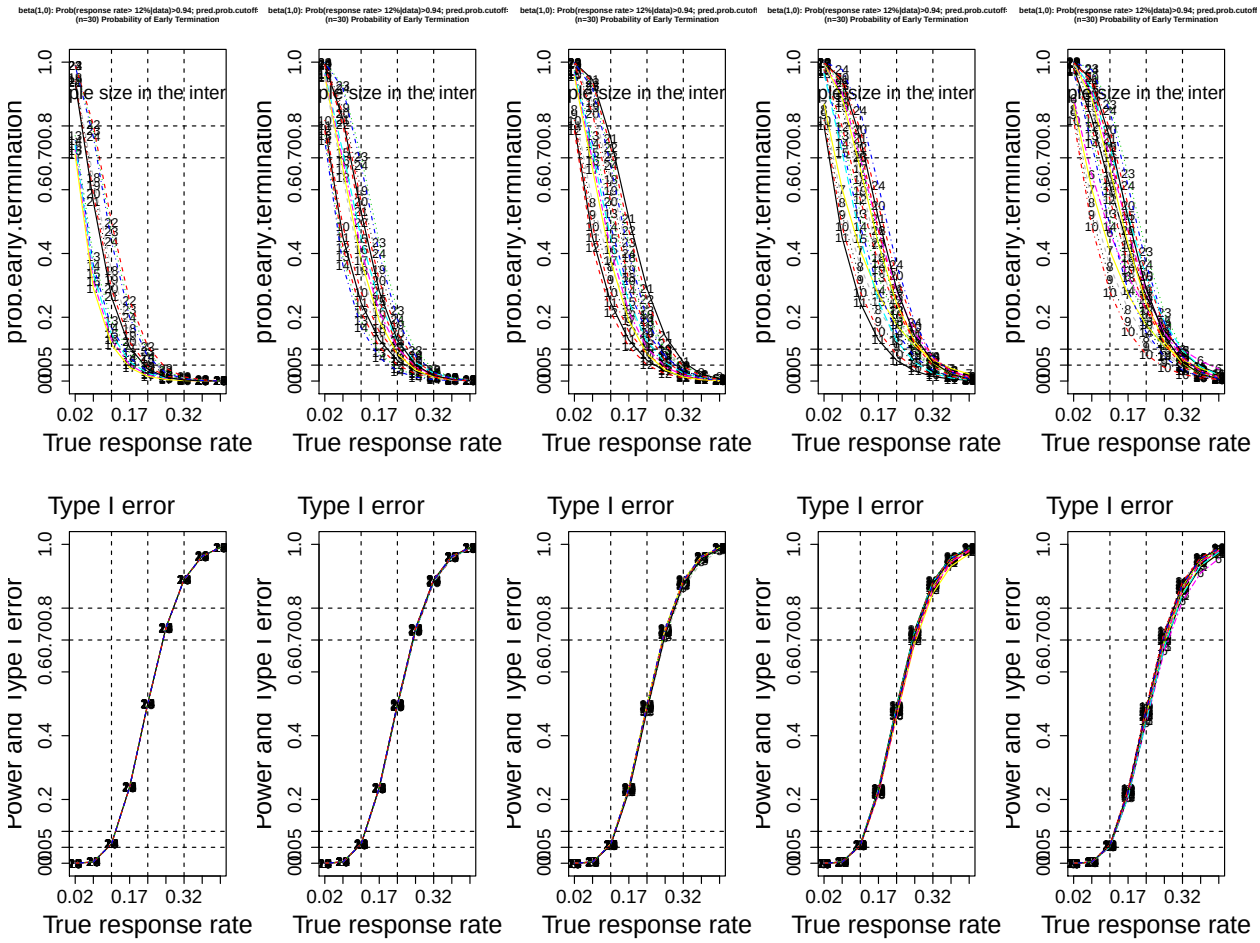
beta(1,0): Prob(response rate> 12%|data)>0.94; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
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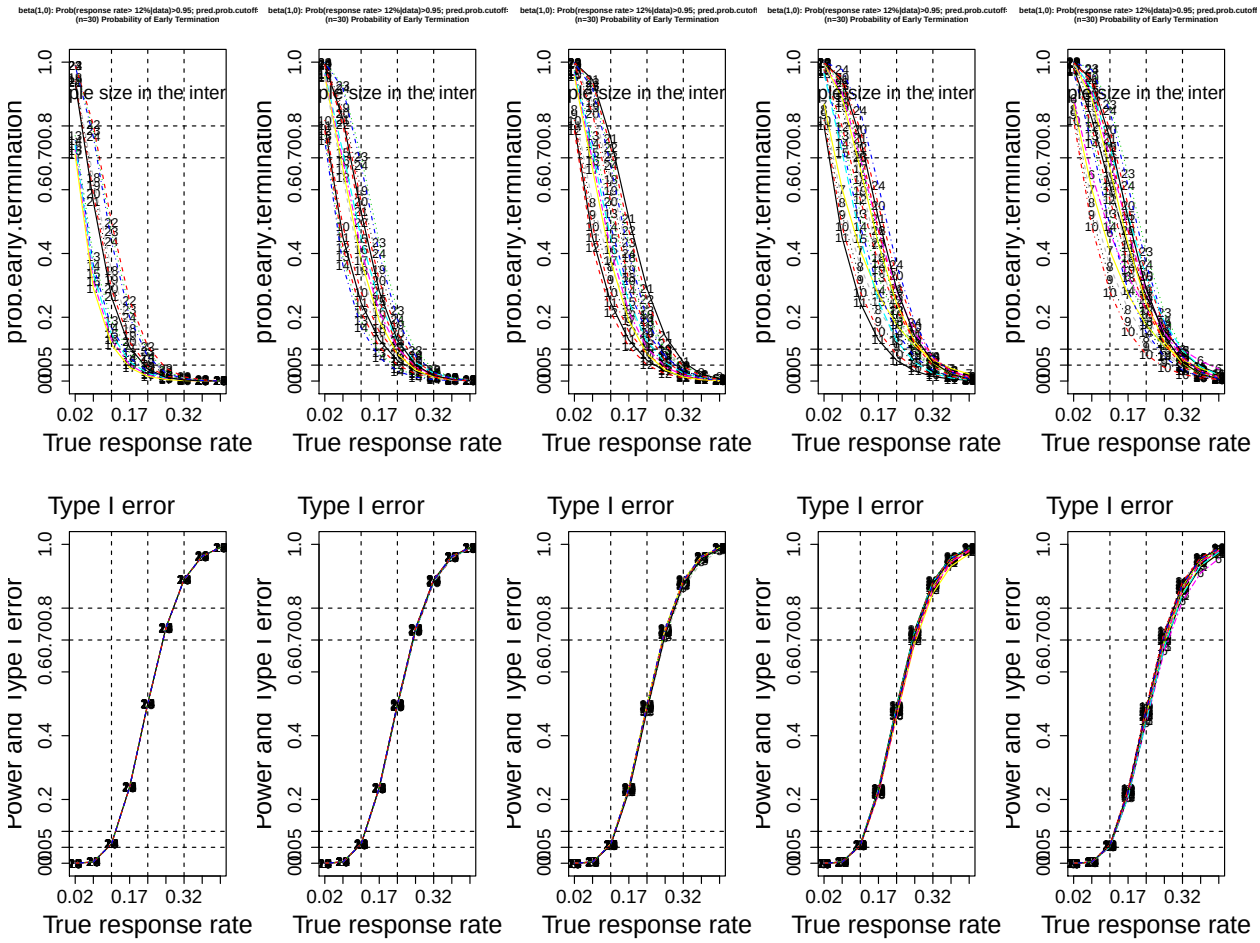
beta(1,0): Prob(response rate> 12%|data)>0.95; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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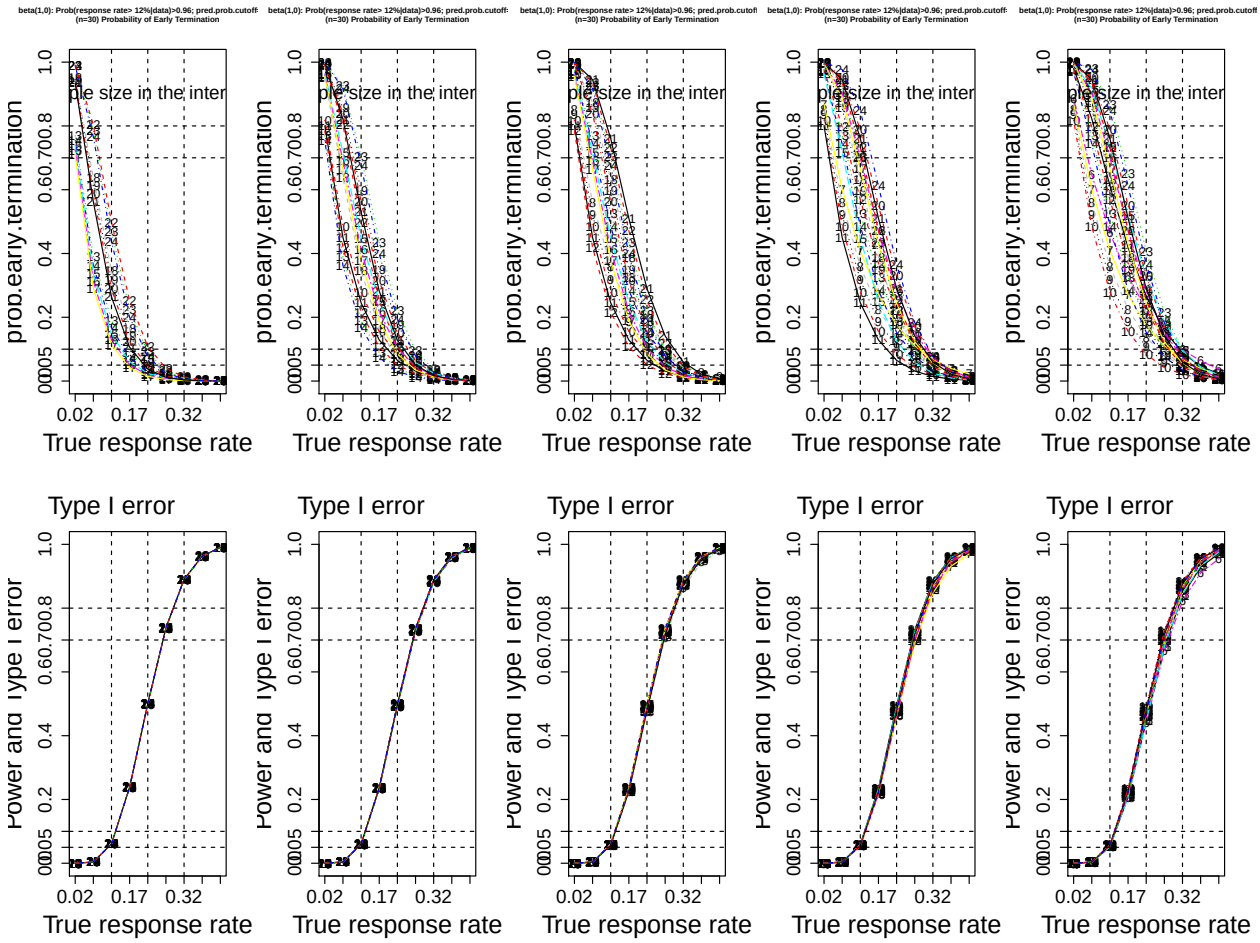
beta(1,0): Prob(response rate> 12%|data)>0.96; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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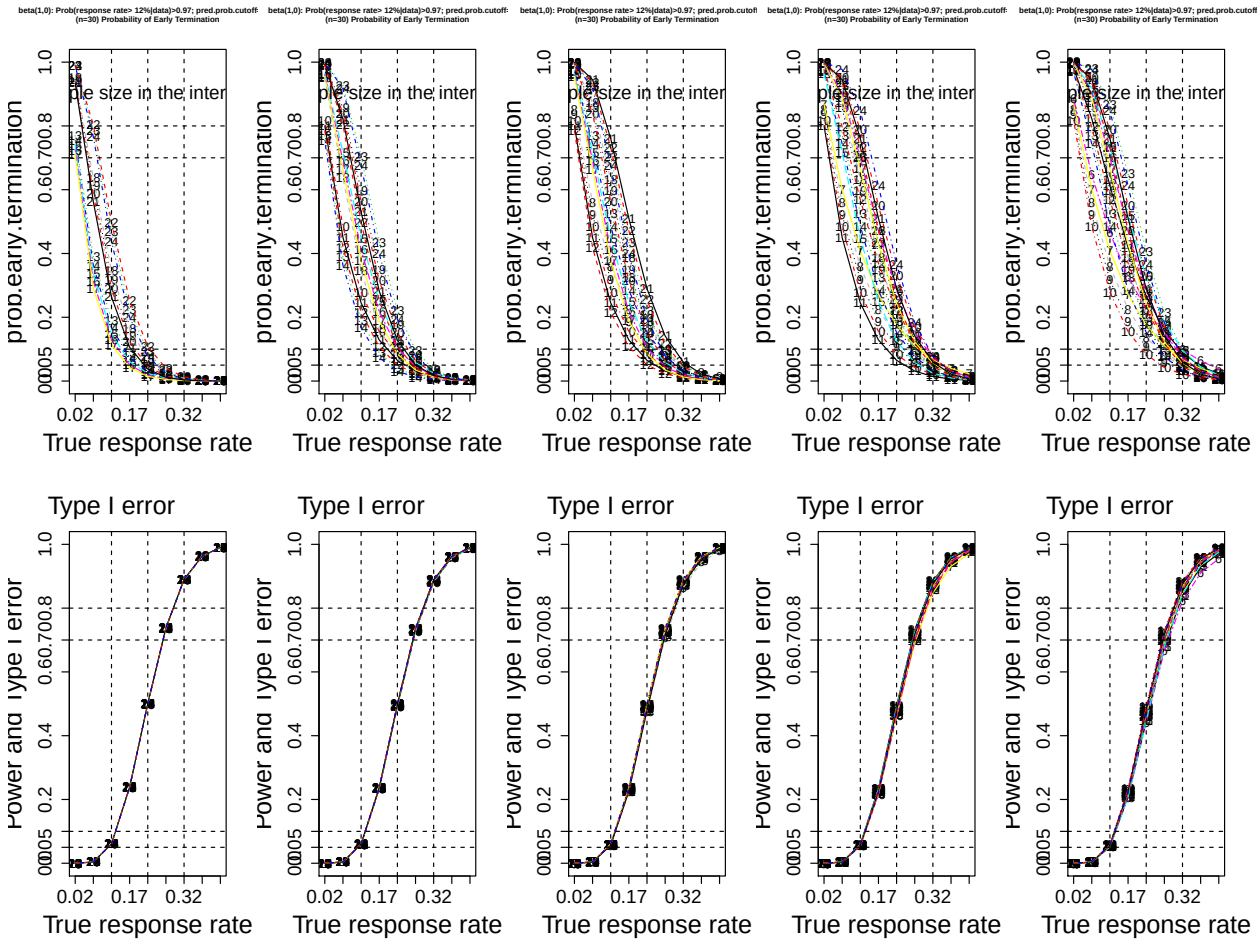
beta(1,0): Prob(response rate> 12%|data)>0.97; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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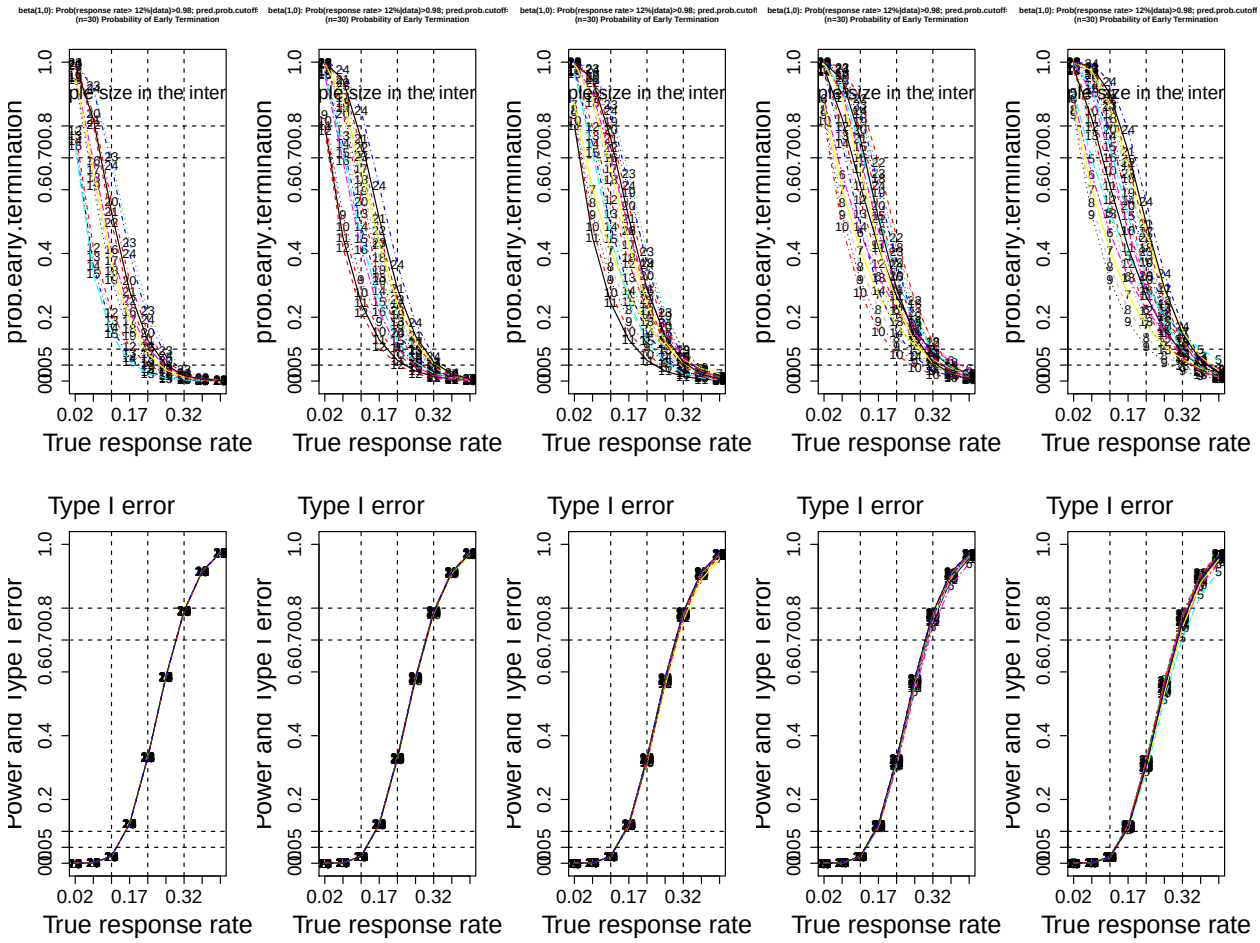
0.0 0.2 0.4 0.6 0.7 0.8 1.0


beta(1,0): Prob(response rate> 12%|data)>0.98; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
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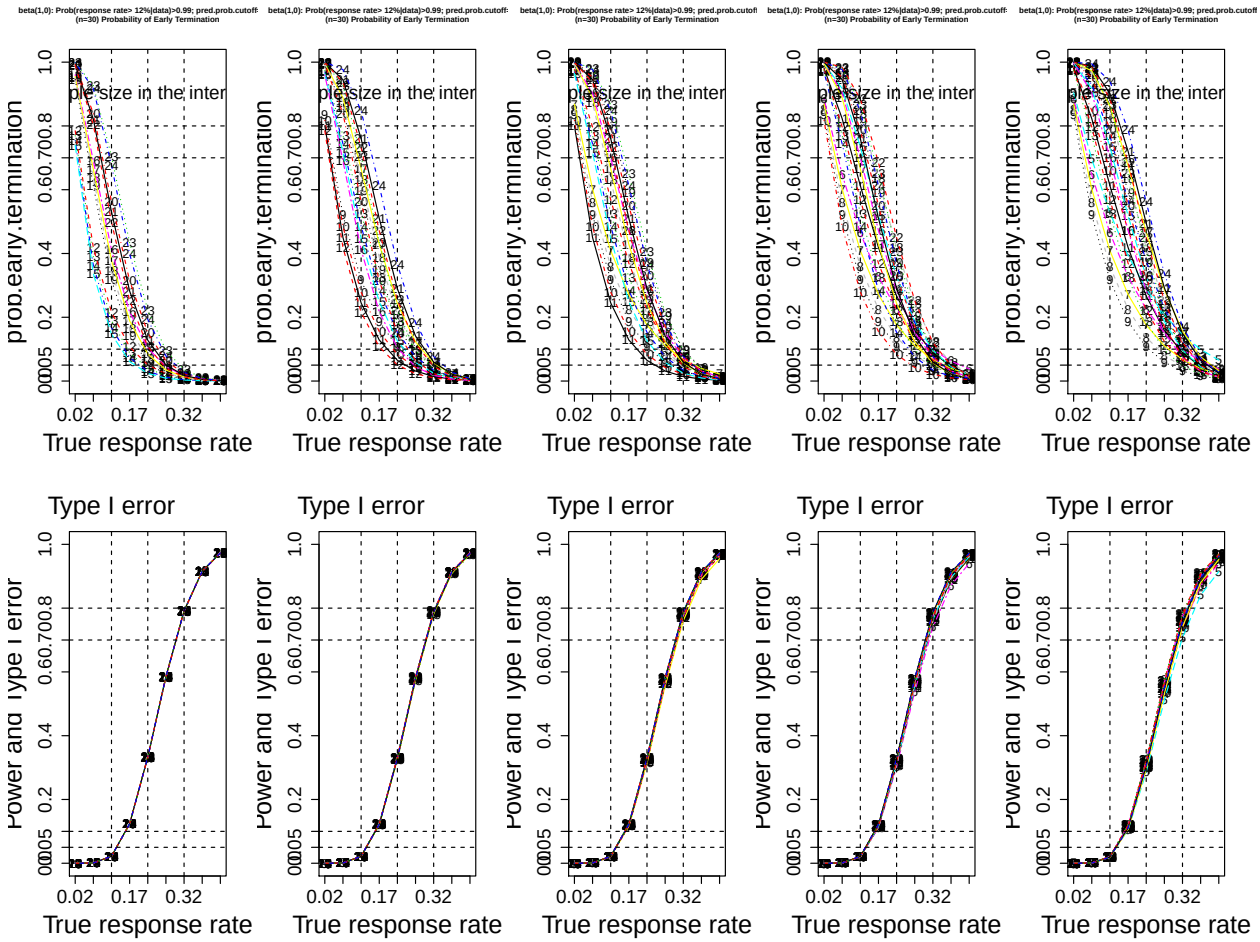
beta(1,0): Prob(response rate> 12%|data)>0.99; pred.prob.cutoff
(n=30) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
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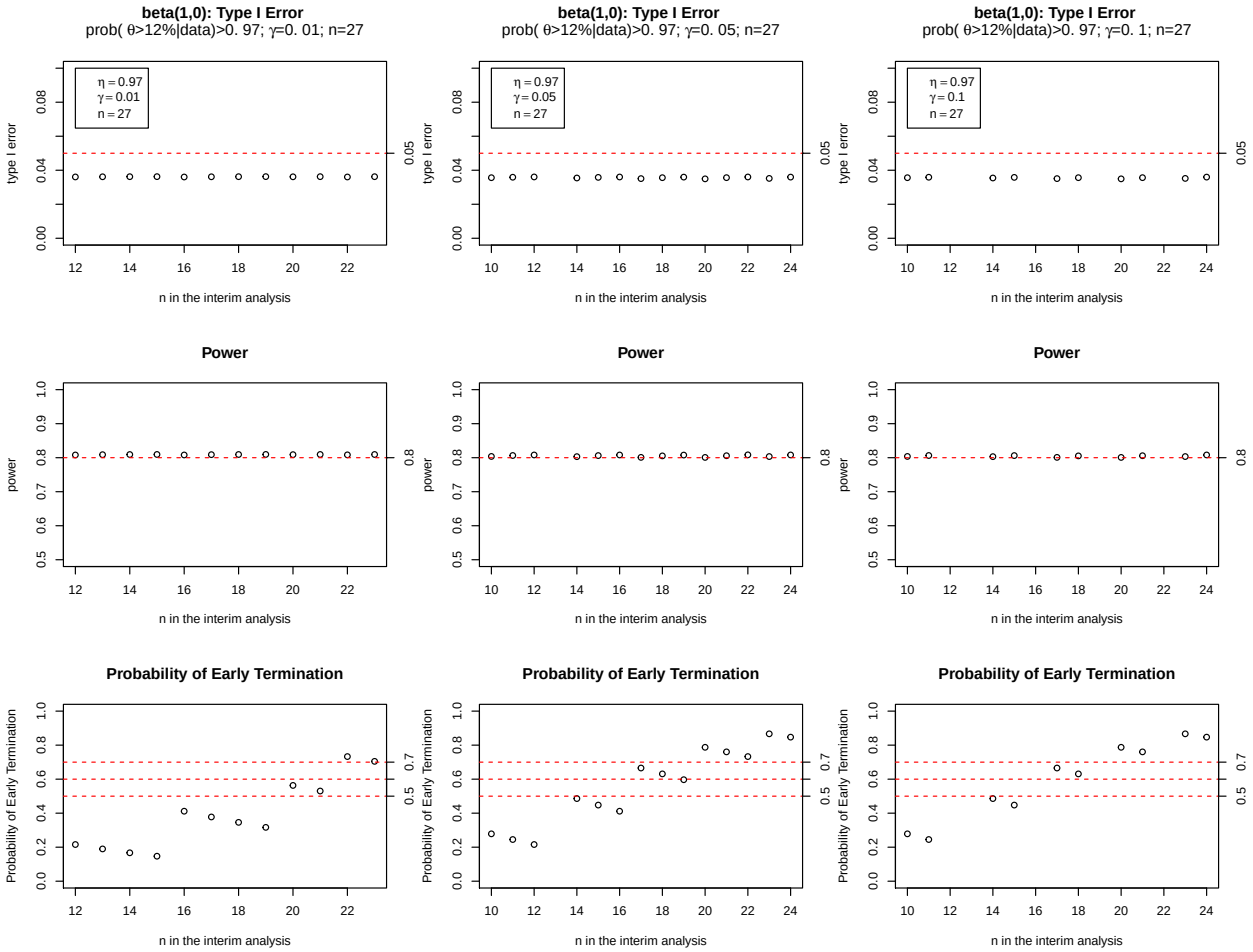
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 01; n=27
η = 0.97
γ = 0.01
n = 27
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 05; n=27
η = 0.97
γ = 0.05
n = 27
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 1; n=27
η = 0.97
γ = 0.1
n = 27
type I error
n in the interim analysis
Power
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n in the interim analysis
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n in the interim analysis
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n in the interim analysis
Probability of Early Termination
Probability of Early Termination
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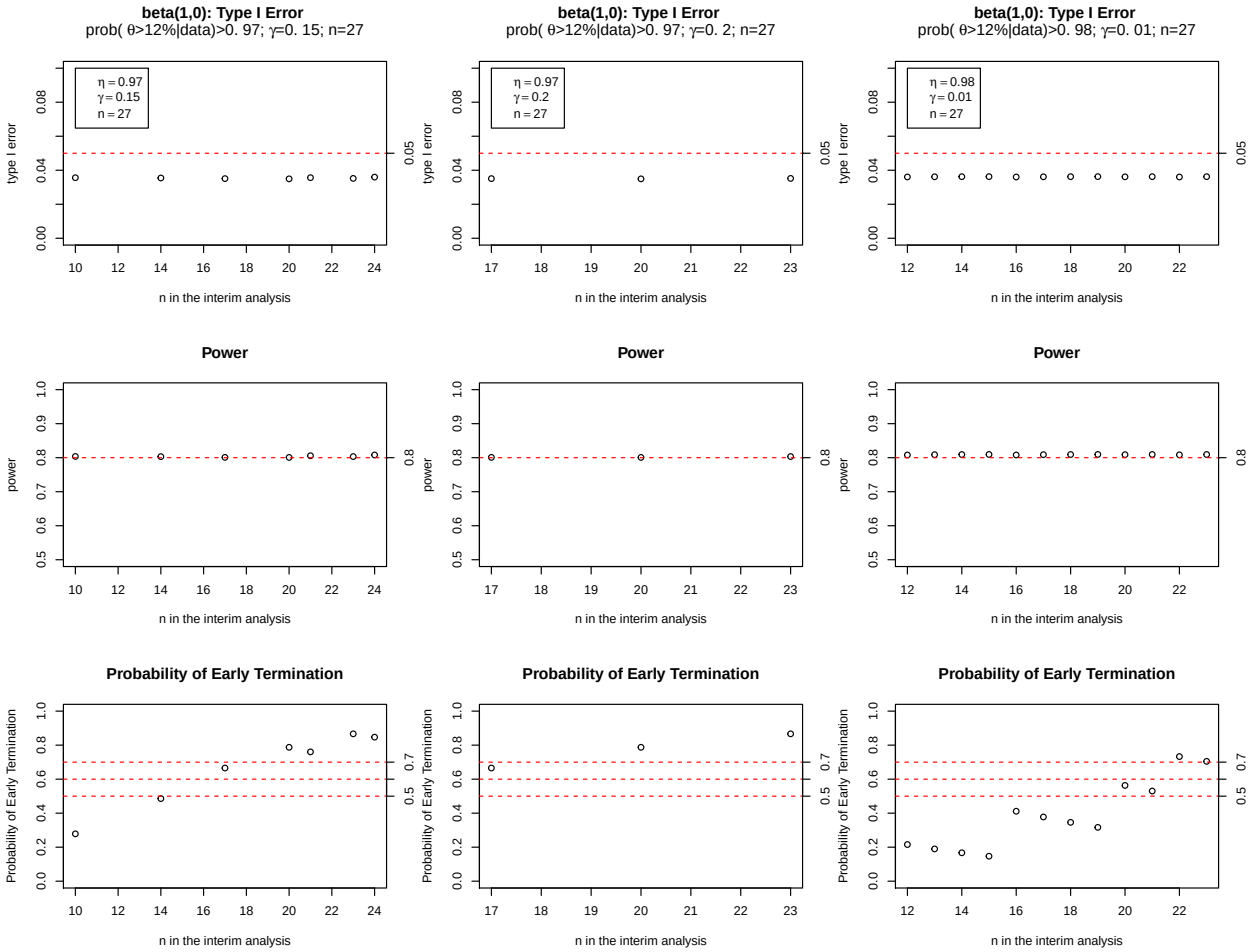
Probability of Early Termination
Probability of Early Termination
n in the interim analysis


beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 15; n=27
η = 0.97
γ = 0.15
n = 27
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 2; n=27
η = 0.97
γ = 0.2
n = 27
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 01; n=27
η = 0.98
γ = 0.01
n = 27
type I error
n in the interim analysis
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n in the interim analysis
Probability of Early Termination
Probability of Early Termination
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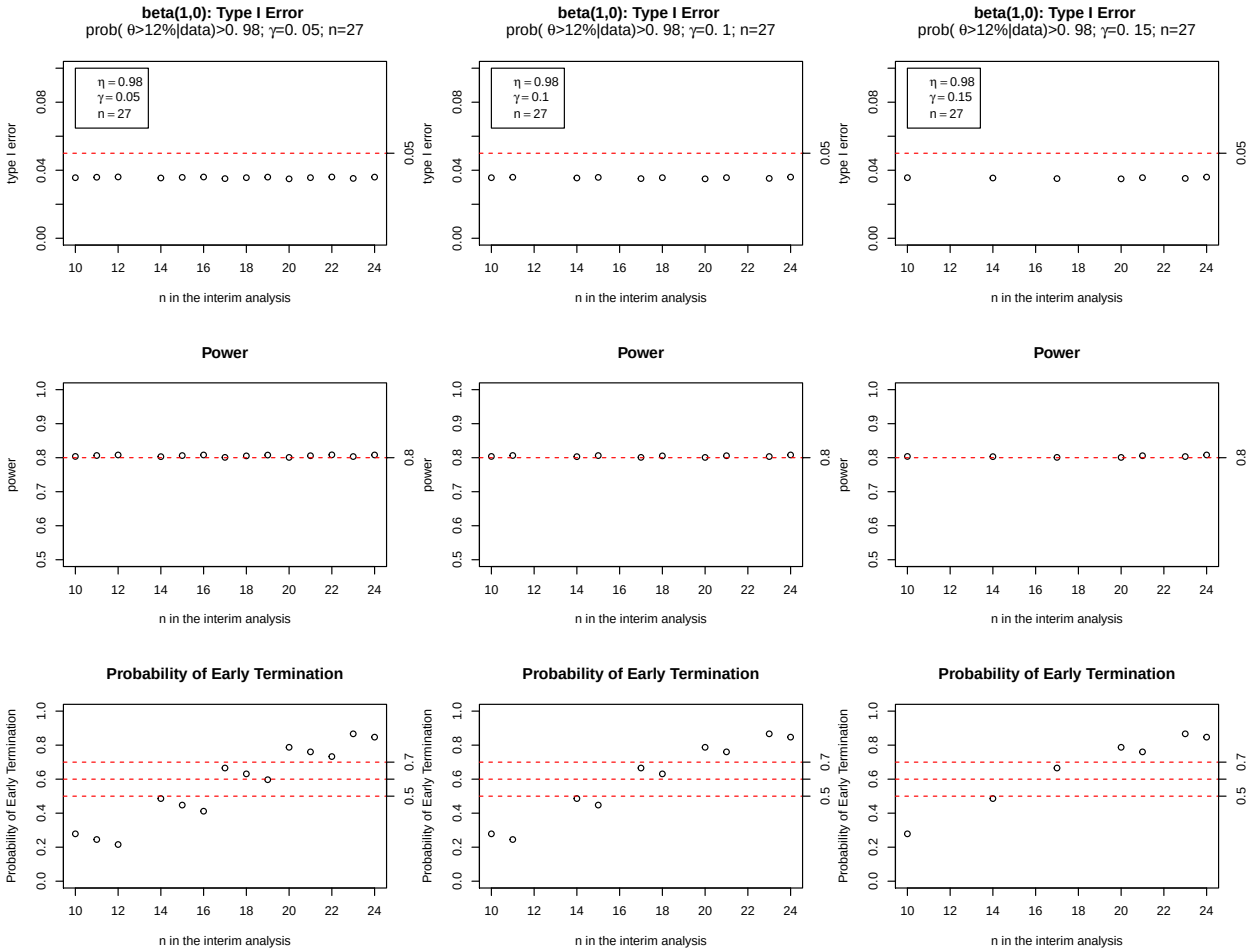
Probability of Early Termination
Probability of Early Termination
n in the interim analysis


beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 05; n=27
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γ = 0.05
n = 27
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 1; n=27
η = 0.98
γ = 0.1
n = 27
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 15; n=27
η = 0.98
γ = 0.15
n = 27
type I error
n in the interim analysis
Power
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n in the interim analysis
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n in the interim analysis
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n in the interim analysis
Probability of Early Termination
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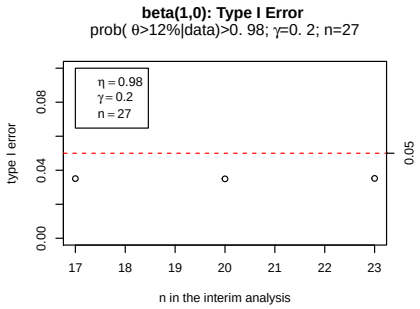
Probability of Early Termination
n in the interim analysis


beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 2; n=27
η = 0.98
γ = 0.2
n = 27
type I error
0.00
0.04
0.08
0.05
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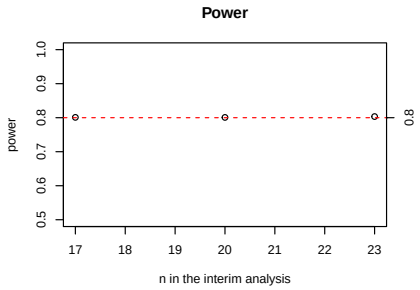
n in the interim analysis


Power
power
0.5
0.6
0.7
0.8
0.9
1.0
0.8
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18
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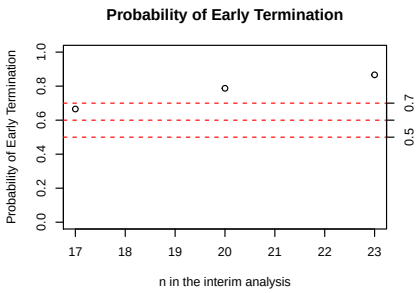
23
n in the interim analysis


Probability of Early Termination
Probability of Early Termination
0.0
0.2
0.4
0.6
0.8
1.0
0.7
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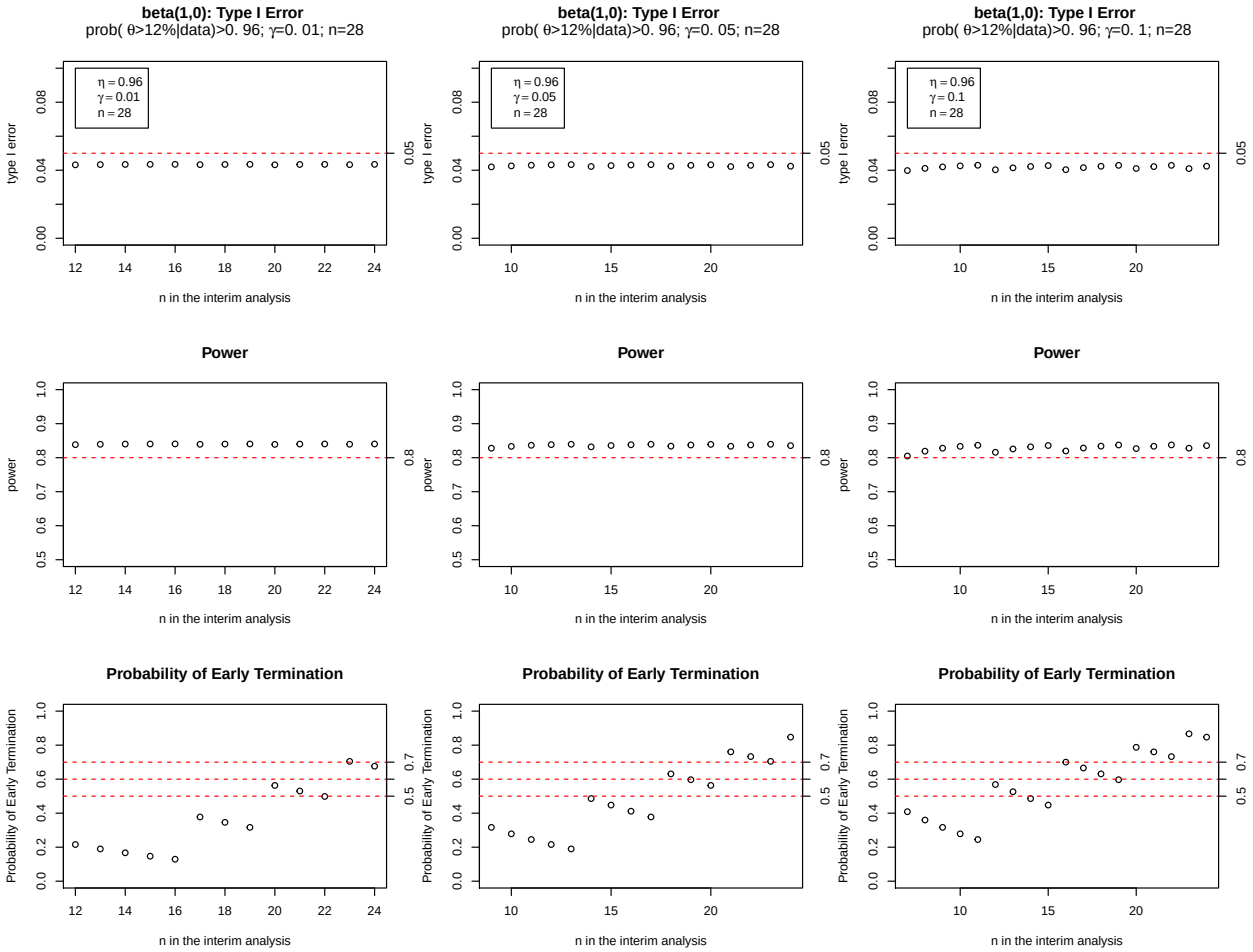
n in the interim analysis


beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 01; n=28
η = 0.96
γ = 0.01
n = 28
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 05; n=28
η = 0.96
γ = 0.05
n = 28
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 1; n=28
η = 0.96
γ = 0.1
n = 28
type I error
n in the interim analysis
Power
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n in the interim analysis
Probability of Early Termination
Probability of Early Termination
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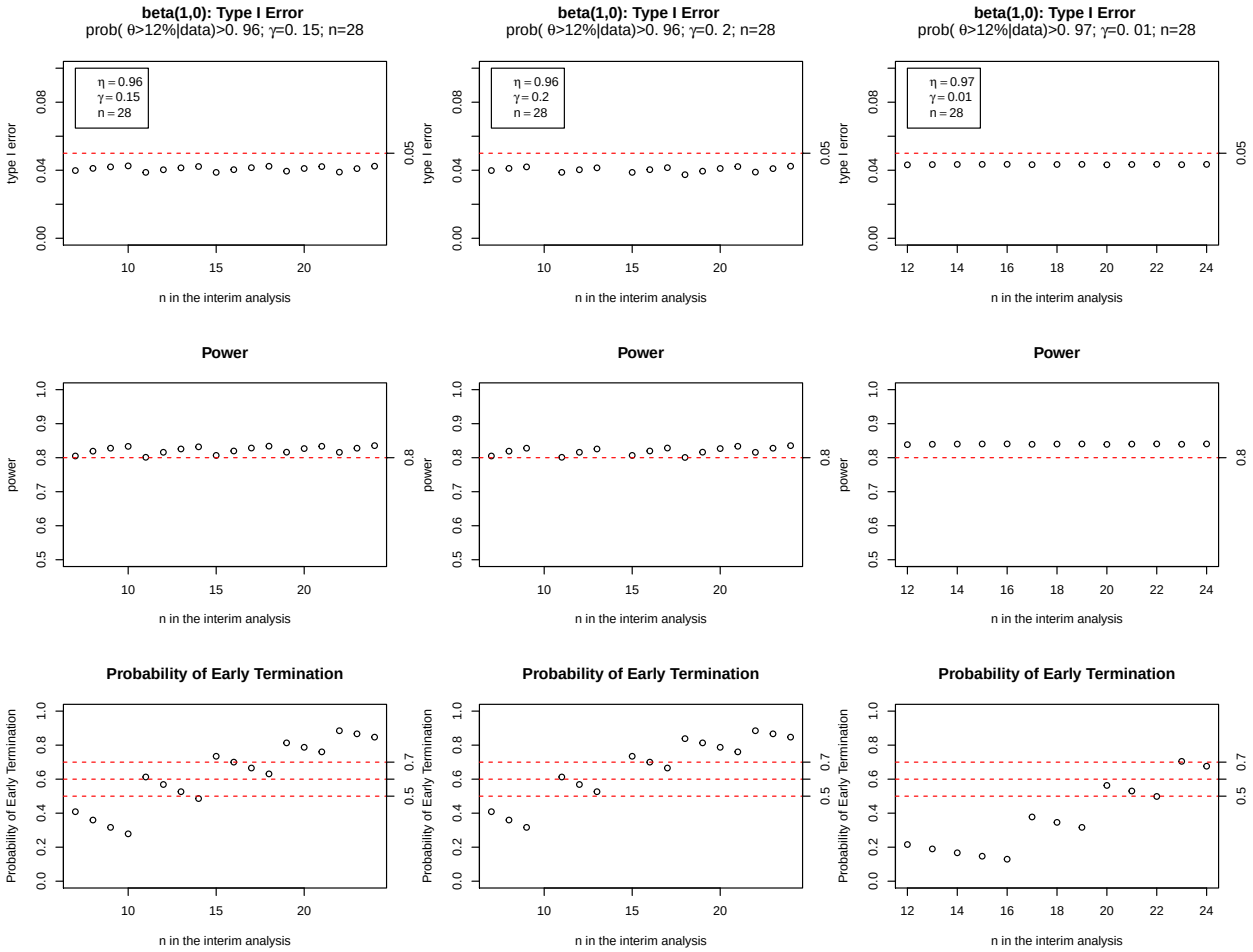
Probability of Early Termination
Probability of Early Termination
n in the interim analysis


beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 15; n=28
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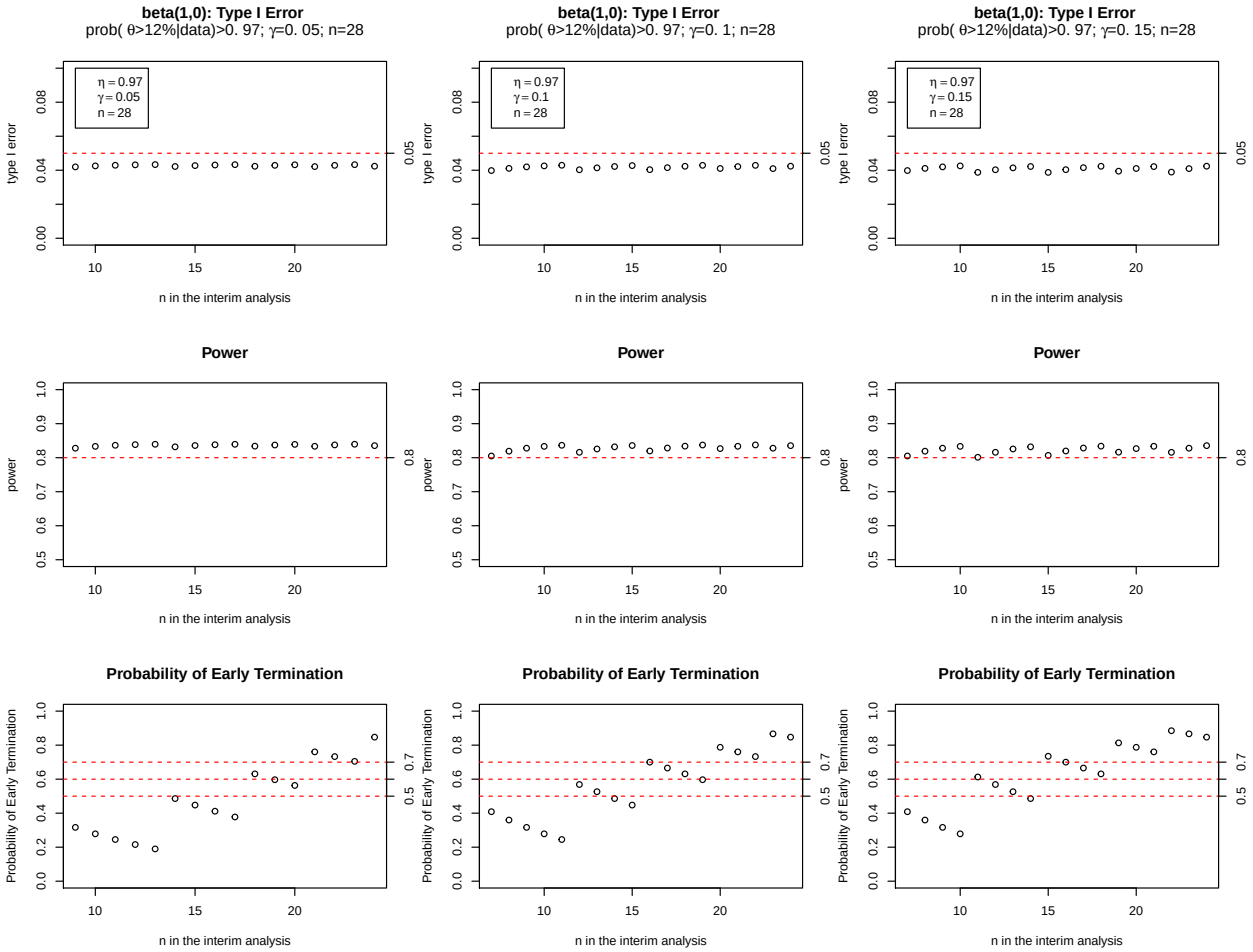
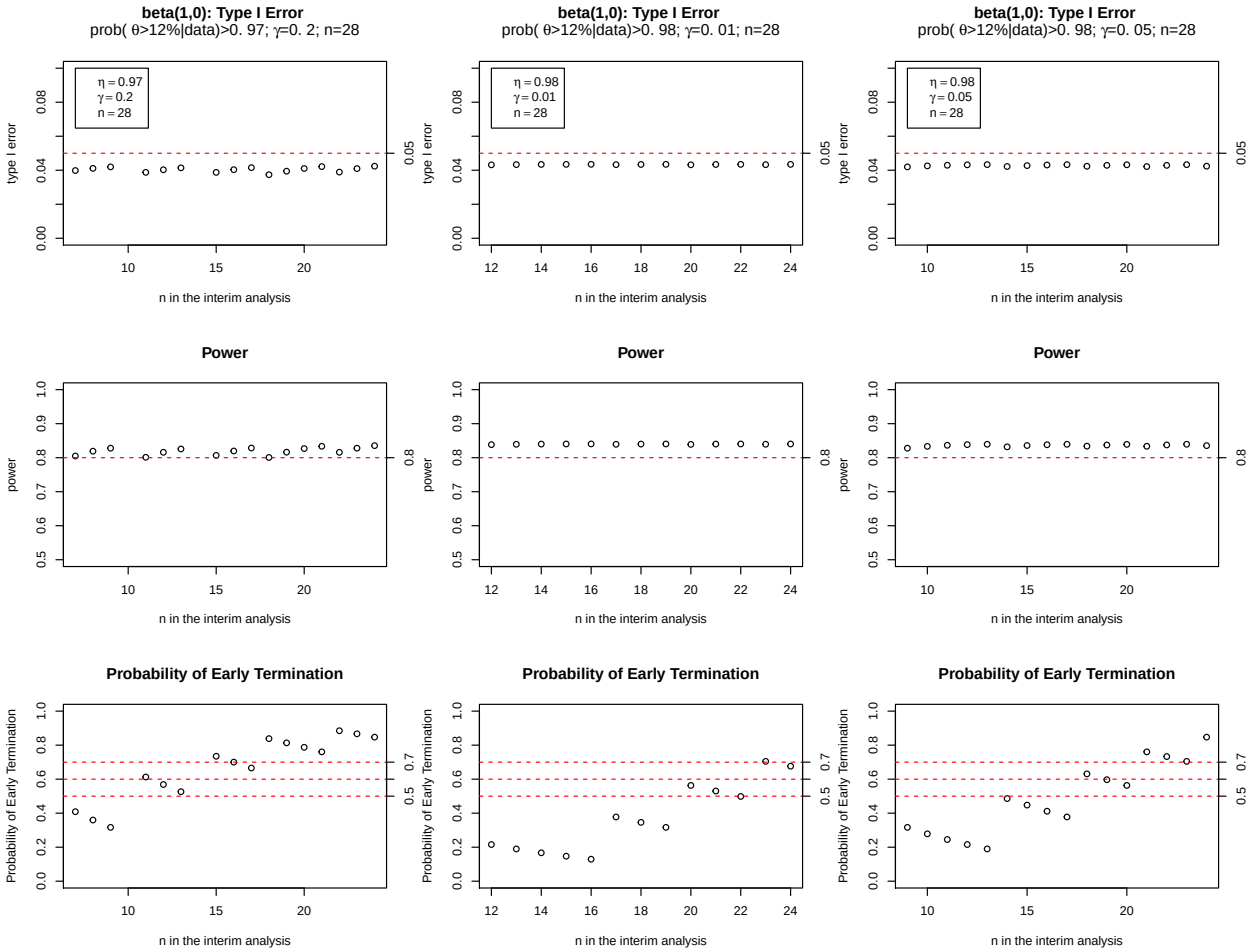
γ = 0.15
n = 28
beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 2; n=28
η = 0.96
γ = 0.2
n = 28
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 01; n=28
η = 0.97
γ = 0.01
n = 28
type I error
n in the interim analysis
Power
power
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis


beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 05; n=28
η = 0.97
γ = 0.05
n = 28
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 1; n=28
η = 0.97
γ = 0.1
n = 28
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 15; n=28
η = 0.97
γ = 0.15
n = 28
type I error
Power
power
Probability of Early Termination
n in the interim analysis


beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 2; n=28
η = 0.97
γ = 0.2
n = 28
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 01; n=28
η = 0.98
γ = 0.01
n = 28
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 05; n=28
η = 0.98
γ = 0.05
n = 28
type I error
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Probability of Early Termination
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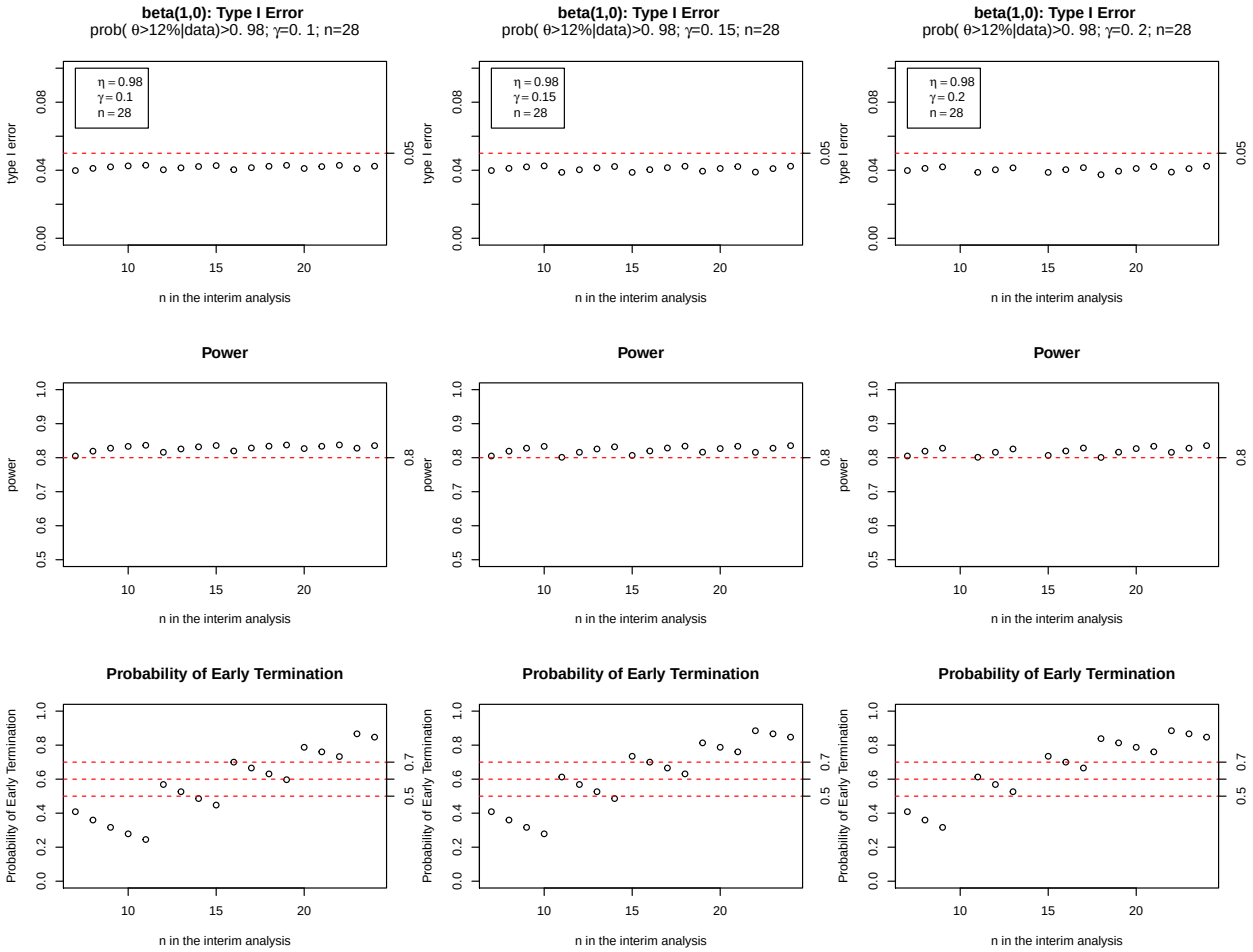
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 1; n=28
η = 0.98
γ = 0.1
n = 28
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 15; n=28
η = 0.98
γ = 0.15
n = 28
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 2; n=28
η = 0.98
γ = 0.2
n = 28
type I error
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Probability of Early Termination
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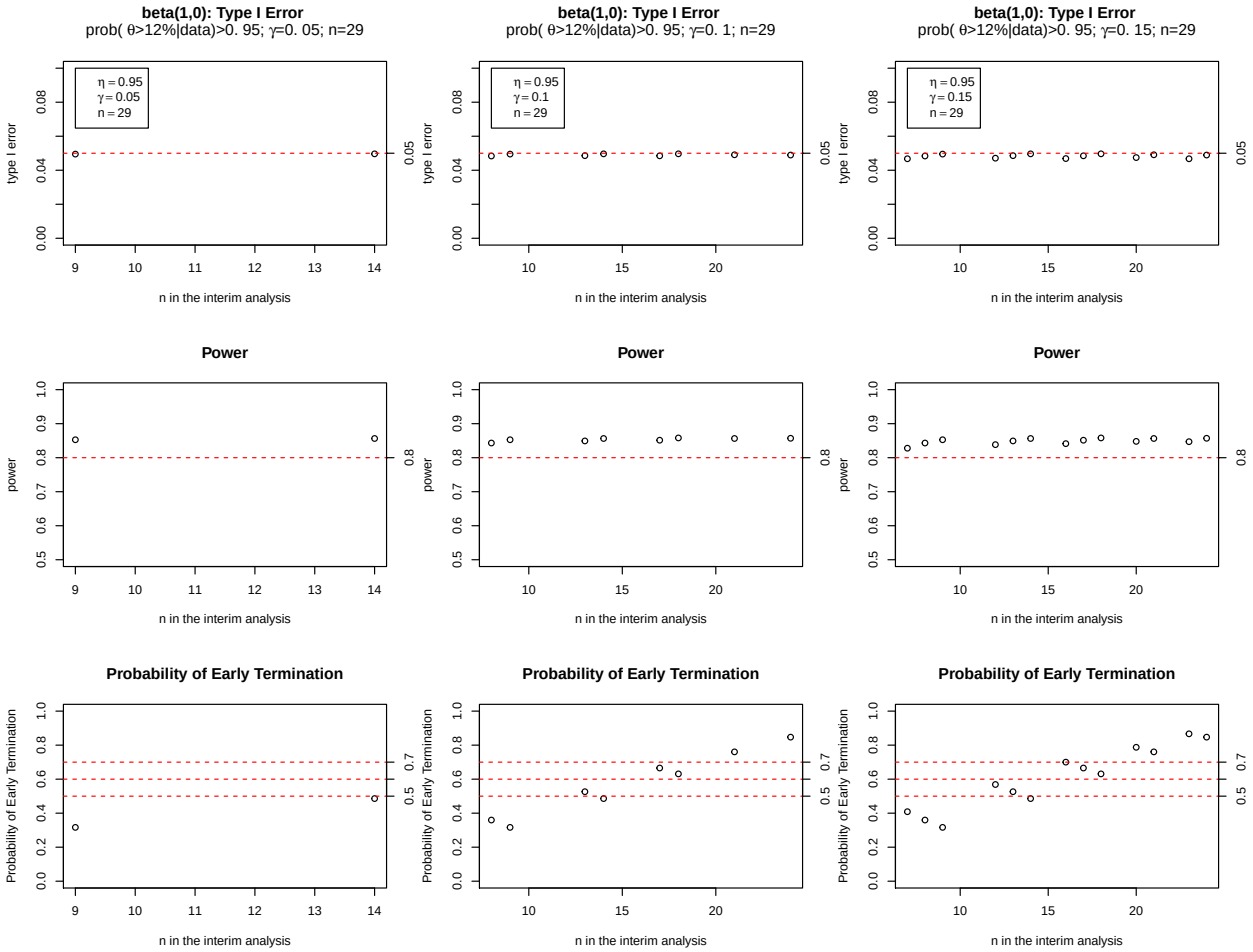
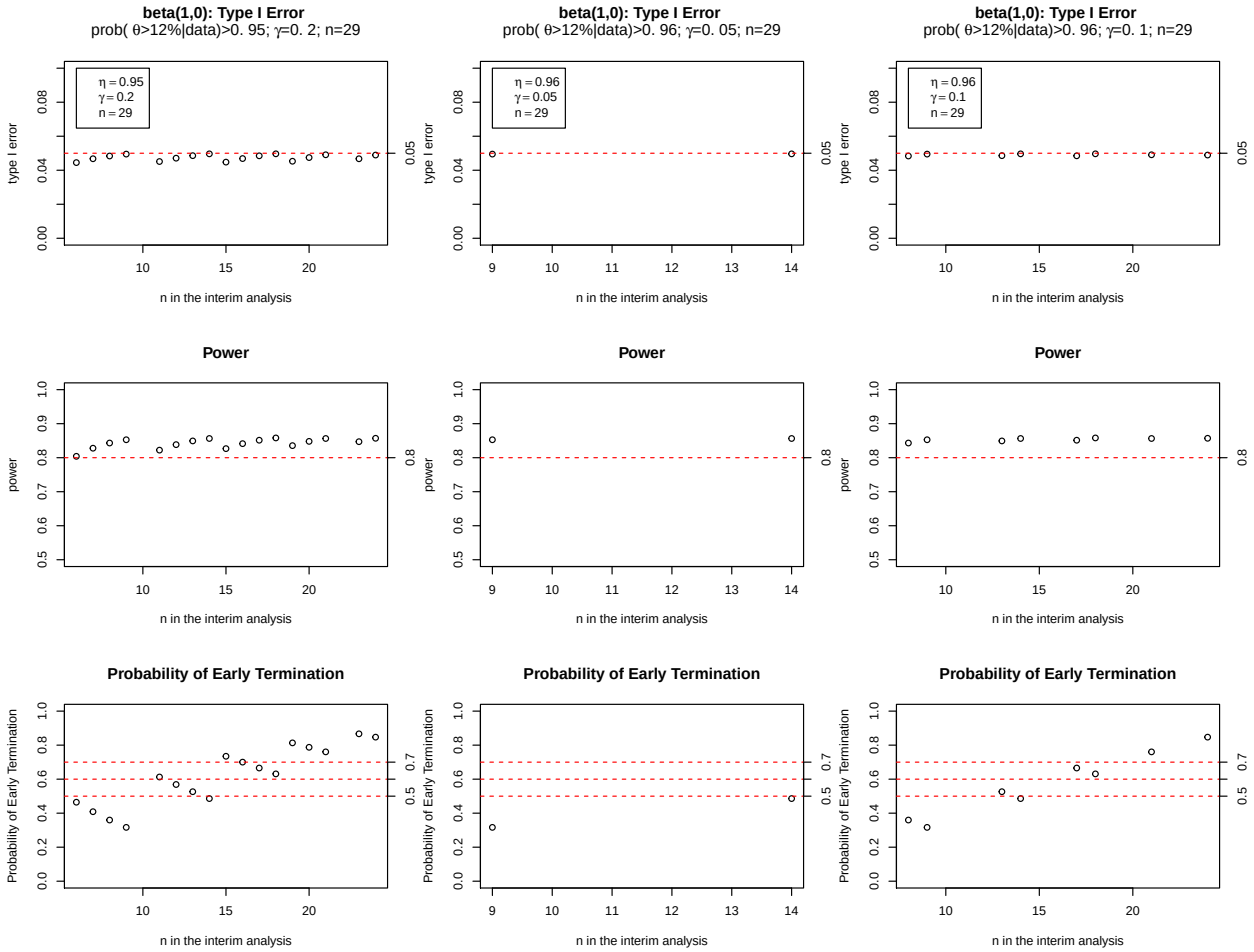
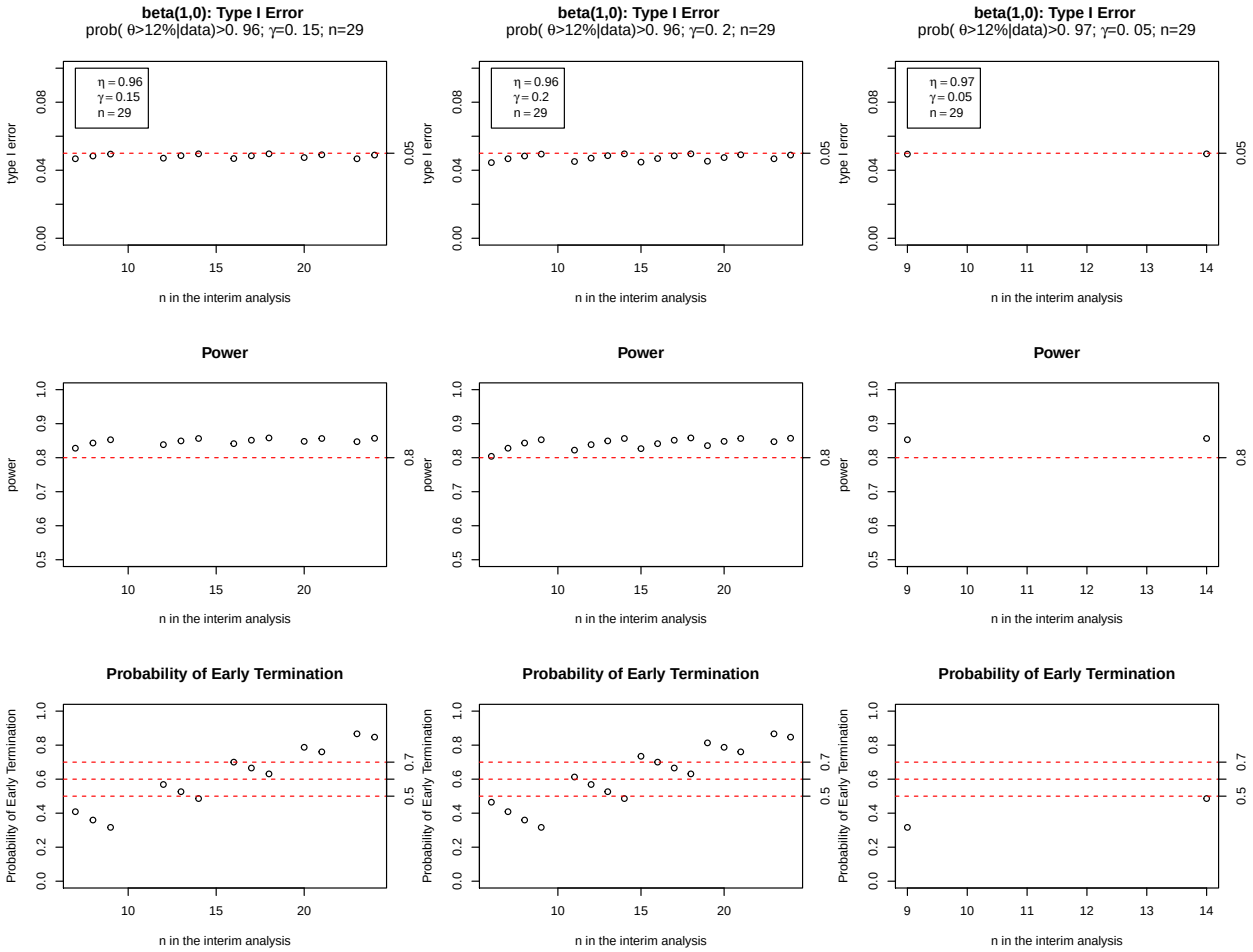
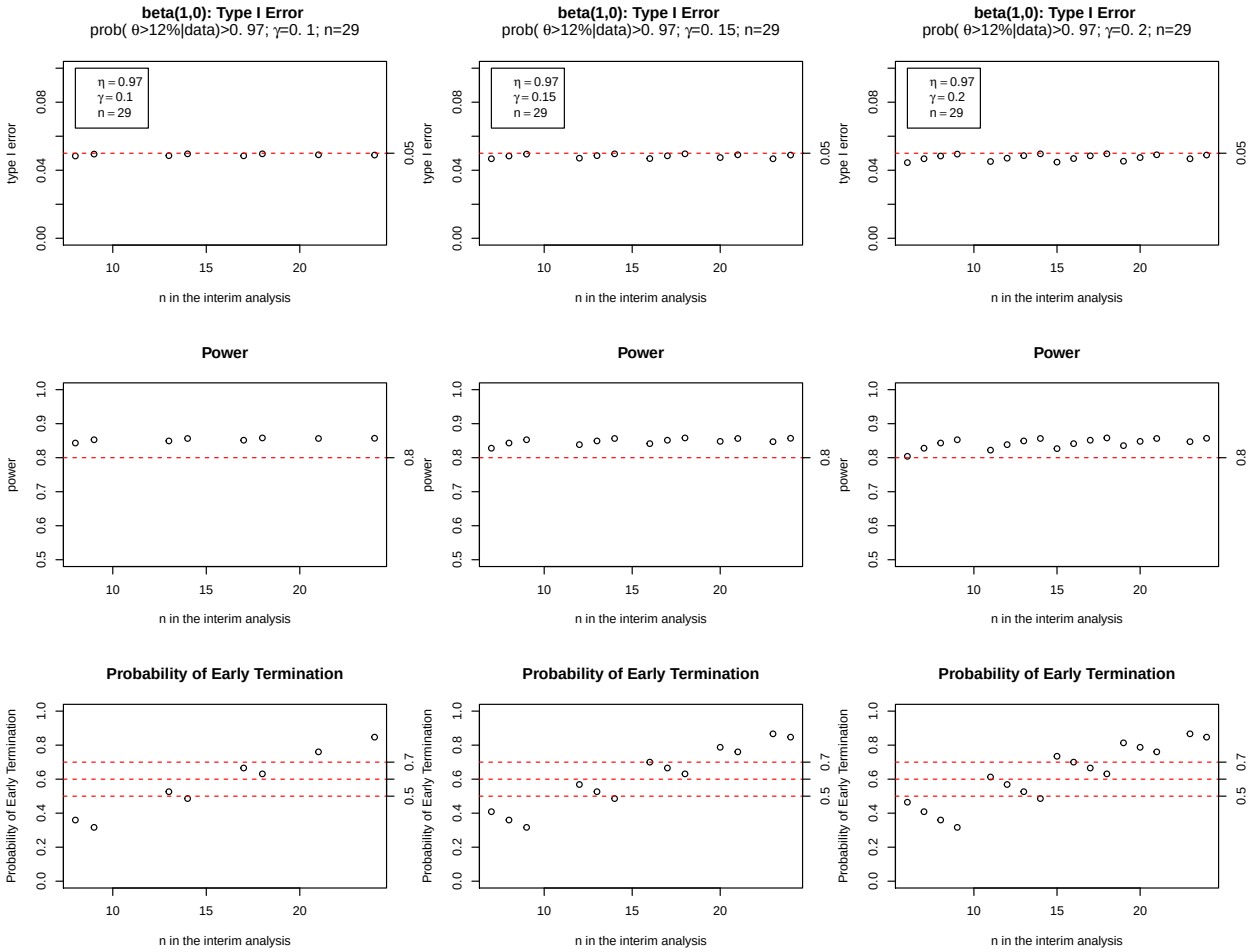
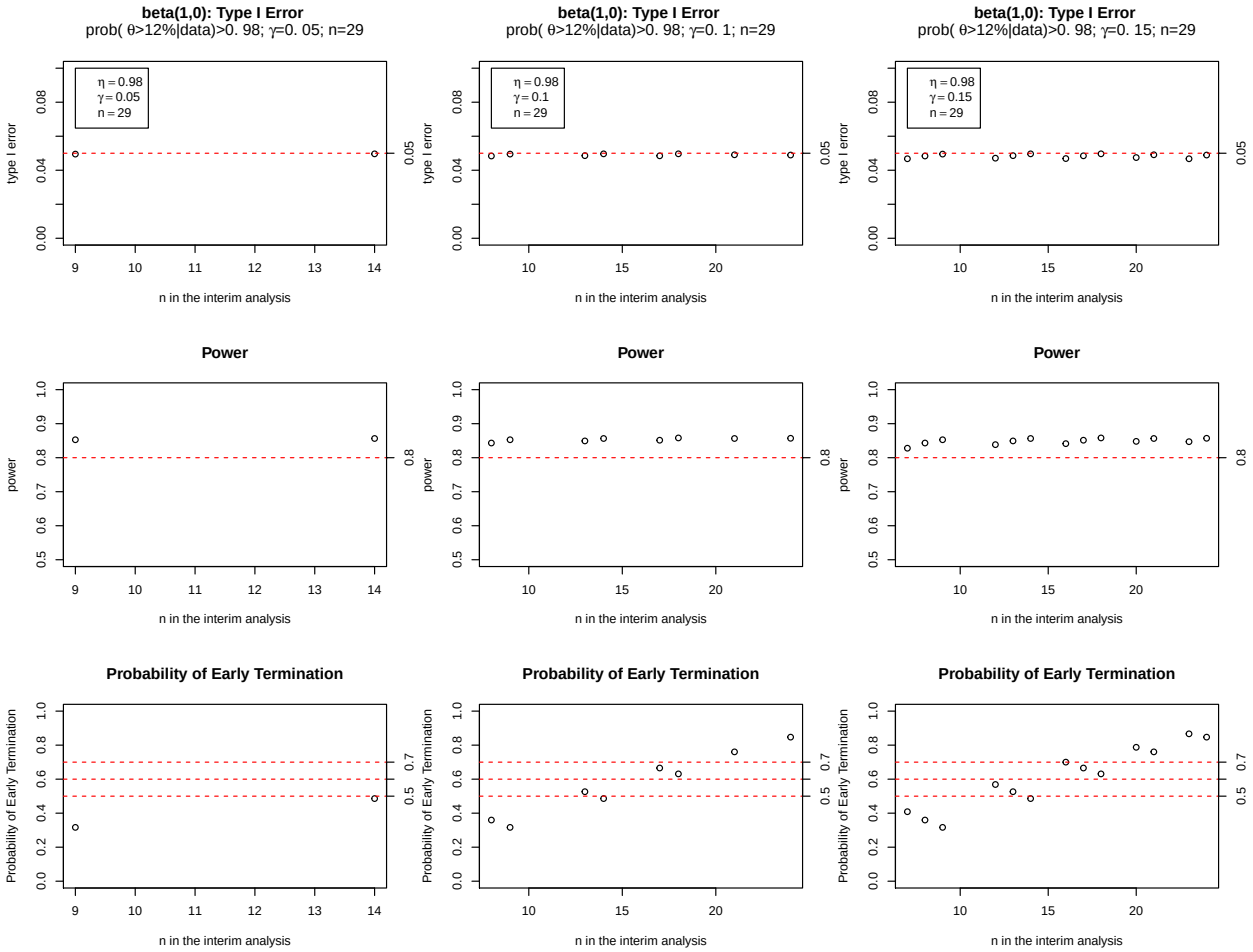
Probability of Early Termination
n in the interim analysis

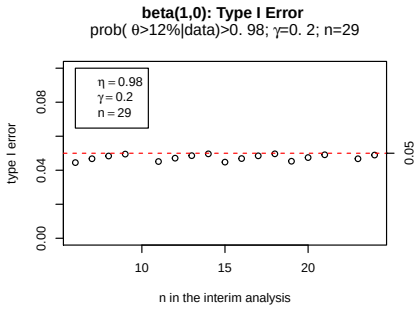

beta(1,0): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 05; n=29
η = 0.95
γ = 0.05
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 1; n=29
η = 0.95
γ = 0.1
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 15; n=29
η = 0.95
γ = 0.15
n = 29
type I error
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis

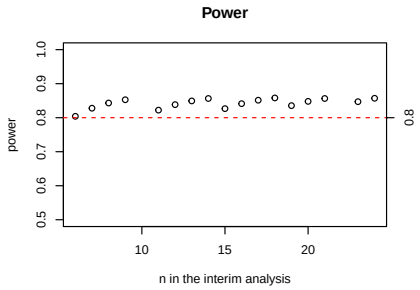

beta(1,0): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 2; n=29
η = 0.95
γ = 0.2
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 05; n=29
η = 0.96
γ = 0.05
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 1; n=29
η = 0.96
γ = 0.1
n = 29
type I error
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis

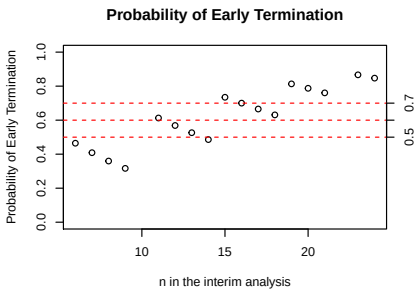

beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 15; n=29
η = 0.96
γ = 0.15
n = 29
beta(1,0): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 2; n=29
η = 0.96
γ = 0.2
n = 29
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 05; n=29
η = 0.97
γ = 0.05
n = 29
type I error
0.00
0.04
0.08
0.05
Power
power
0.5
0.6
0.7
0.8
0.9
1.0
0.8
Probability of Early Termination
Probability of Early Termination
0.0
0.2
0.4
0.6
0.8
1.0
0.5
0.7
n in the interim analysis
9
10
11
12
13
14
15
20


beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 1; n=29
η = 0.97
γ = 0.1
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 15; n=29
η = 0.97
γ = 0.15
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 2; n=29
η = 0.97
γ = 0.2
n = 29
type I error
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis

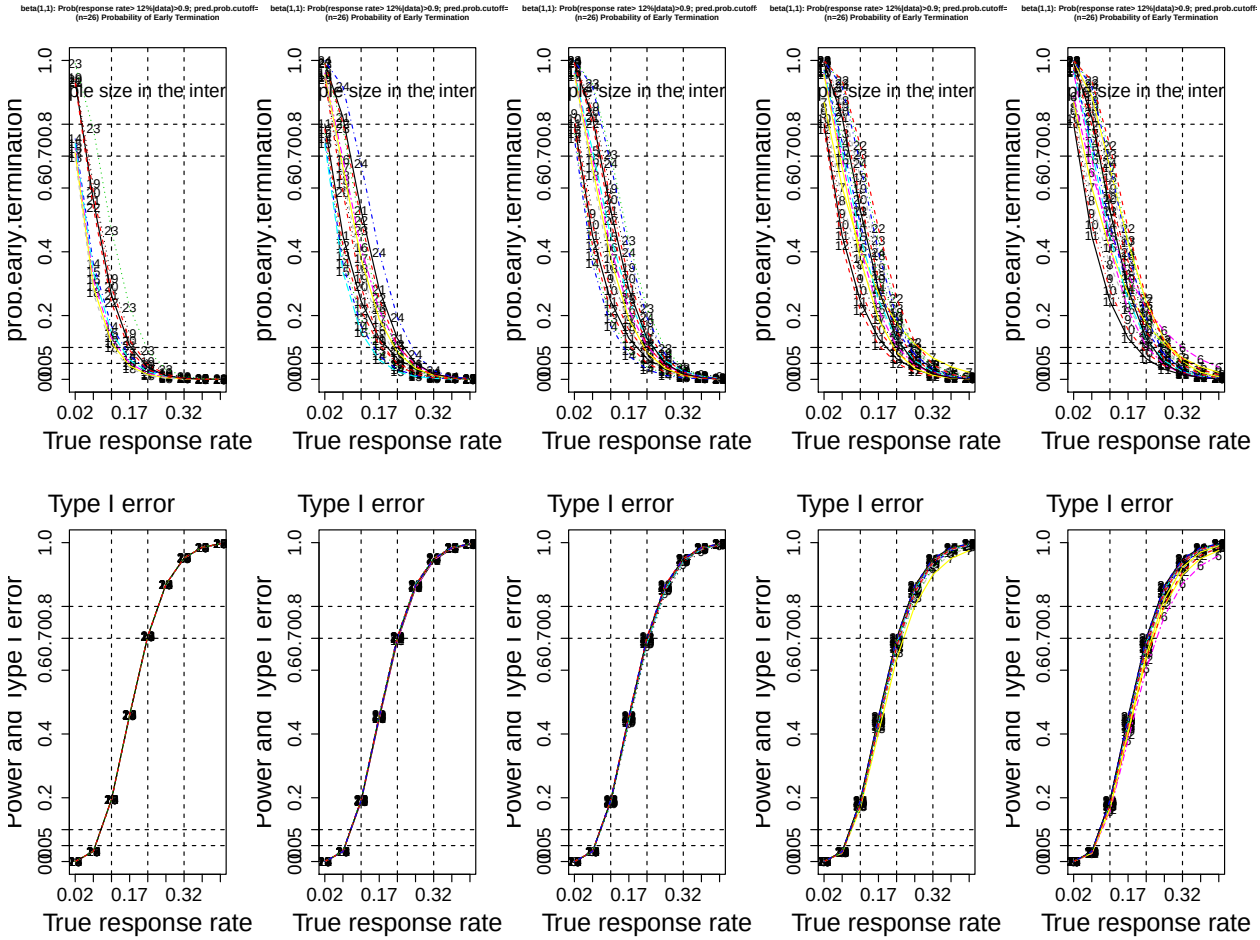

beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 05; n=29
η = 0.98
γ = 0.05
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 1; n=29
η = 0.98
γ = 0.1
n = 29
type I error
n in the interim analysis
beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 15; n=29
η = 0.98
γ = 0.15
n = 29
type I error
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Power
power
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis
Probability of Early Termination
Probability of Early Termination
n in the interim analysis

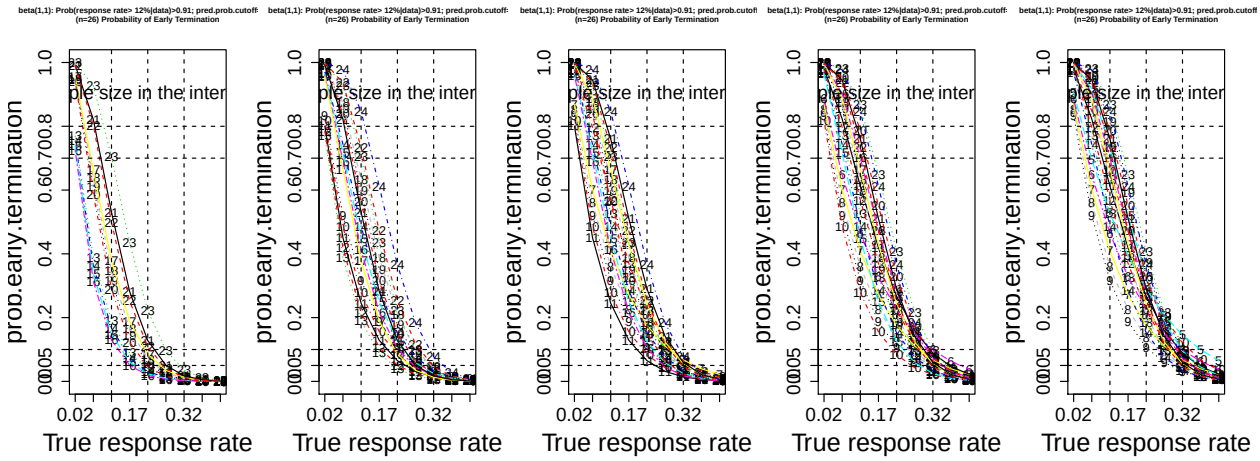

beta(1,0): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 2; n=29
η = 0.98
γ = 0.2
n = 29
type I error
0.00
0.04
0.08
0.05
10
15
20
n in the interim analysis

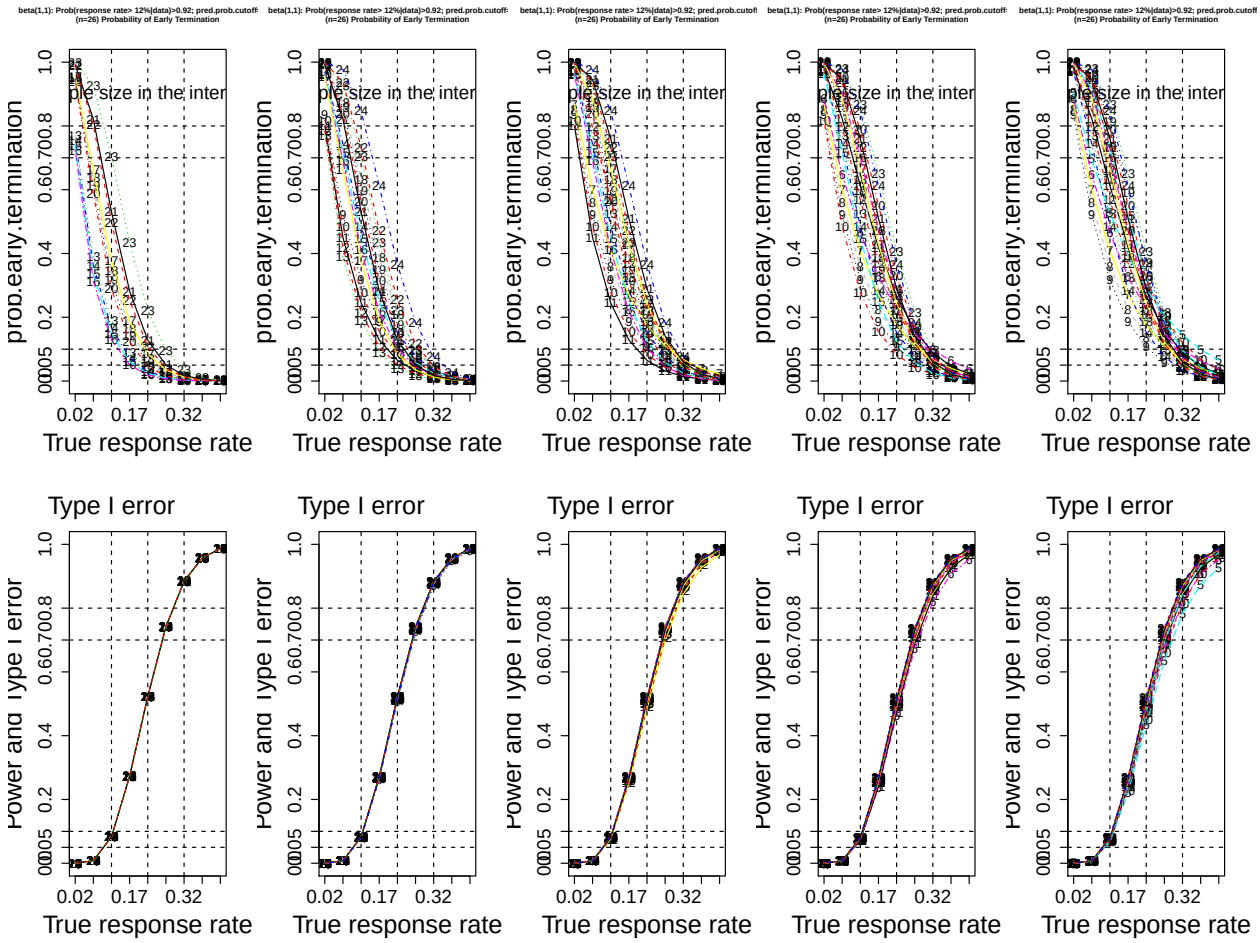

Power
power
0.5
0.6
0.7
0.8
0.9
1.0
0.8
10
15
20
n in the interim analysis

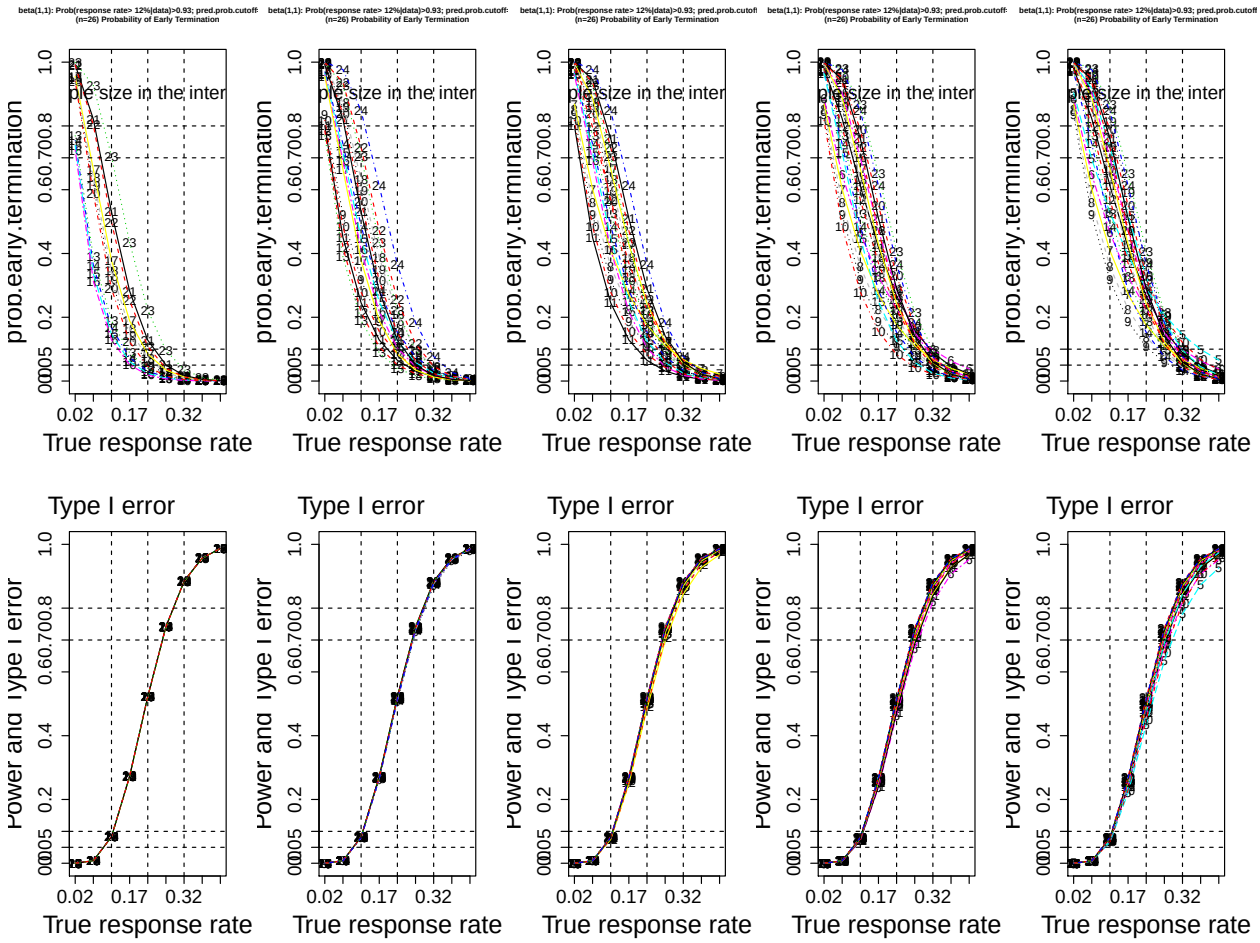

Probability of Early Termination
Probability of Early Termination
0.0
0.2
0.4
0.6
0.8
1.0
0.7
0.5
10
15
20
n in the interim analysis

Prior Distribution: beta(1,1)






beta(1,1): Prob(response rate> 12%|data)>0.92; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
0.32


beta(1,1): Prob(response rate> 12%|data)>0.93; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
0.32
0.0
0.2
0.4
0.6
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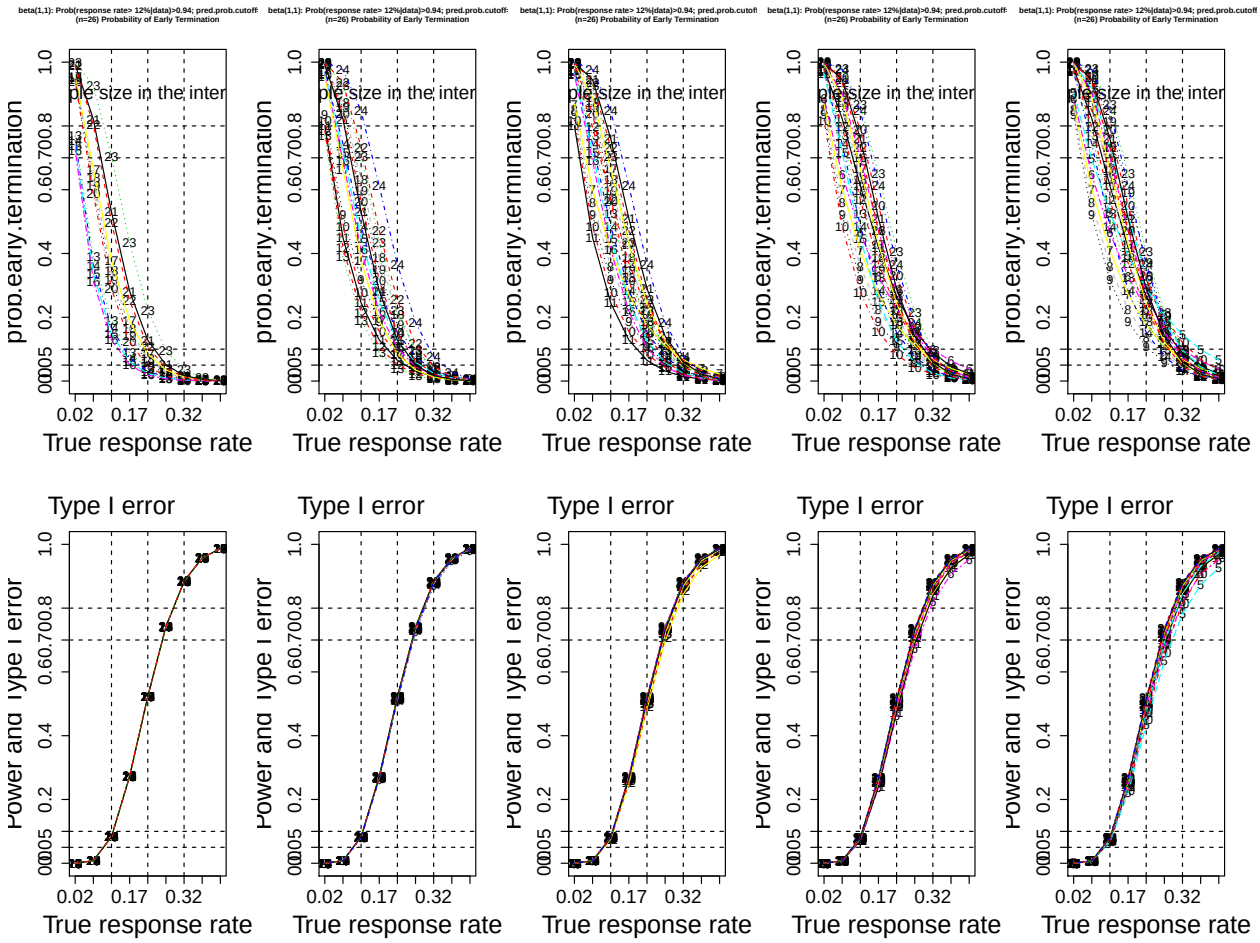
1.0


beta(1,1): Prob(response rate> 12%|data)>0.94; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
0.32
0.0
0.2
0.4
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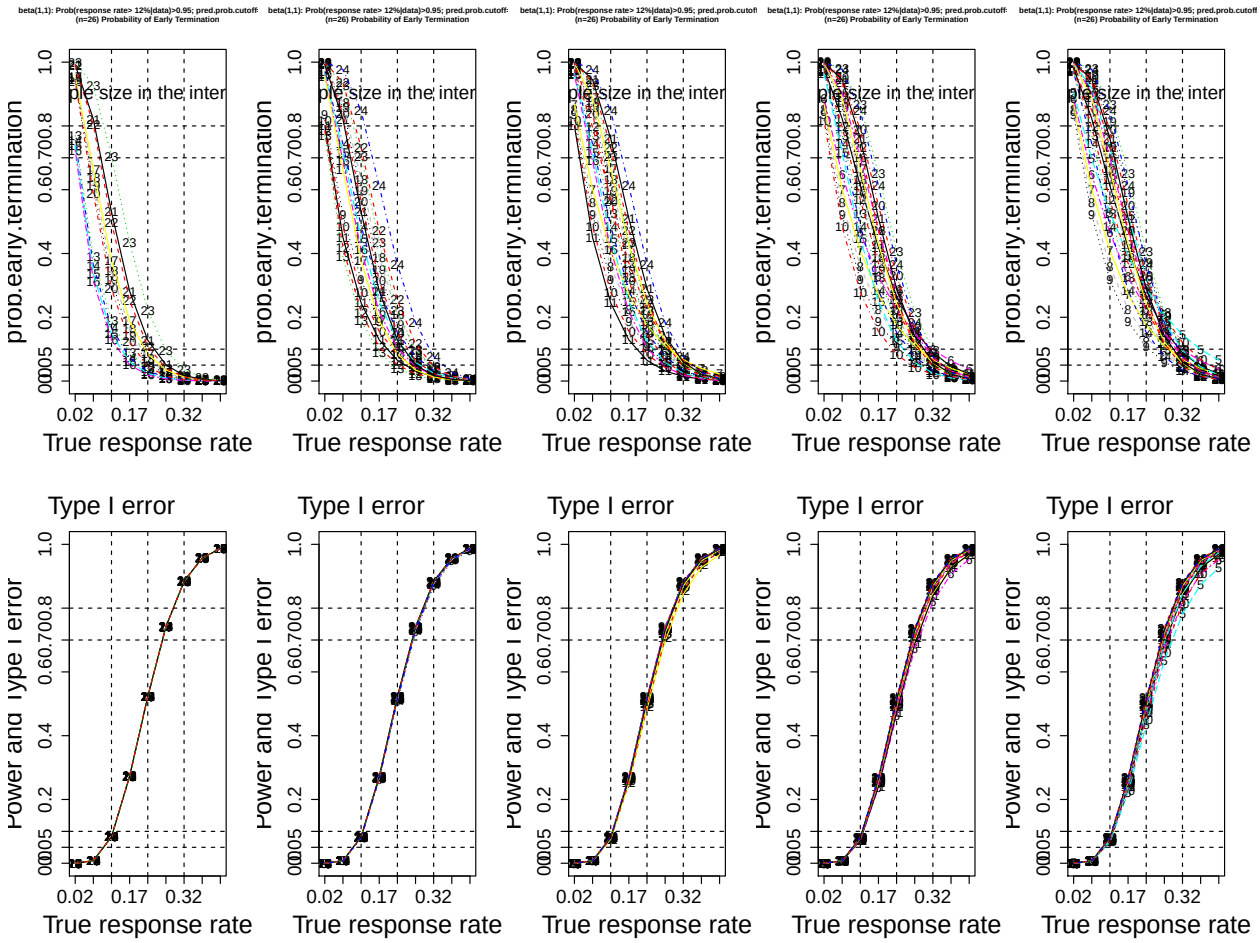
0.8
1.0


beta(1,1): Prob(response rate> 12%|data)>0.95; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
0.17
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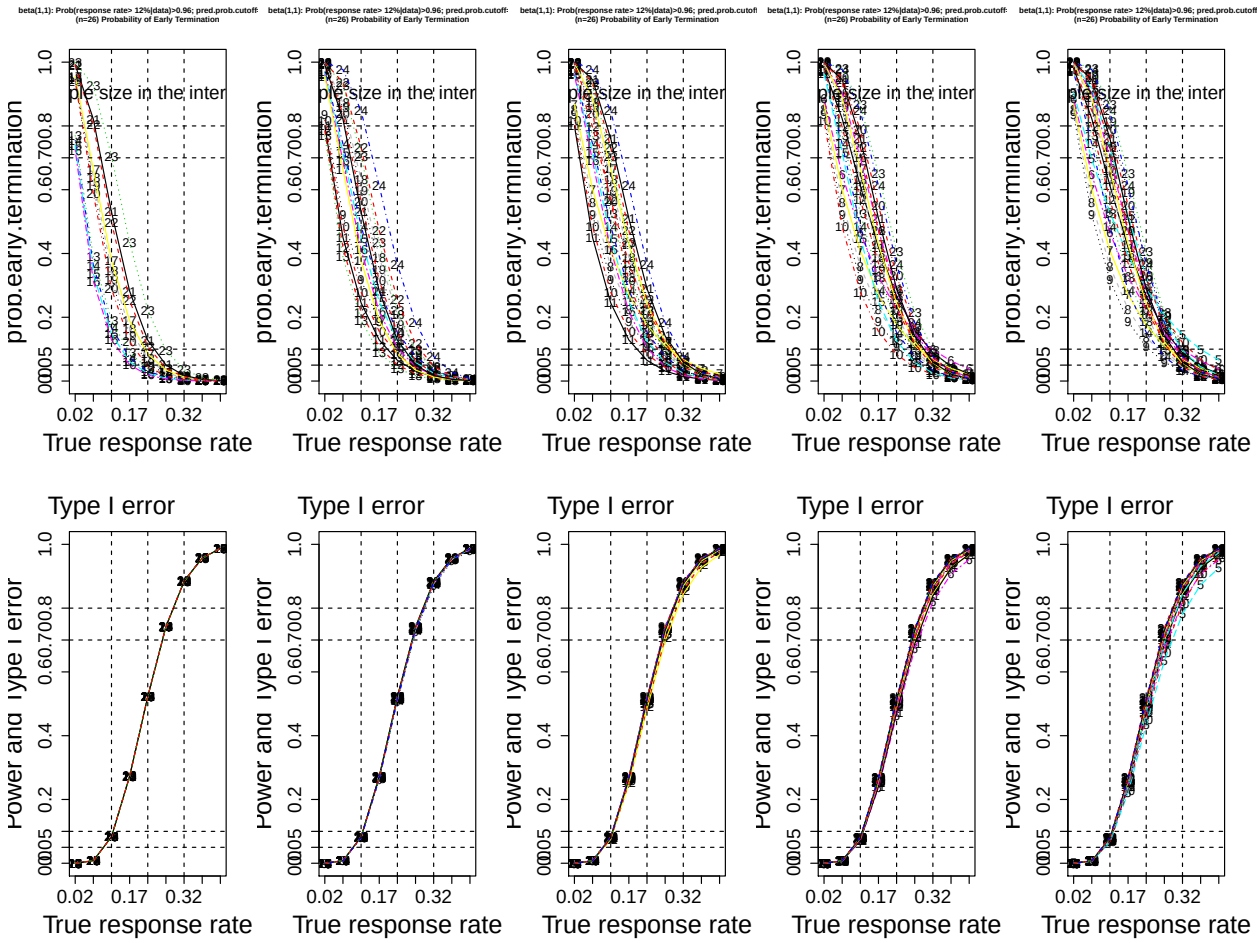
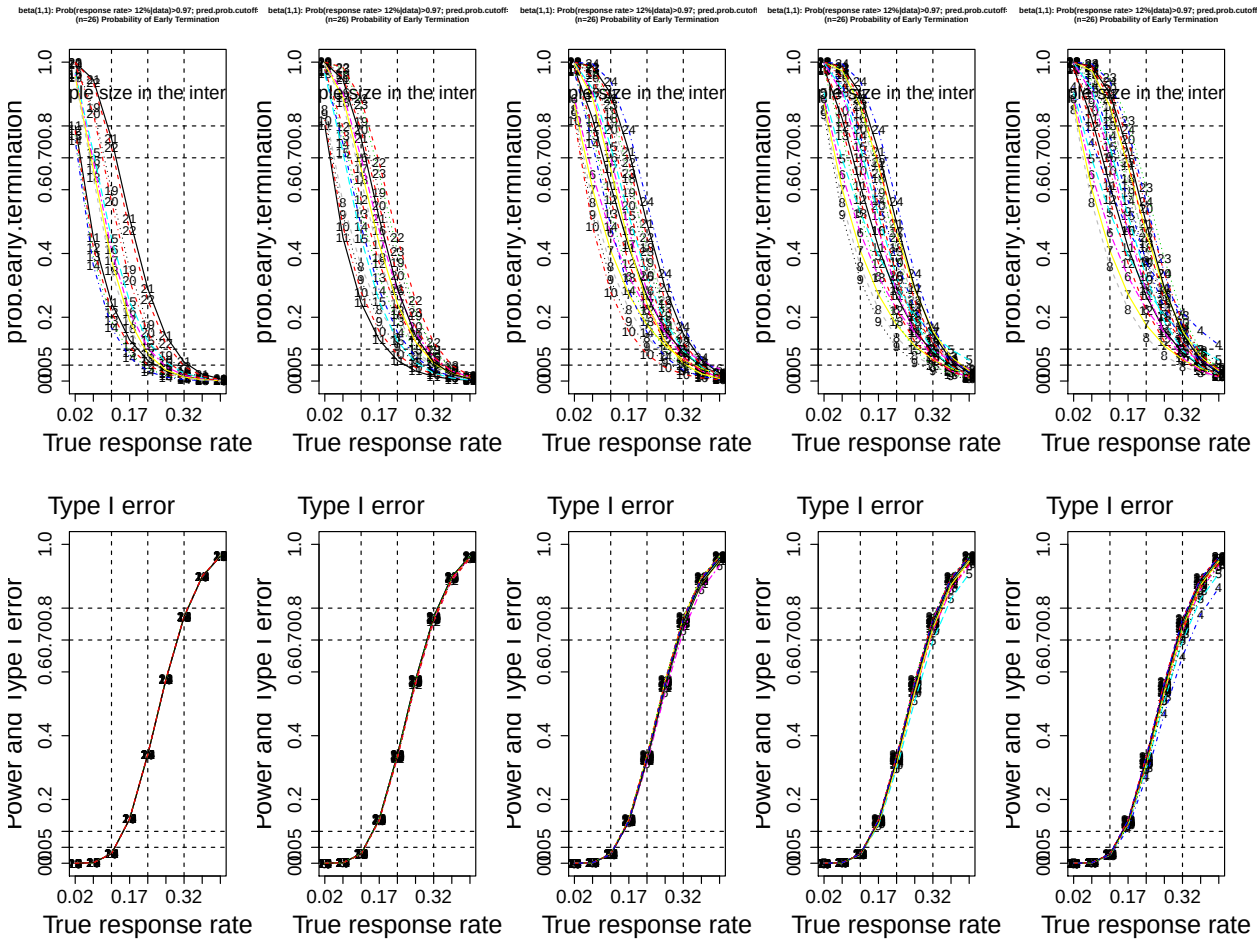

beta(1,1): Prob(response rate> 12%|data)>0.96; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
0.17
0.32


beta(1,1): Prob(response rate> 12%|data)>0.97; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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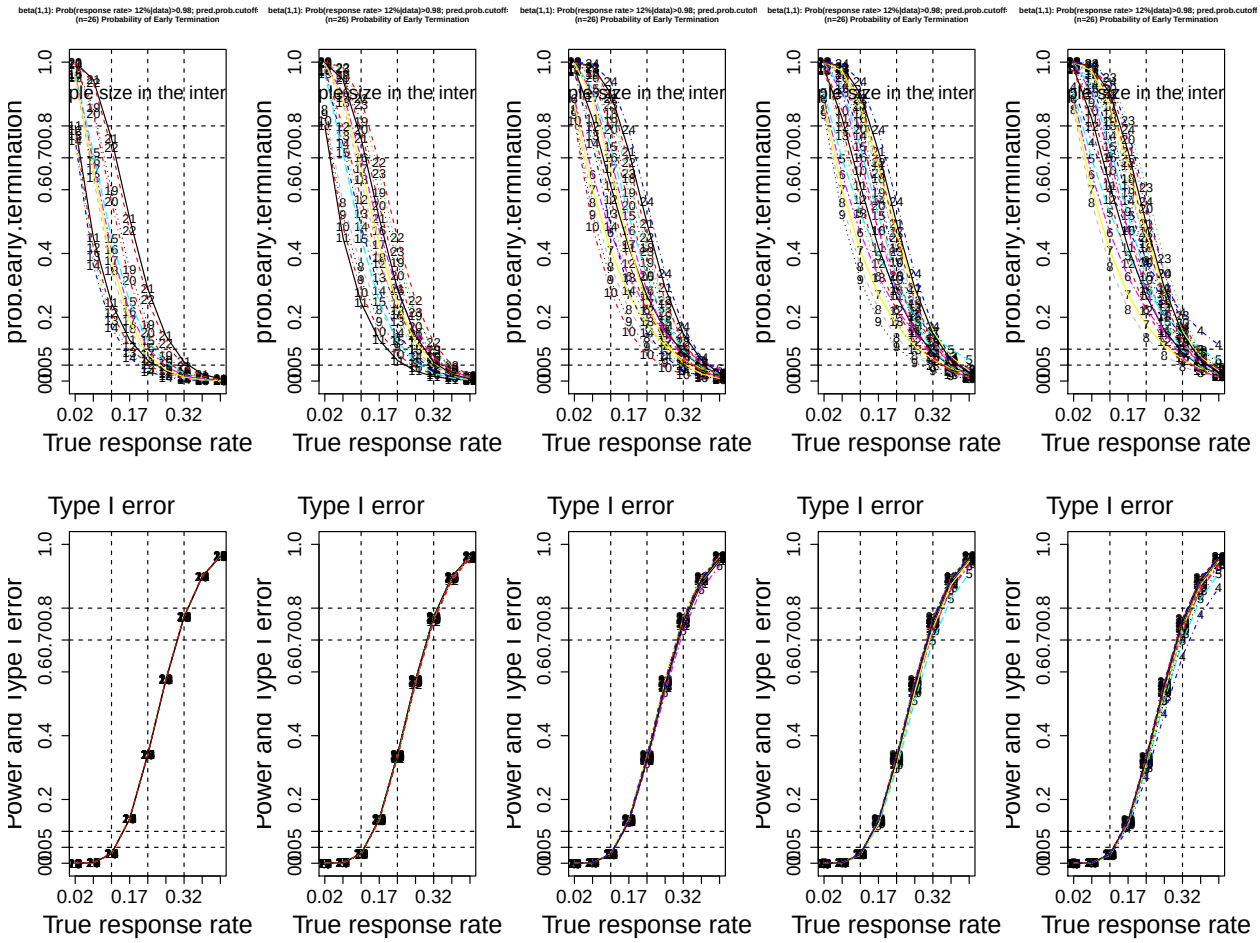
beta(1,1): Prob(response rate> 12%|data)>0.98; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
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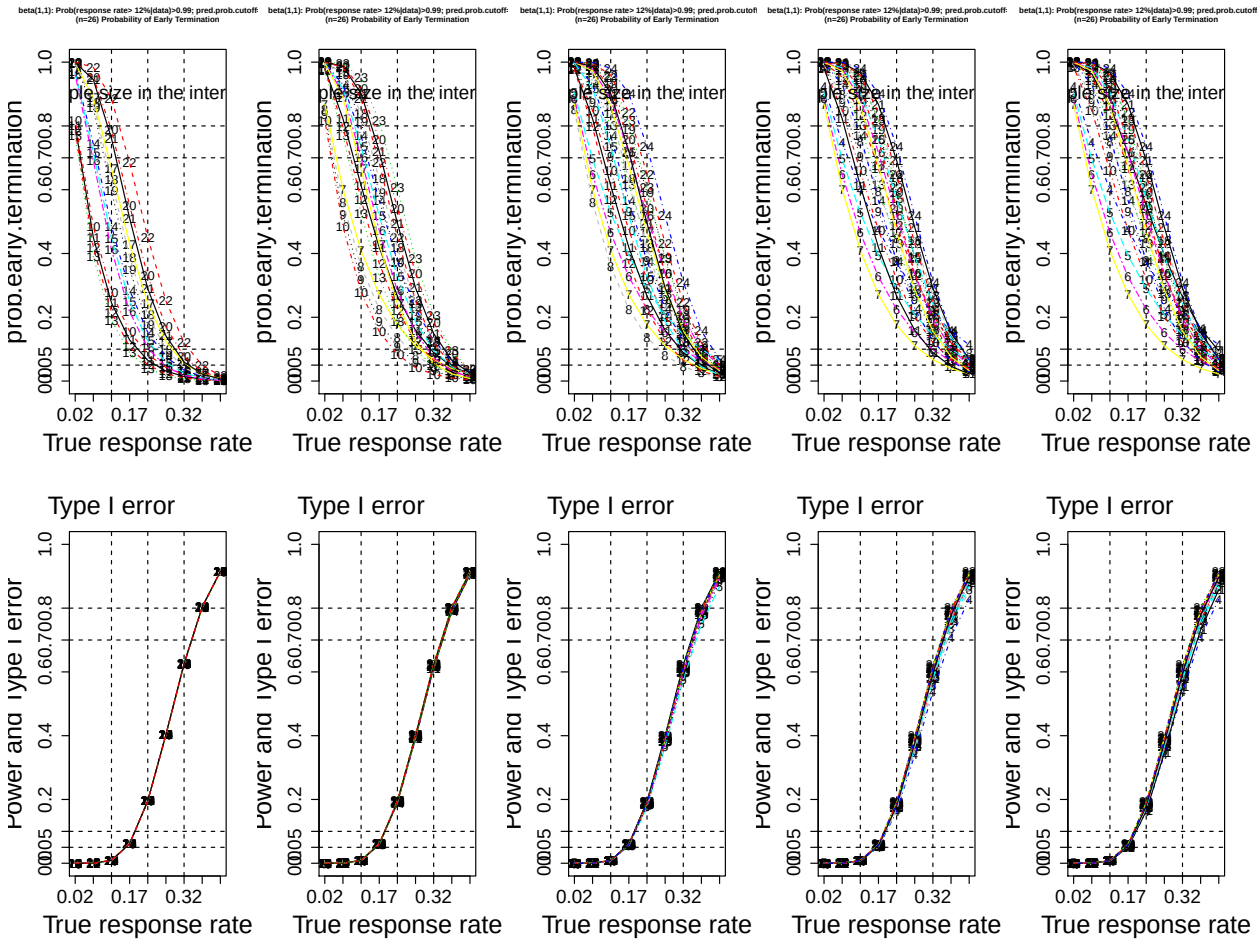
beta(1,1): Prob(response rate> 12%|data)>0.99; pred.prob.cutoff
(n=26) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
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0.4
0.6
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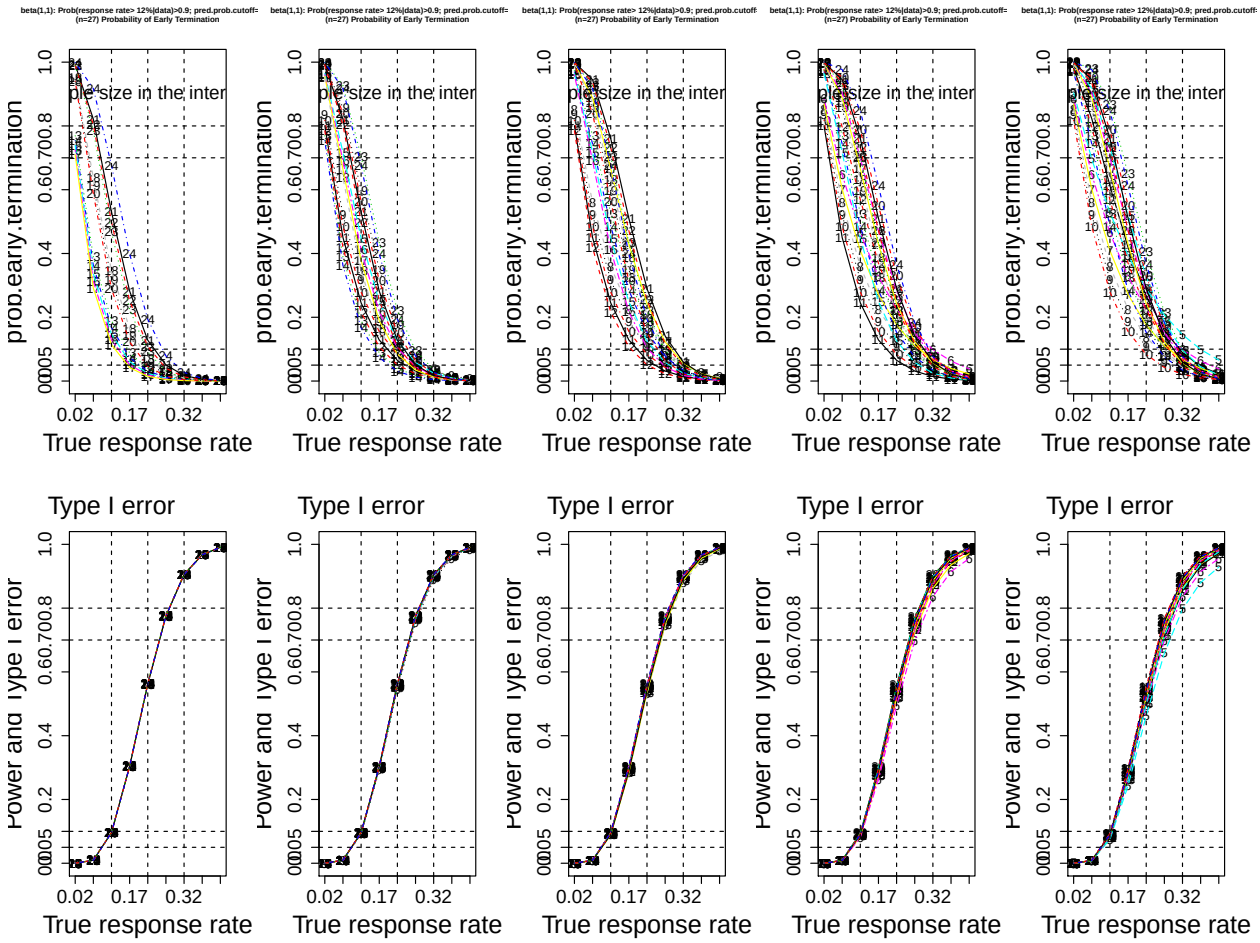
beta(1,1): Prob(response rate> 12%|data)>0.9; pred.prob.cutoff=
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
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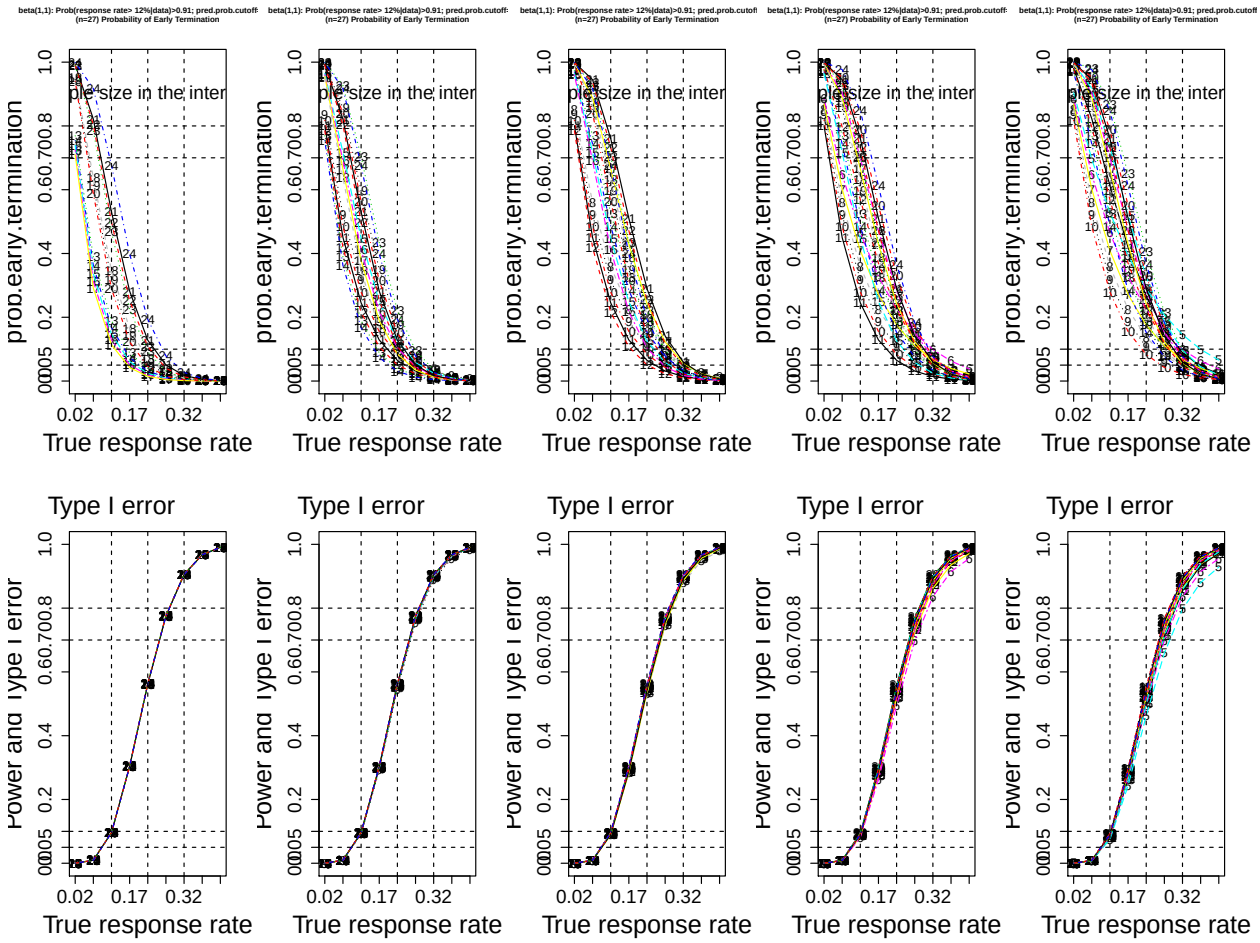
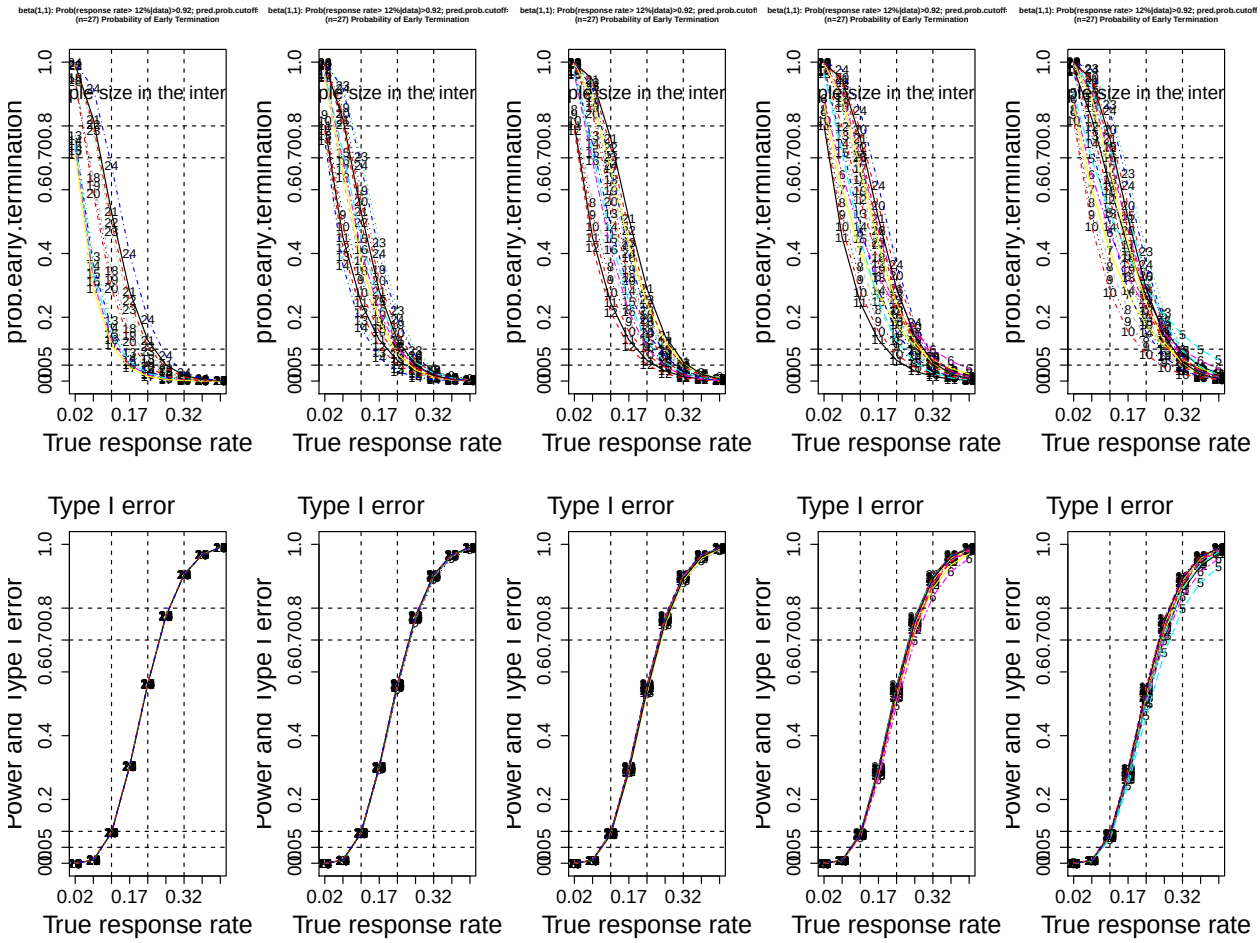

beta(1,1): Prob(response rate> 12%|data)>0.91; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
0.17
0.32


beta(1,1): Prob(response rate> 12%|data)>0.92; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
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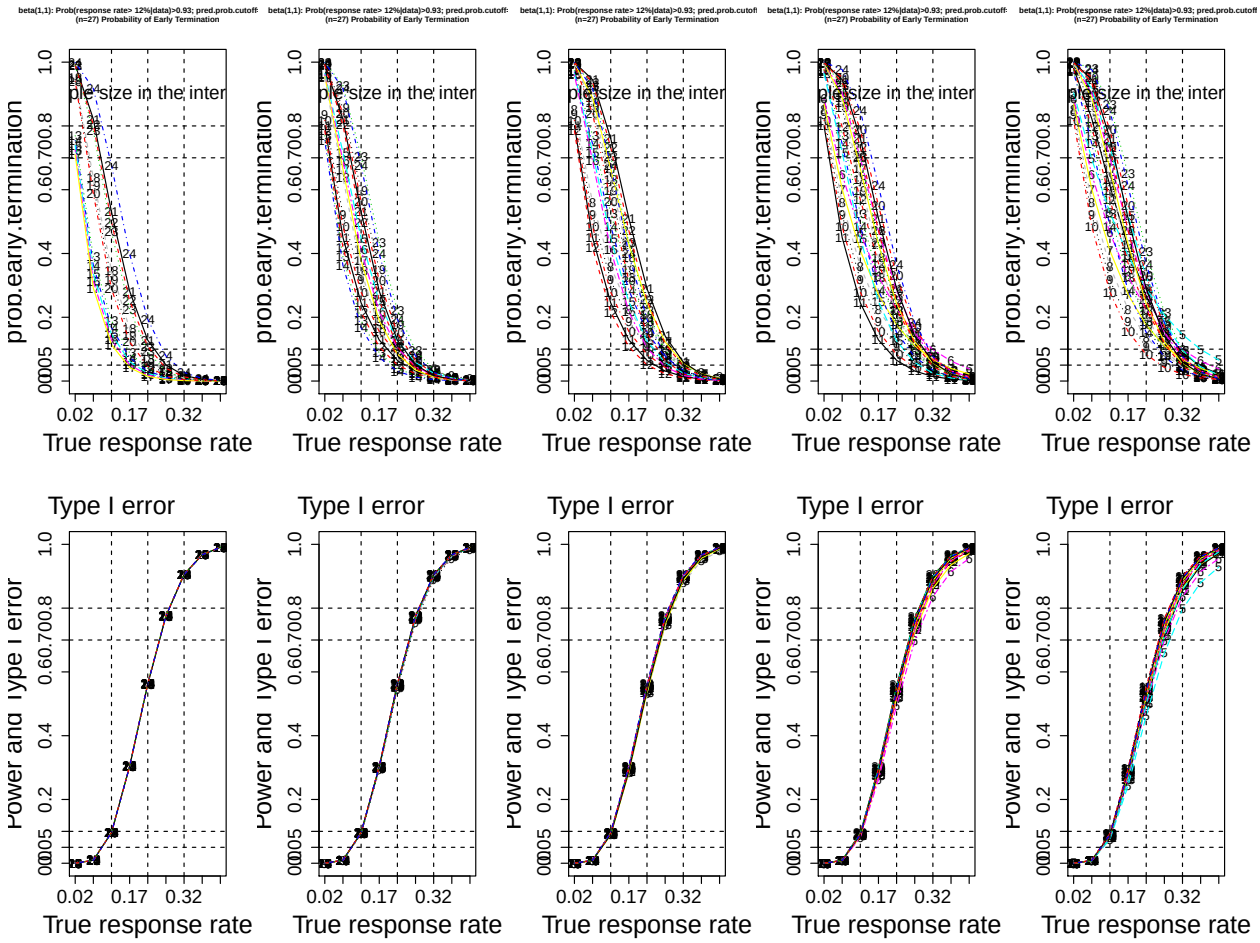
0.32


beta(1,1): Prob(response rate> 12%|data)>0.93; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
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0.2
0.4
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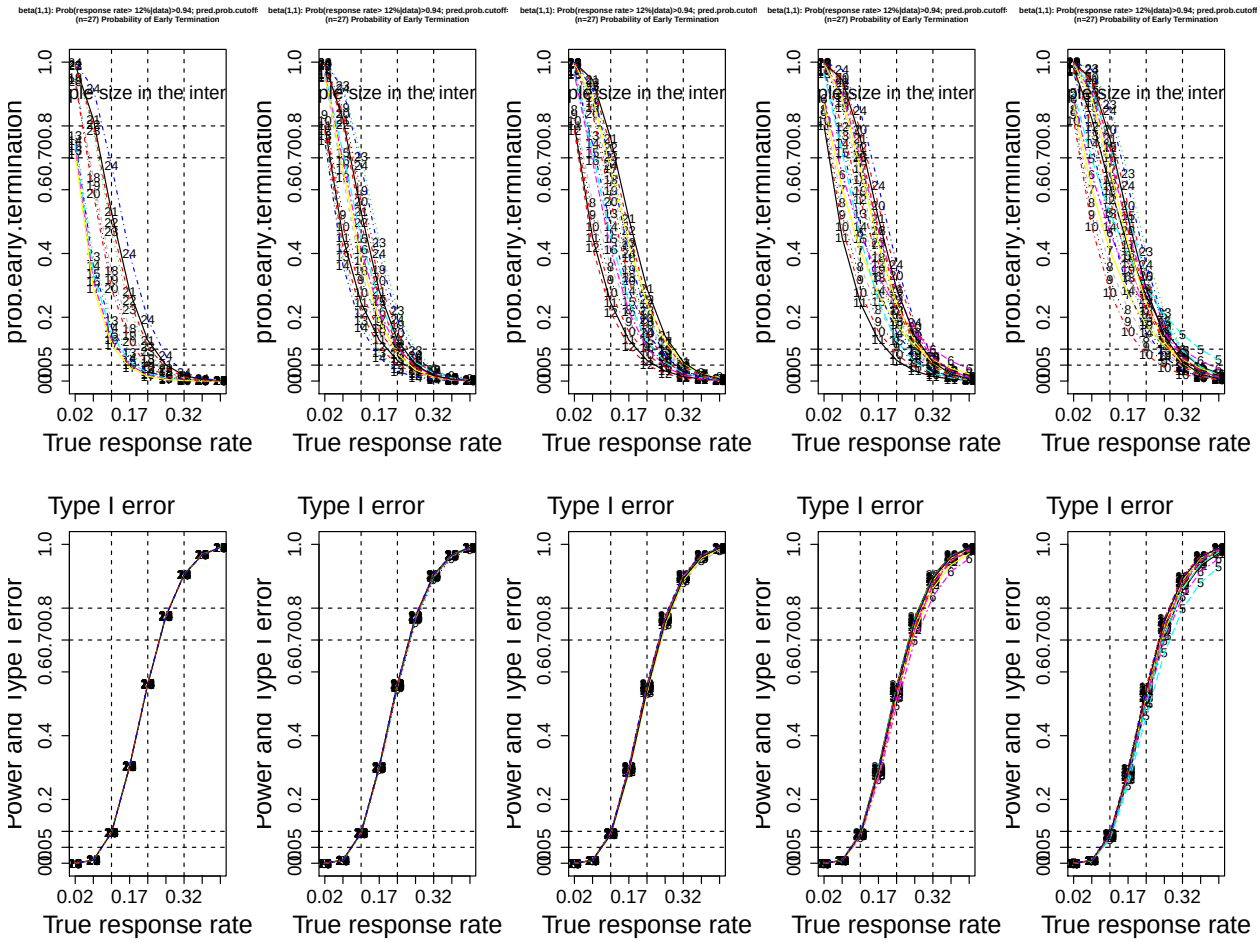
0.8
1.0


beta(1,1): Prob(response rate> 12%|data)>0.94; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
Power and Type I error
Type I error
True response rate
0.02
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0.8
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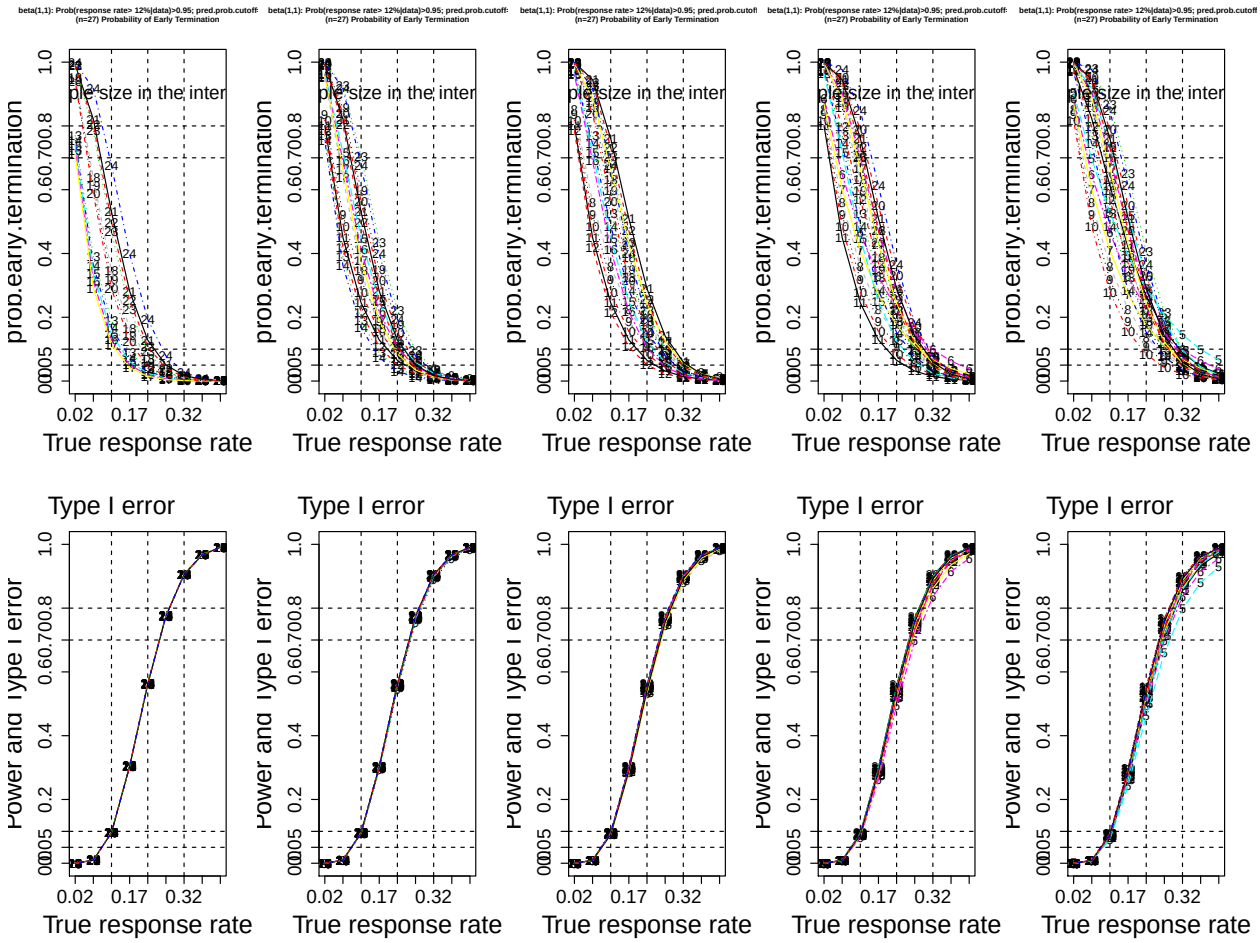
beta(1,1): Prob(response rate> 12%|data)>0.95; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
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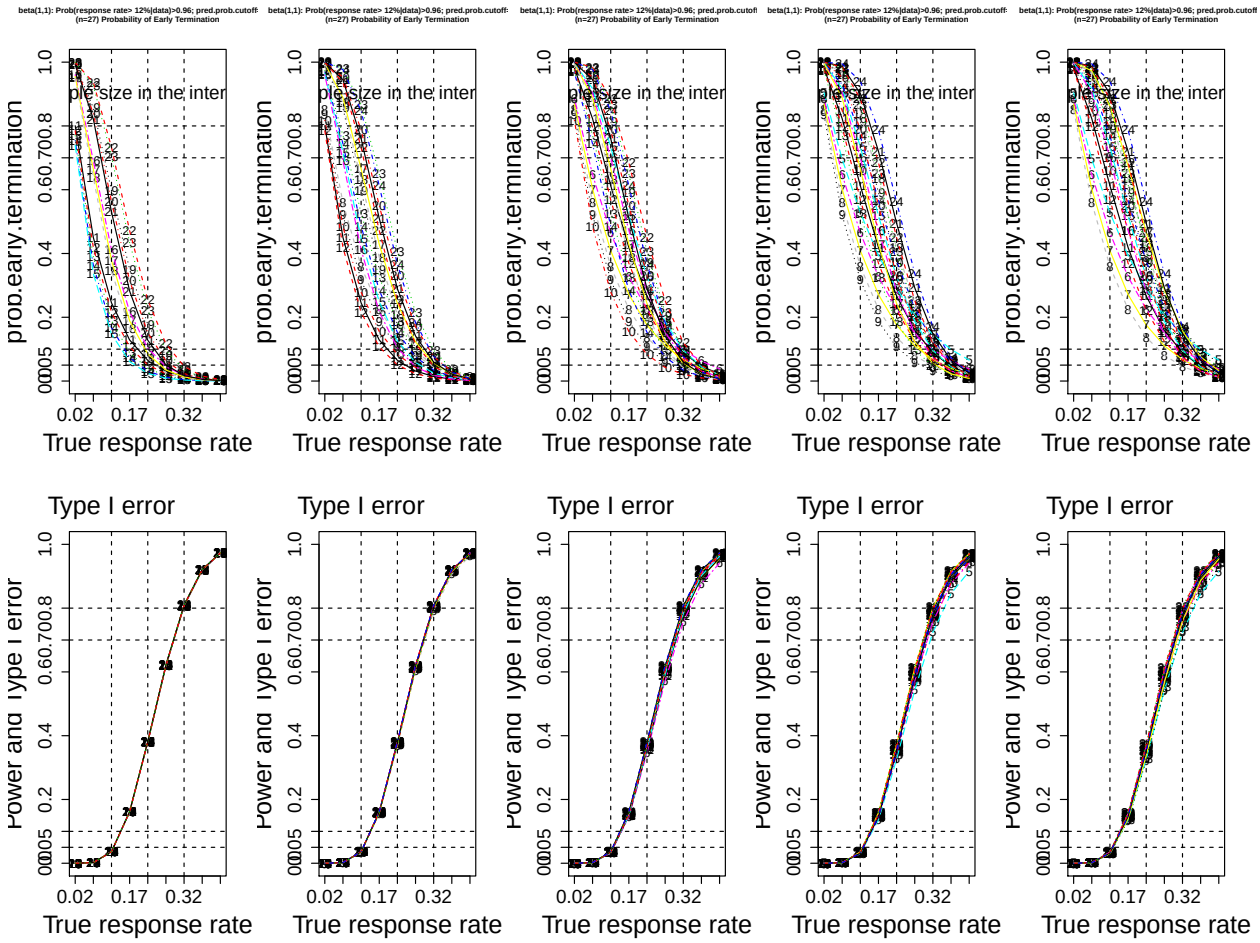
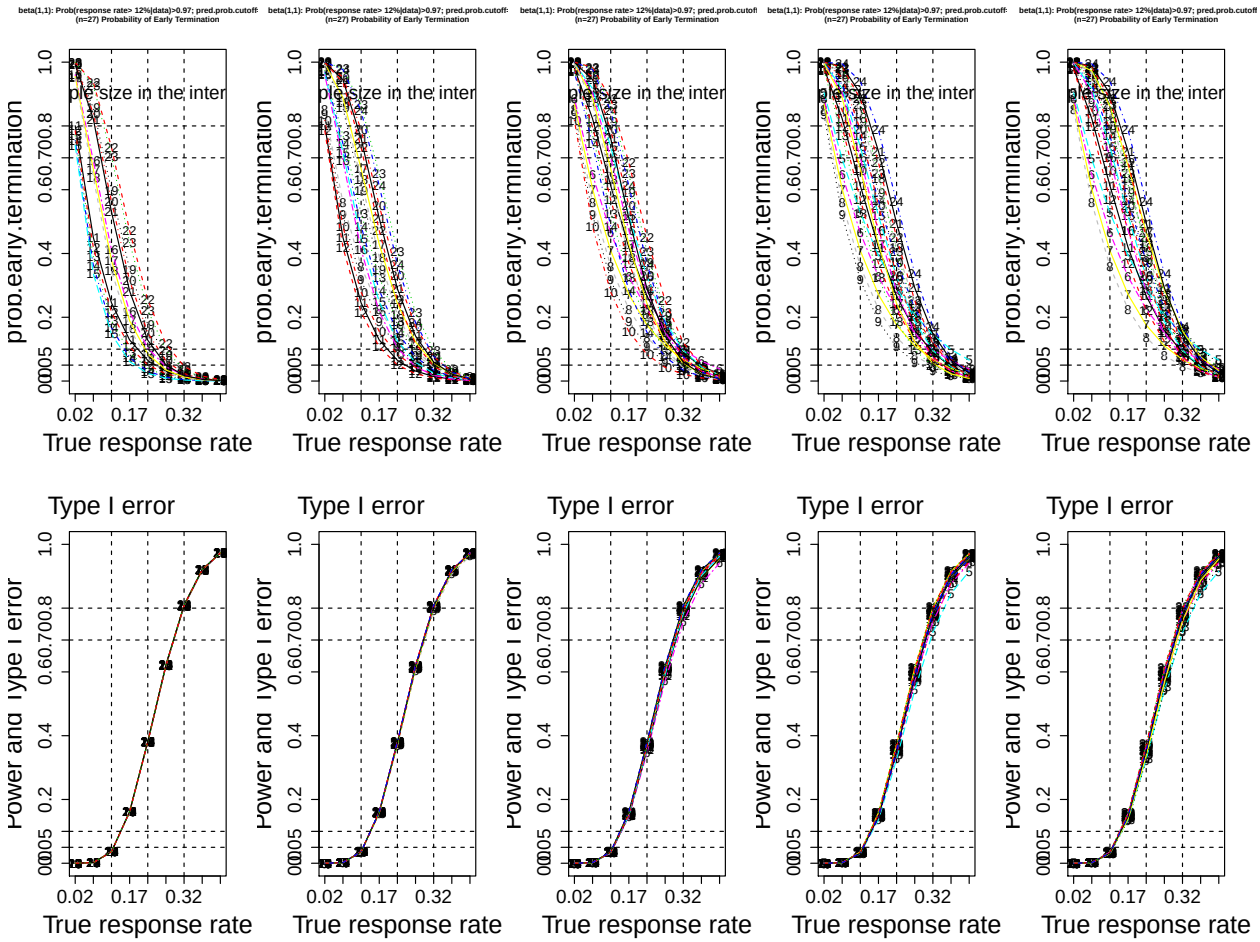

beta(1,1): Prob(response rate> 12%|data)>0.96; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
True response rate


beta(1,1): Prob(response rate> 12%|data)>0.97; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
Type I error
Power and Type I error
True response rate
0.02
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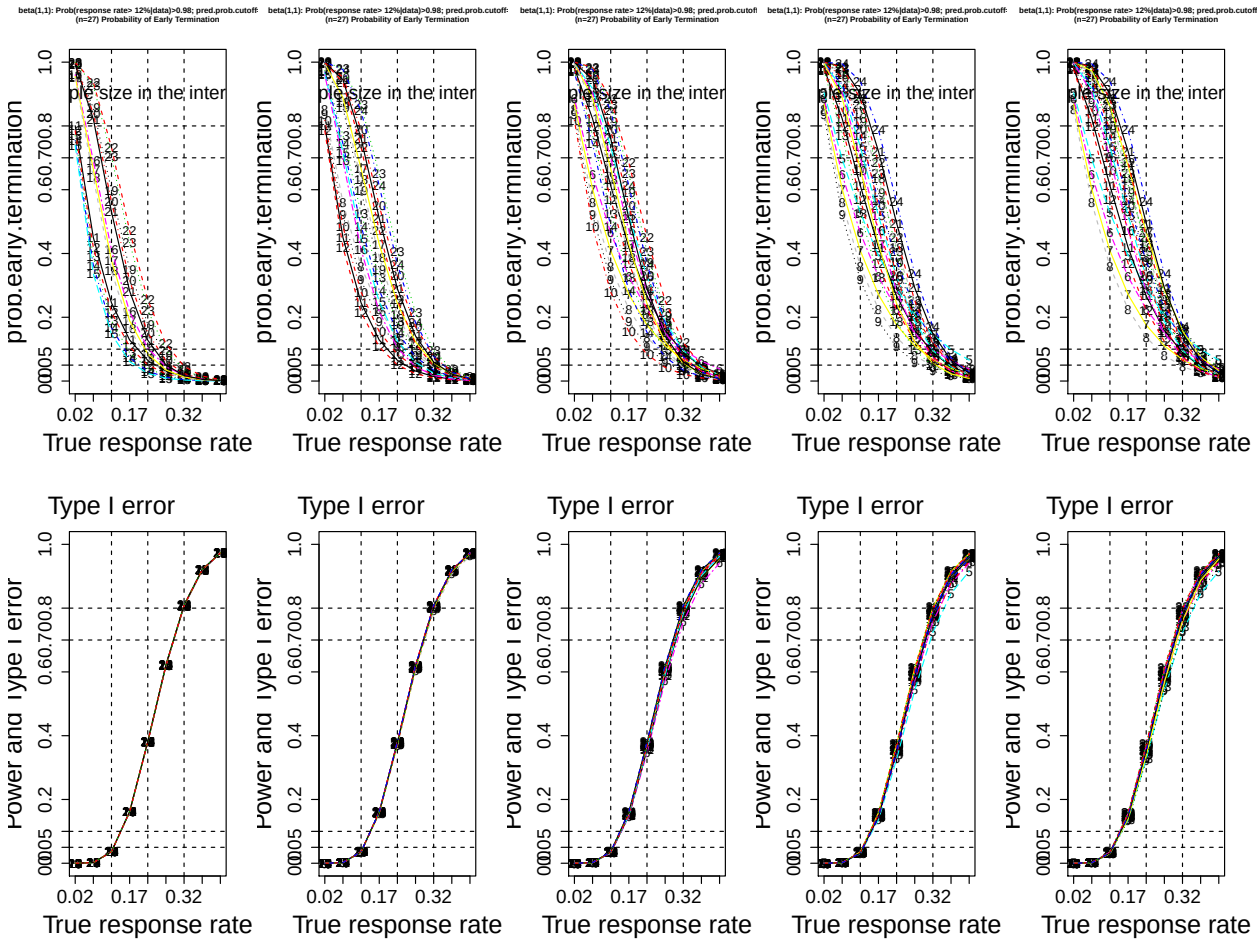
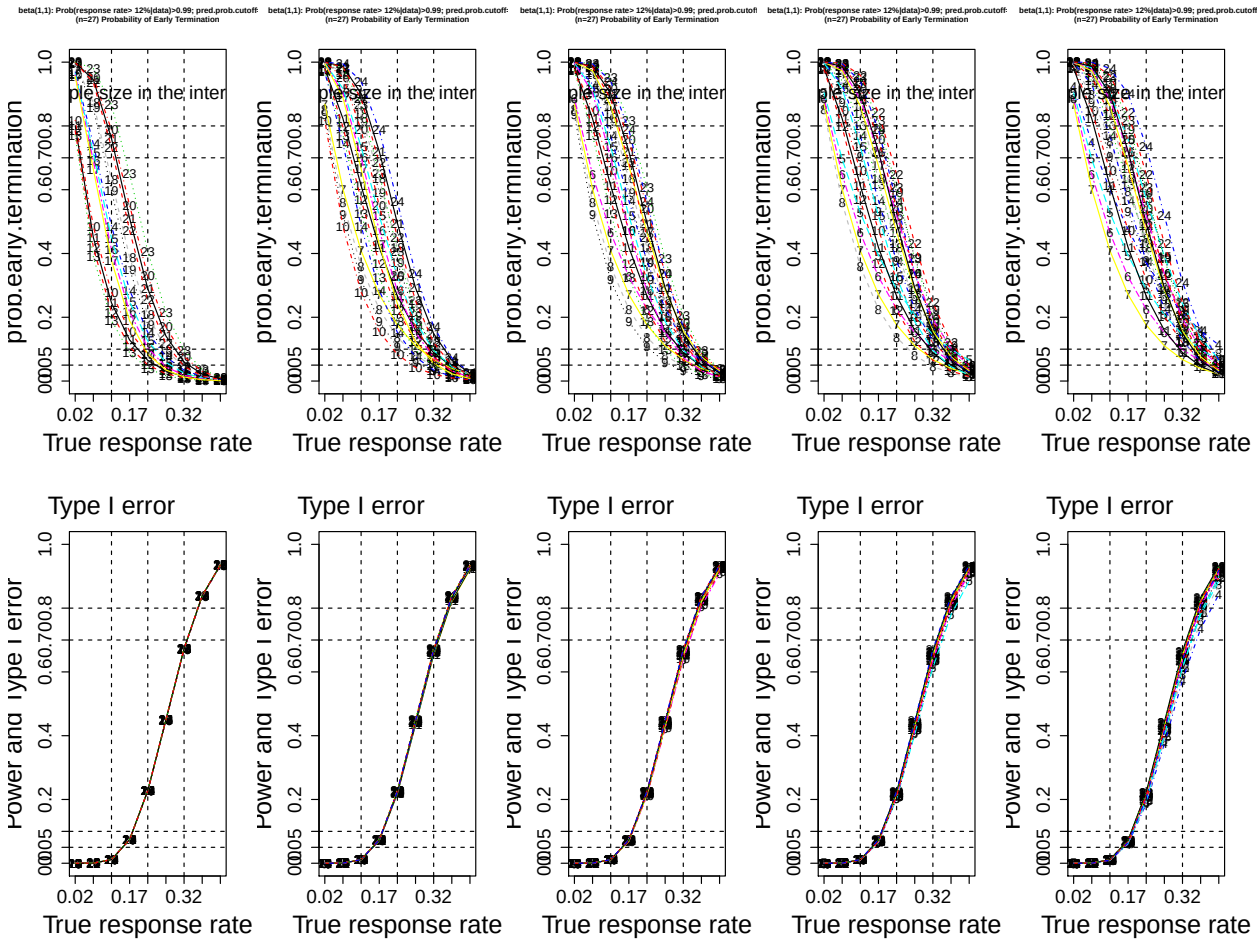
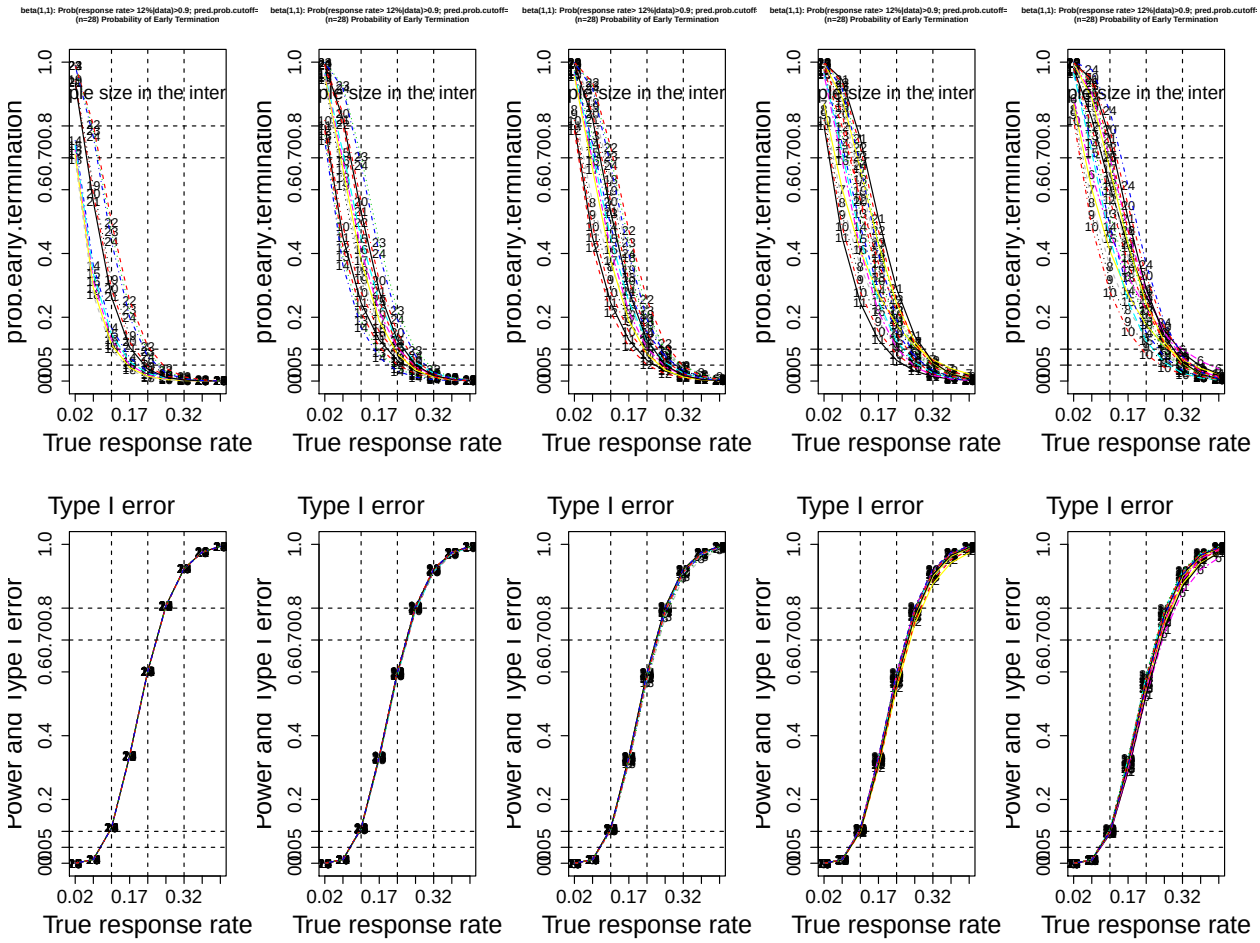
0.32
0.0
0.2
0.4
0.6
0.7
0.8
1.0


beta(1,1): Prob(response rate> 12%|data)>0.98; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
0.17
0.32


beta(1,1): Prob(response rate> 12%|data)>0.99; pred.prob.cutoff
(n=27) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
0.17
0.32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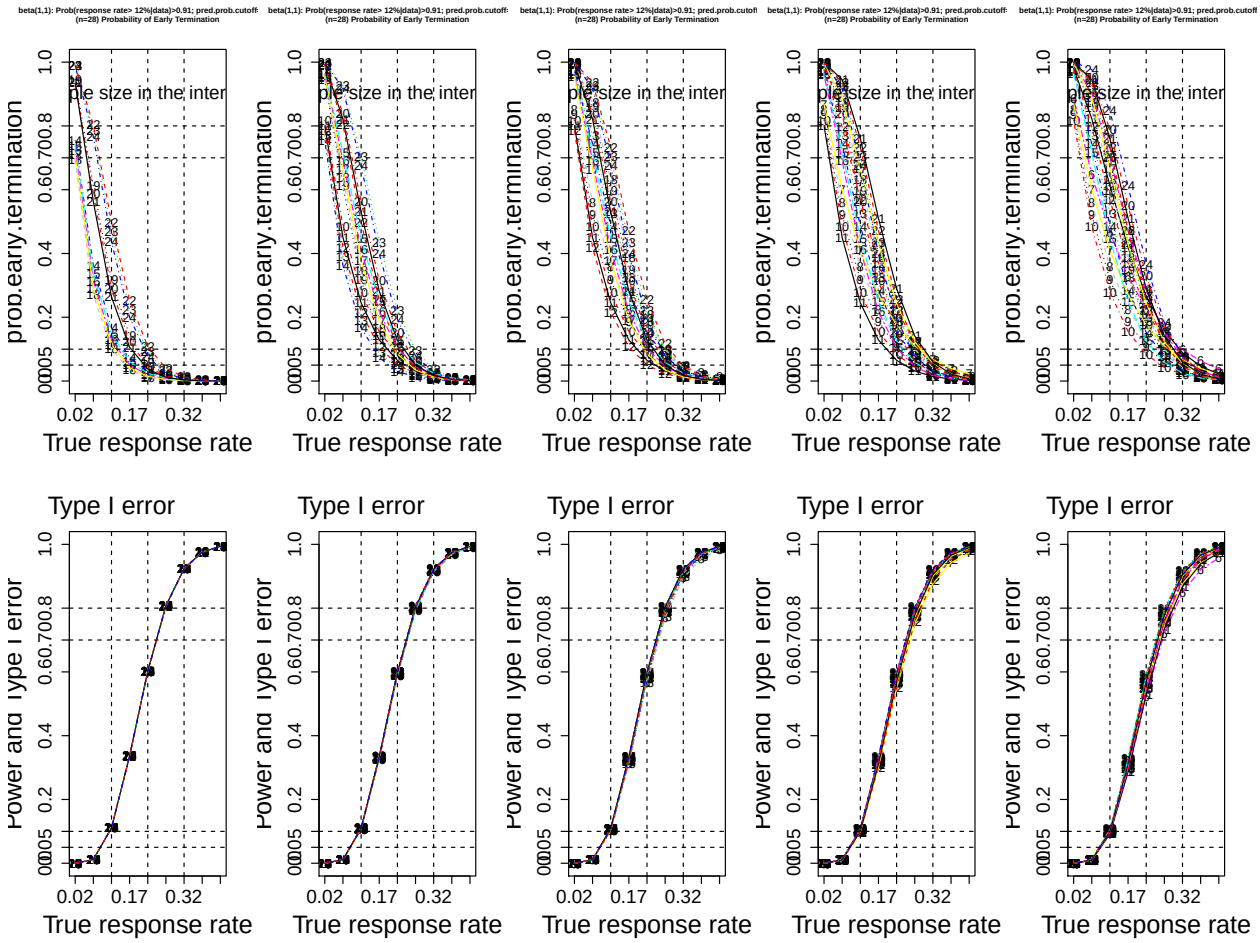
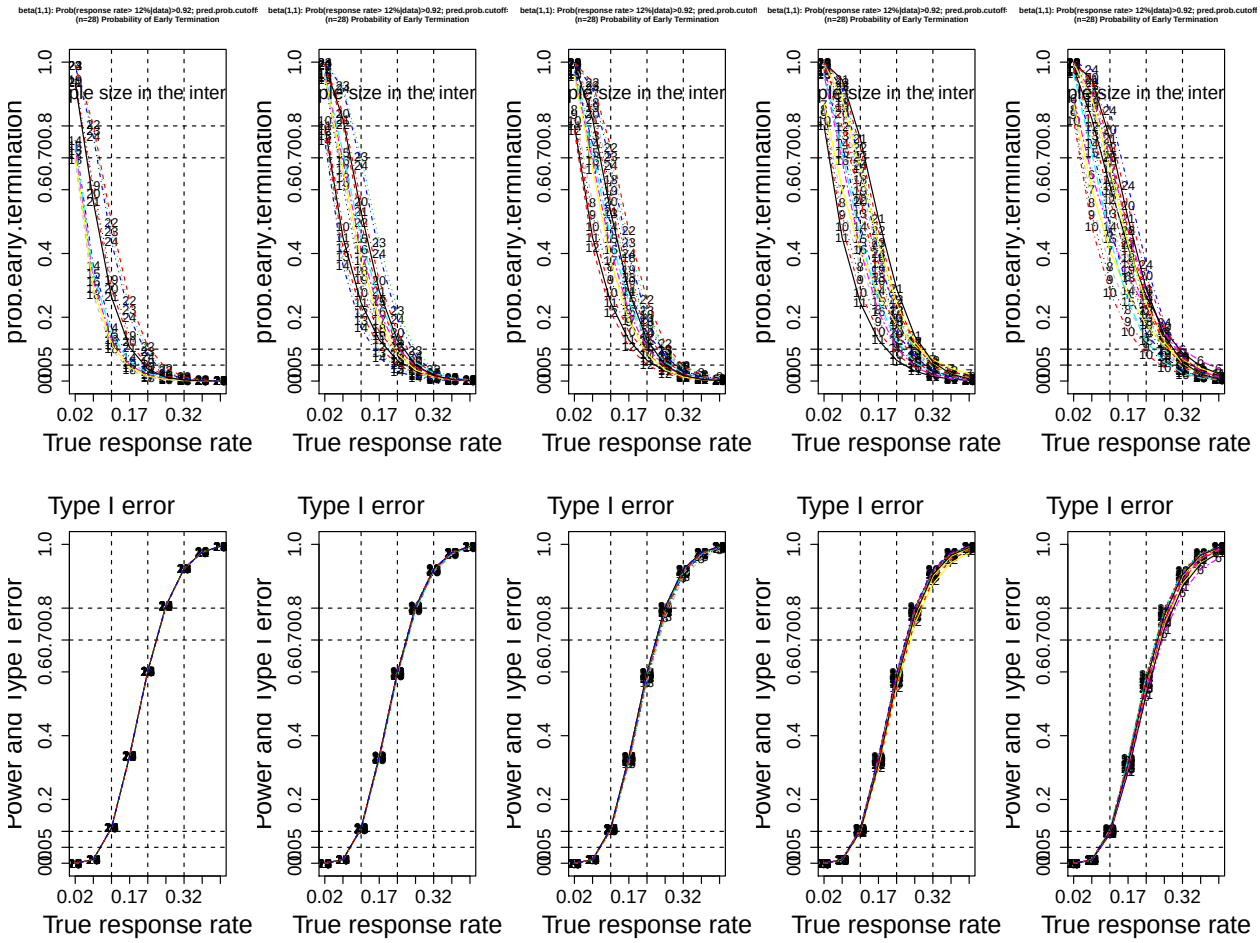
(n=28) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02 0.17 0.32
0.0 0.2 0.4 0.6 0.7 0.8 1.0


beta(1,1): Prob(response rate> 12%|data)>0.91; pred.prob.cutoff
(n=28) Probability of Early Termination
prob.early.termination
ple size in the inter
True response rate
Type I error
Power and Type I error
0.02
0.17
0.32
0.0
0.2
0.4
0.6
0.8
1.0


beta(1,1): Prob(response rate> 12%|data)>0.92; pred.prob.cutoff
(n=28) Probability of Early Termination
prob.early.termination
Power and Type I error
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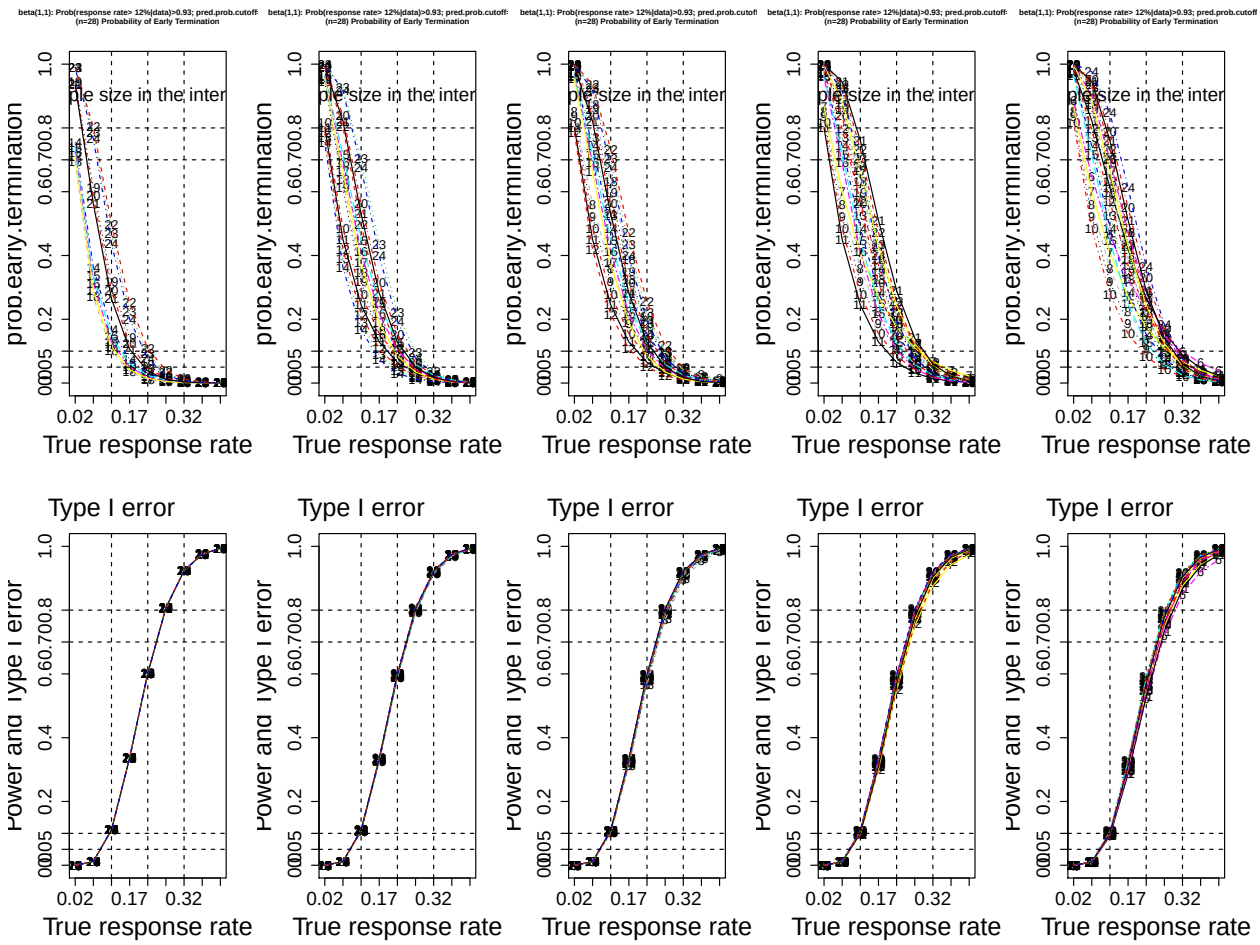
beta(1,1): Prob(response rate> 12%|data)>0.93; pred.prob.cutoff
(n=28) Probability of Early Termination
prob.early.termination
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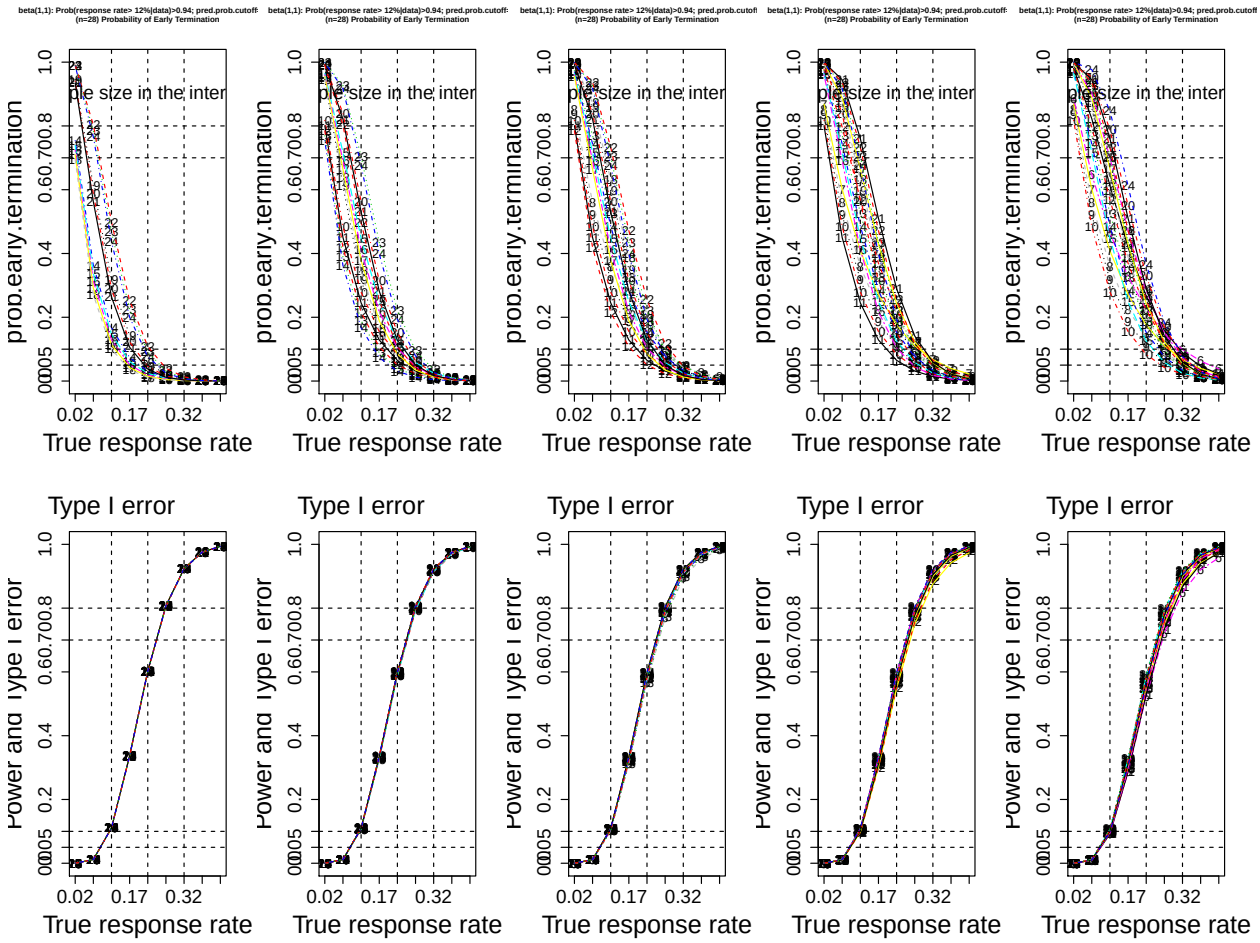
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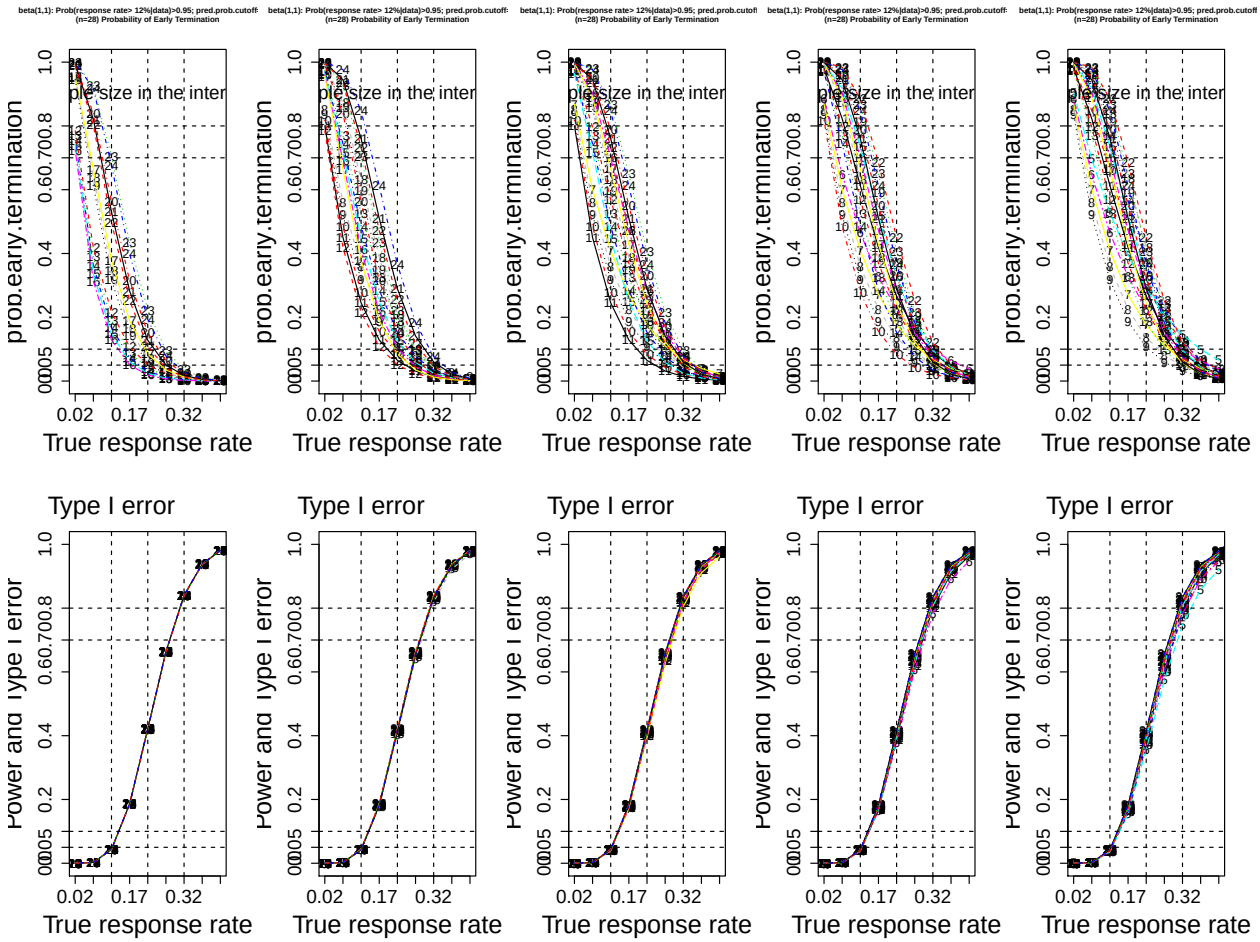
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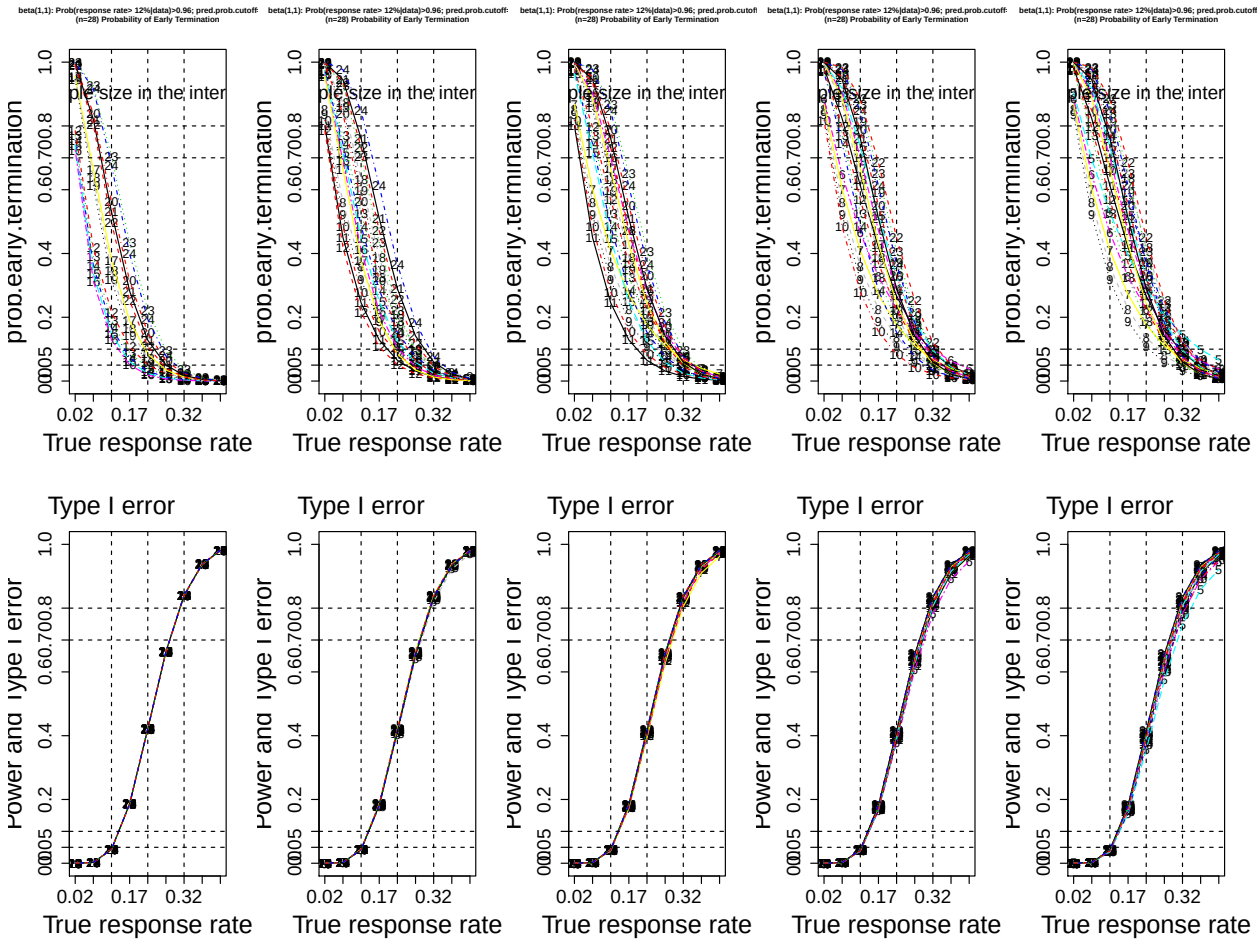
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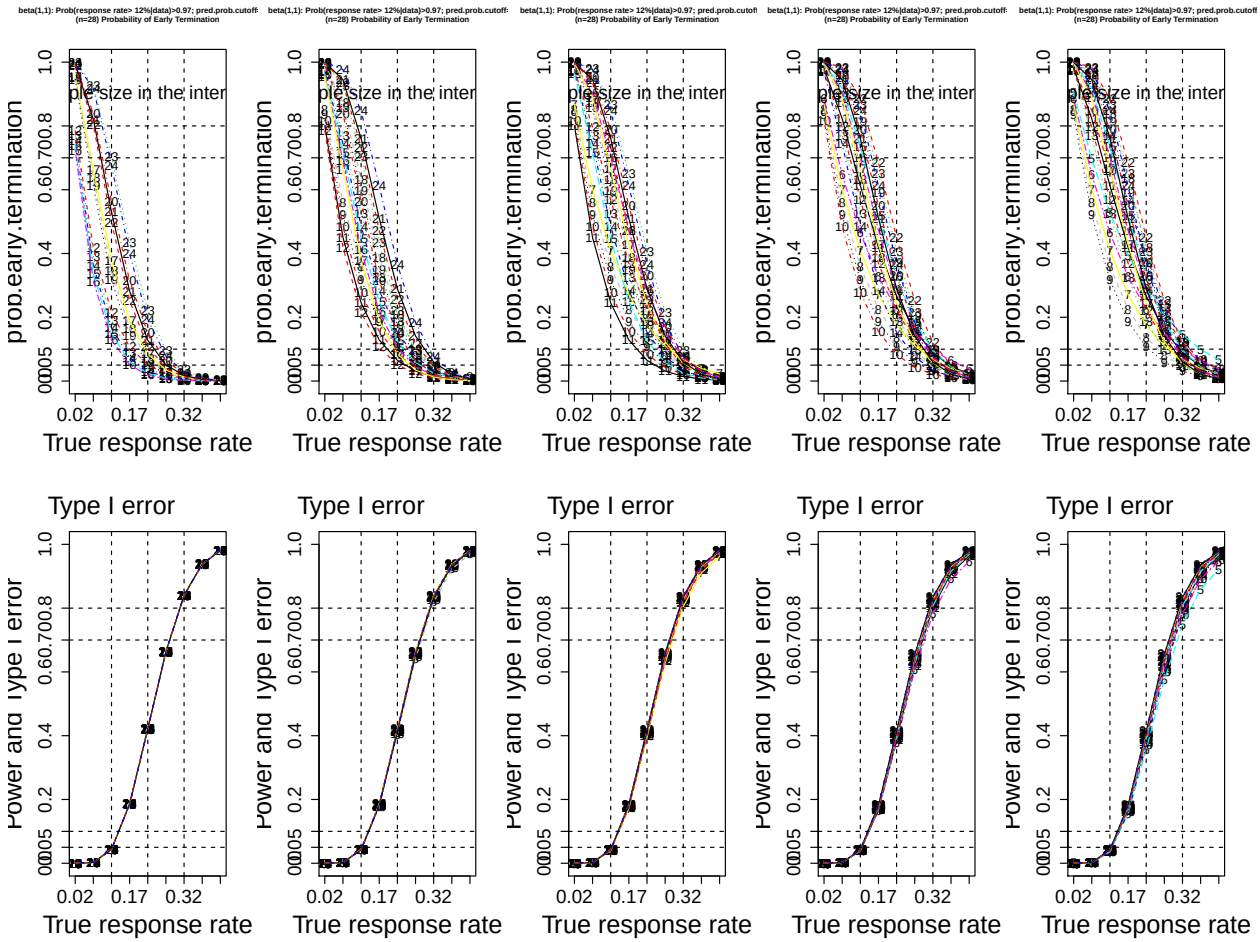
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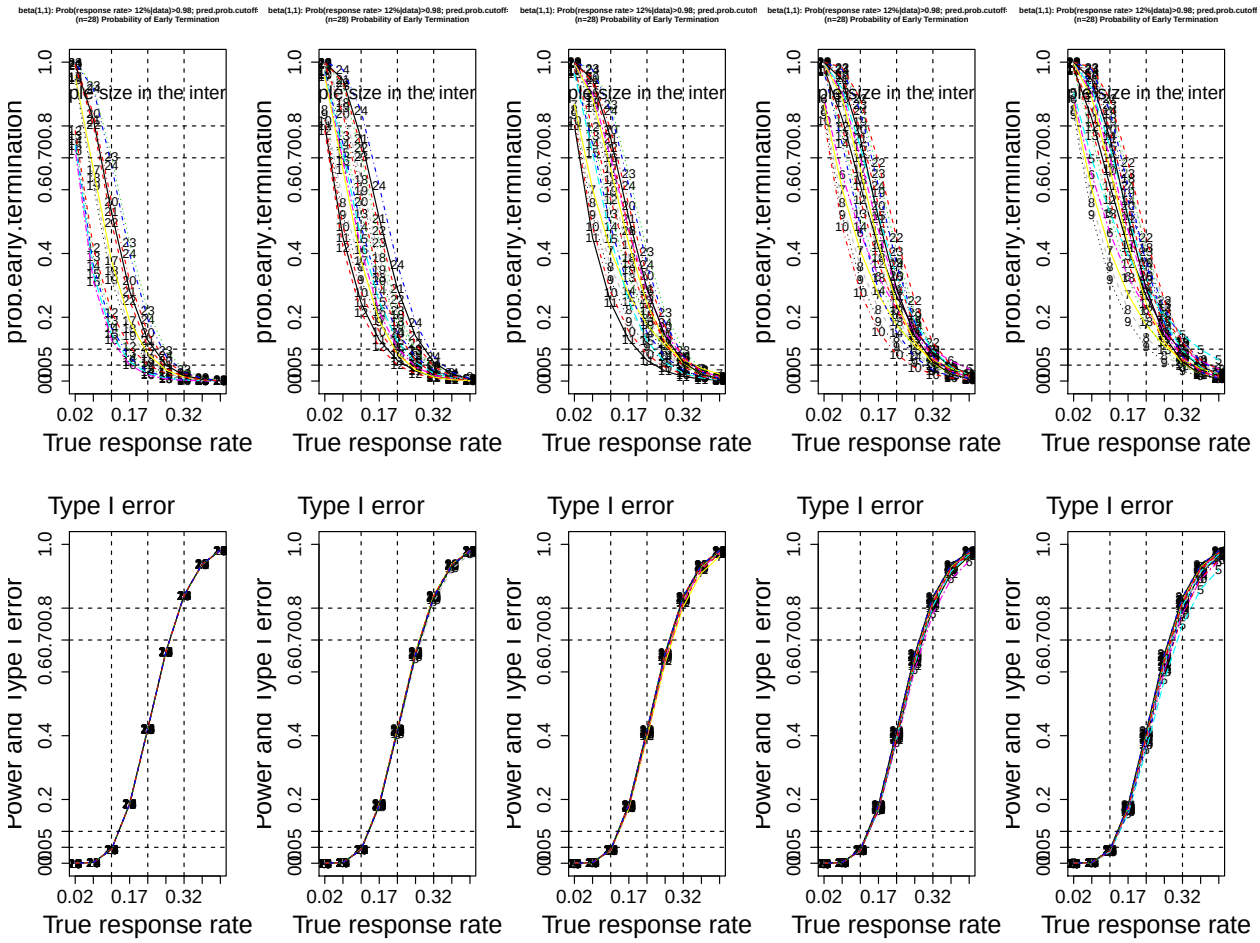
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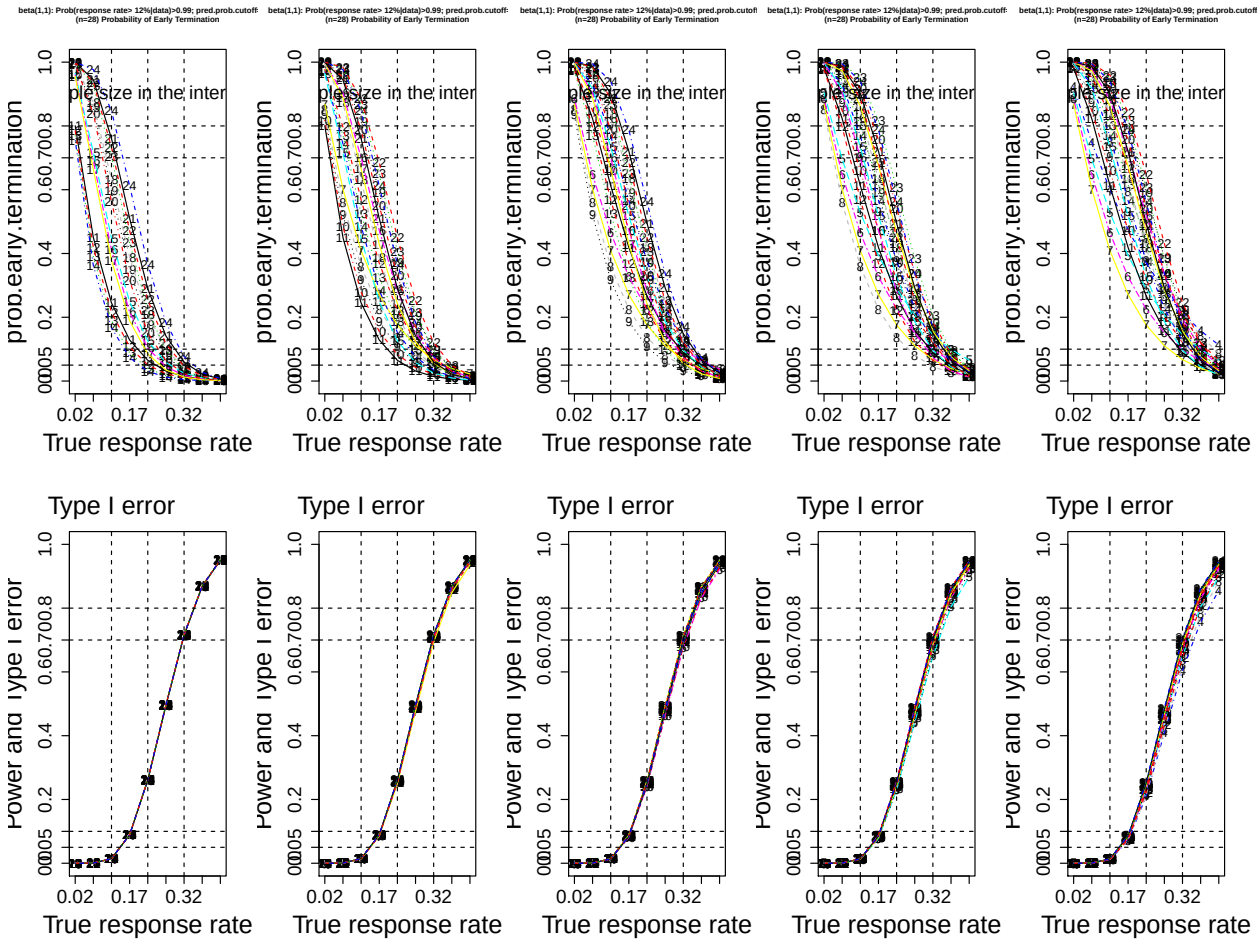
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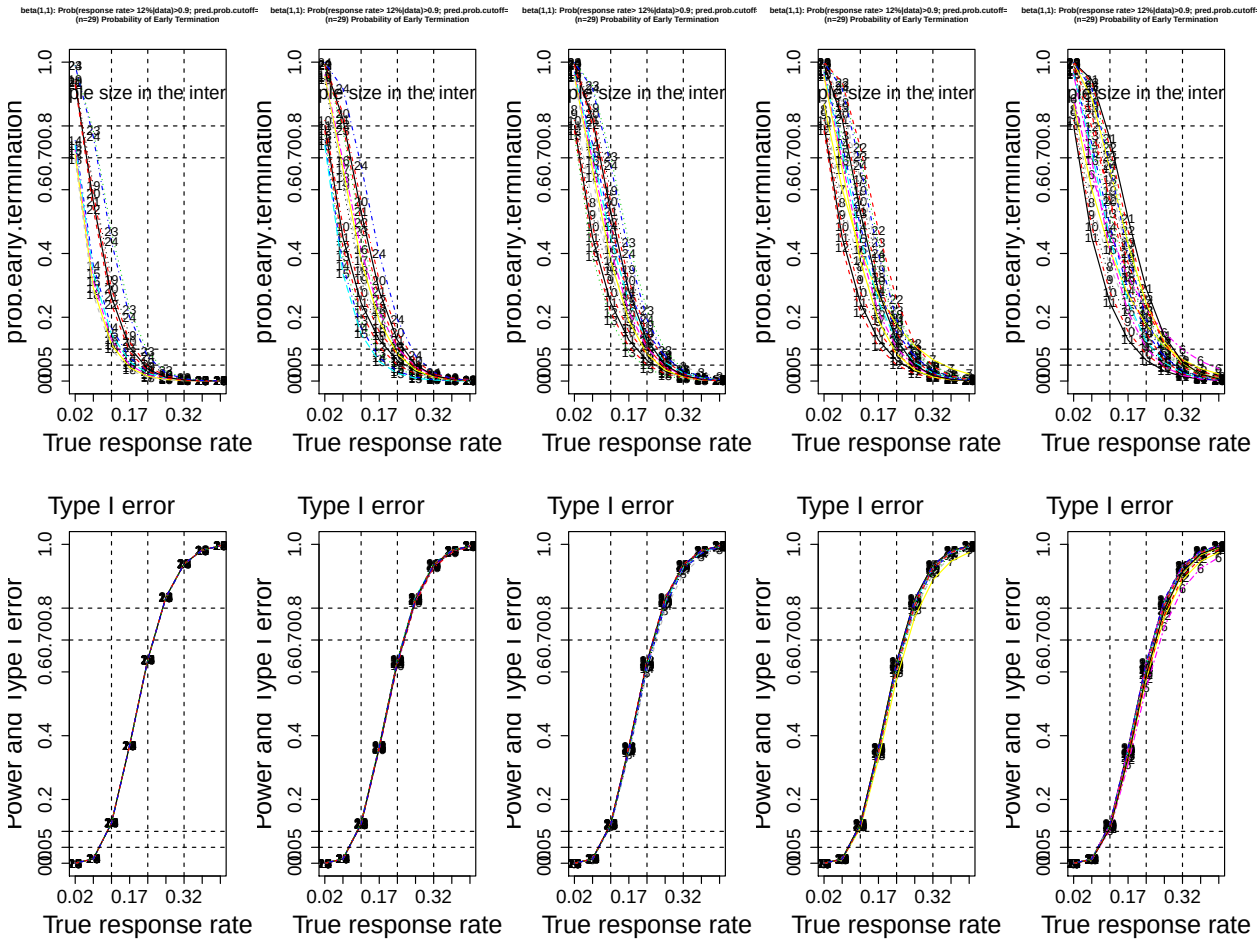
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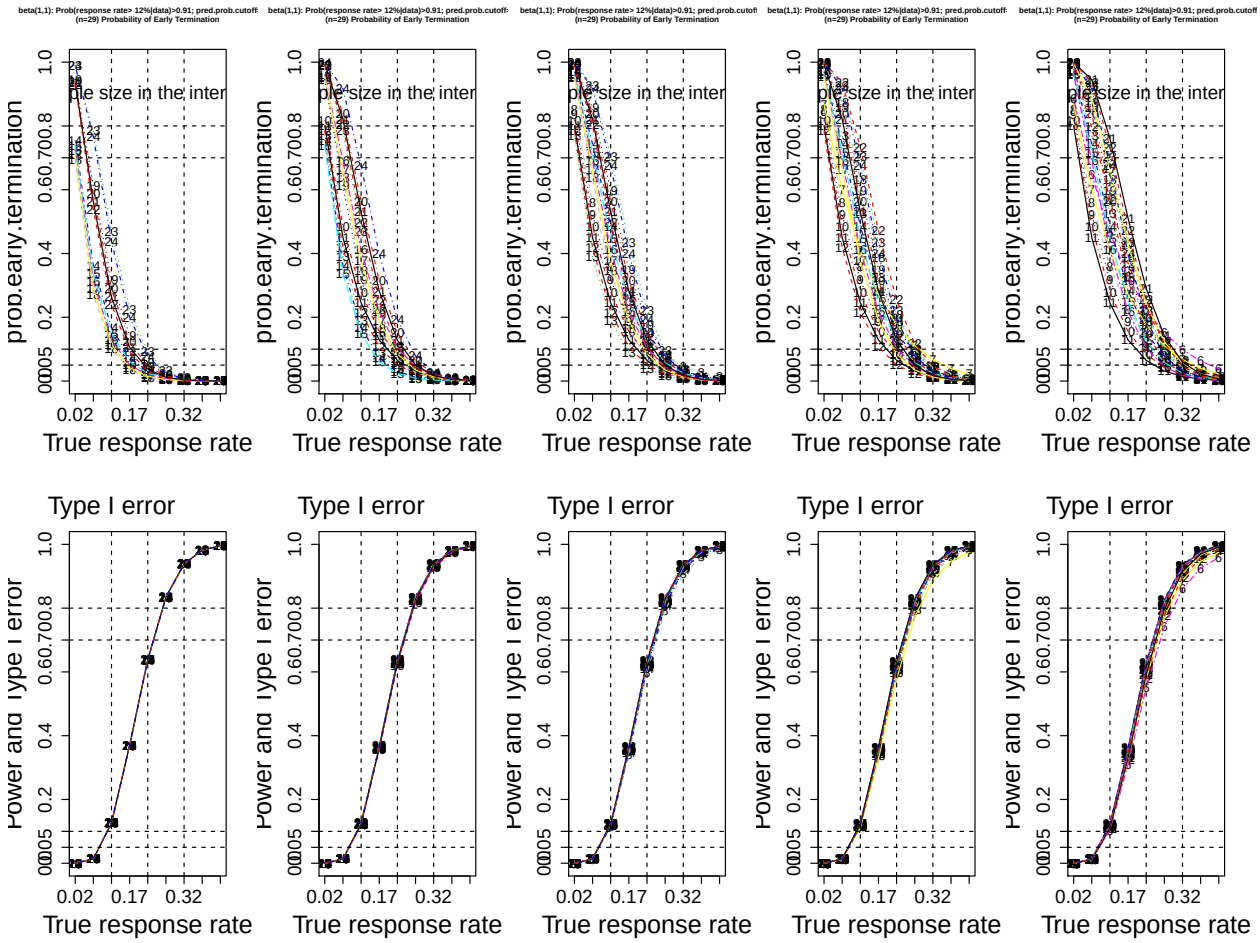
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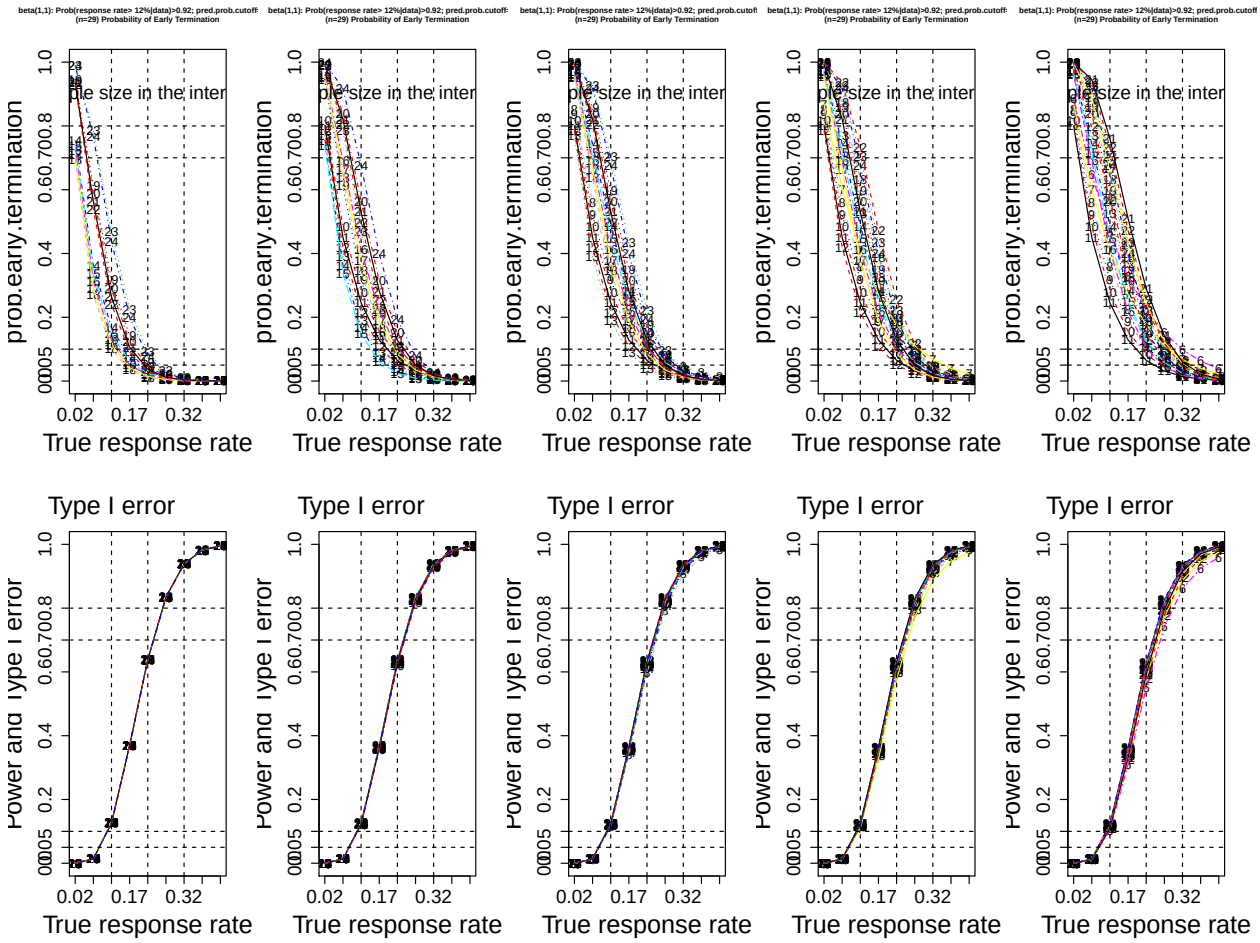
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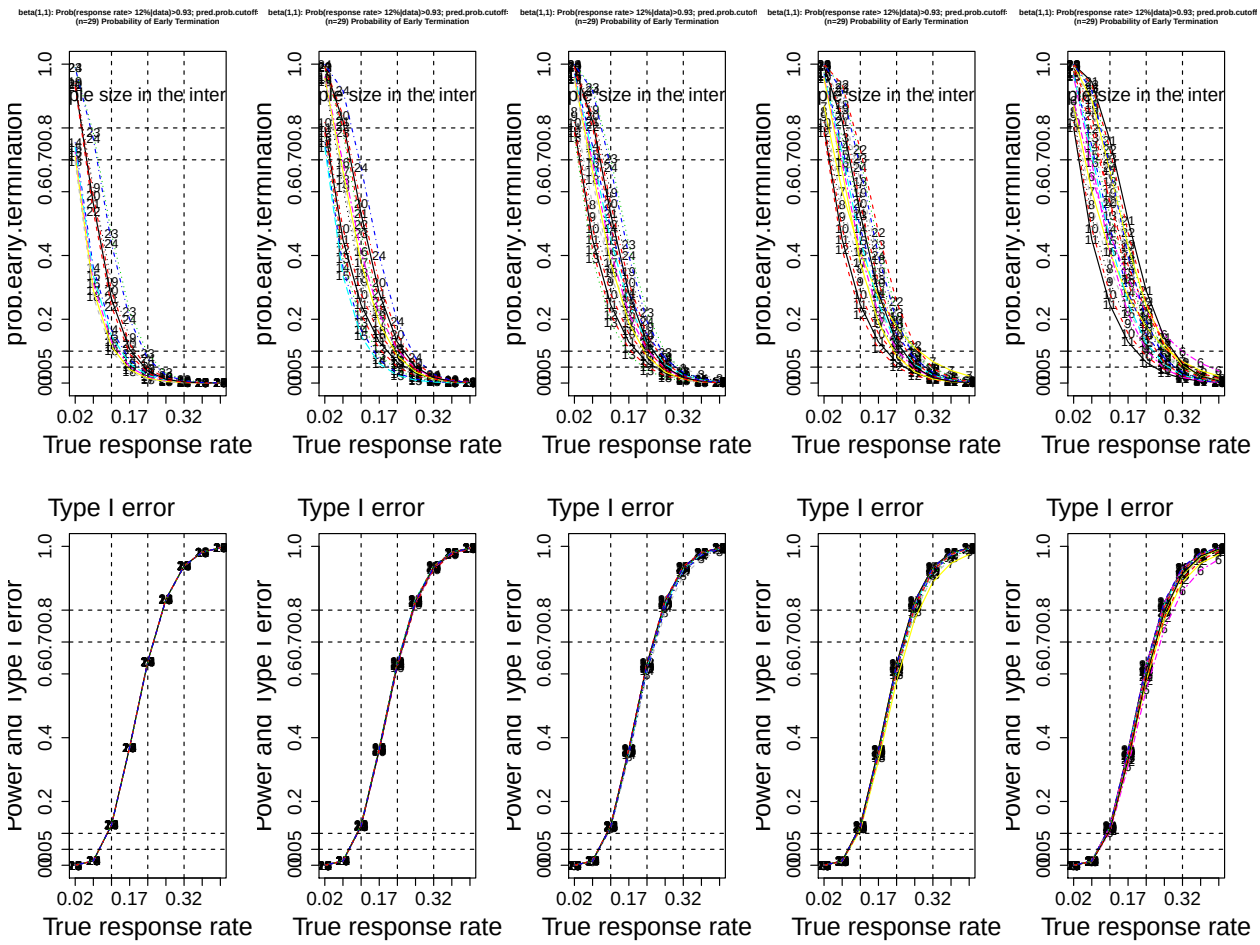
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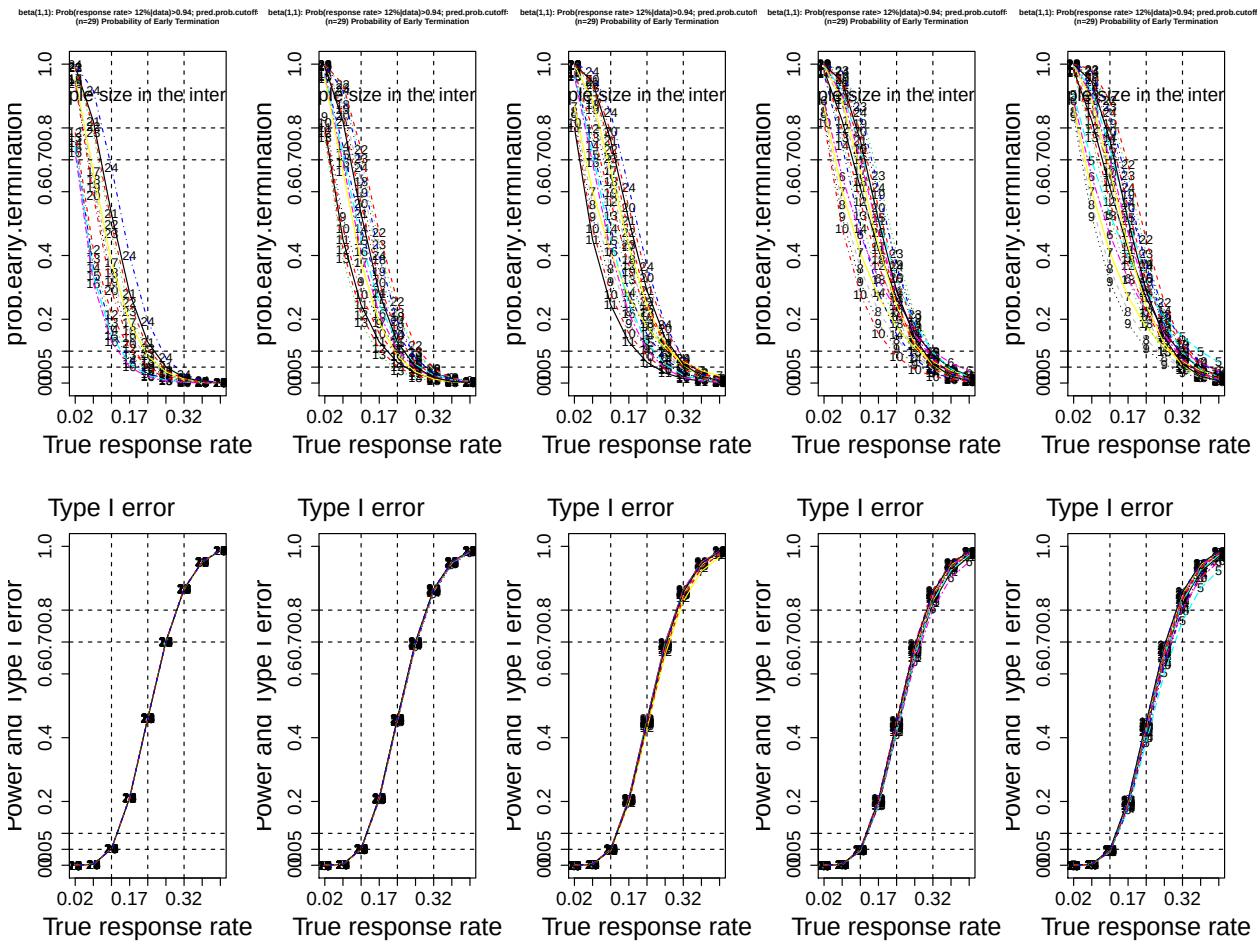
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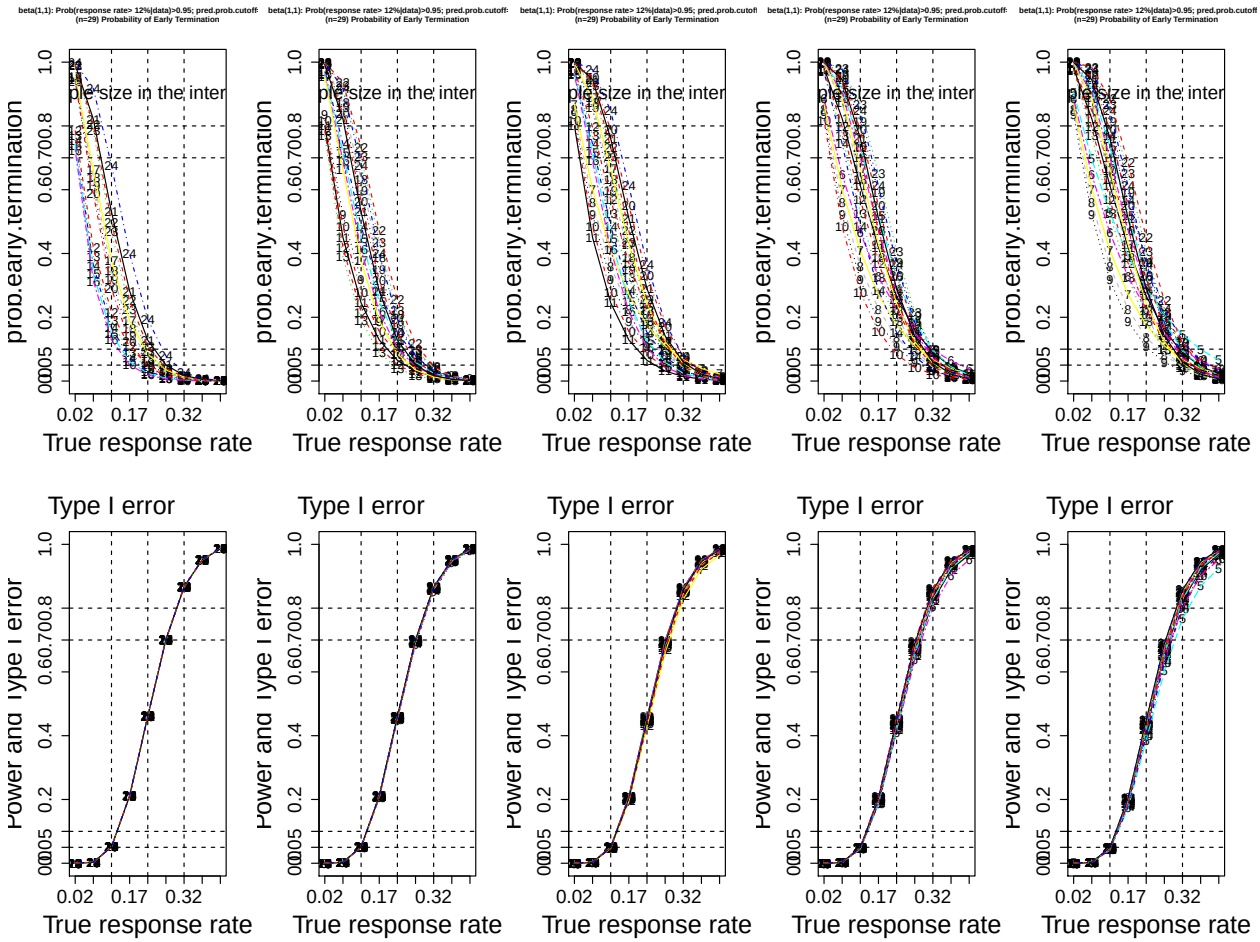
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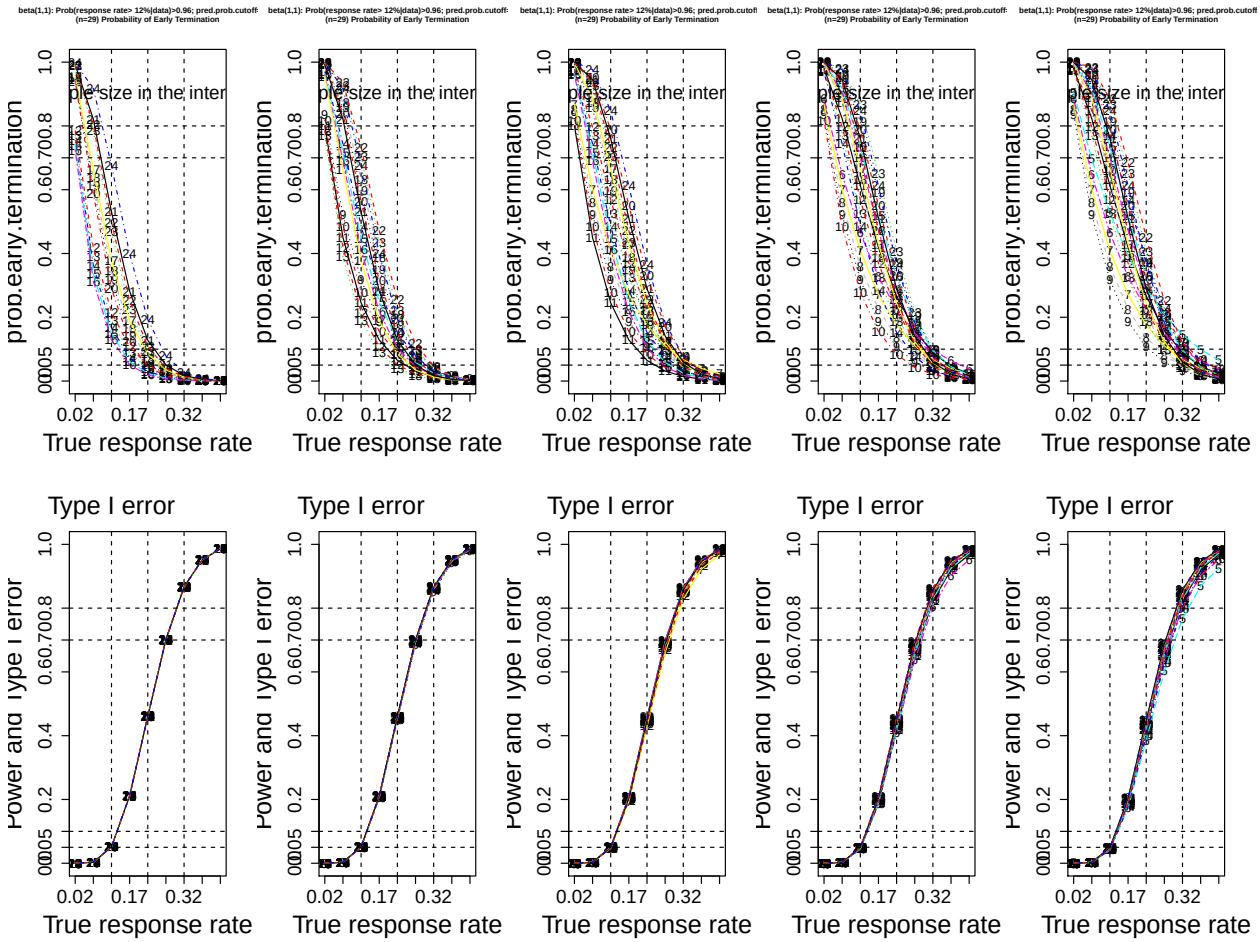
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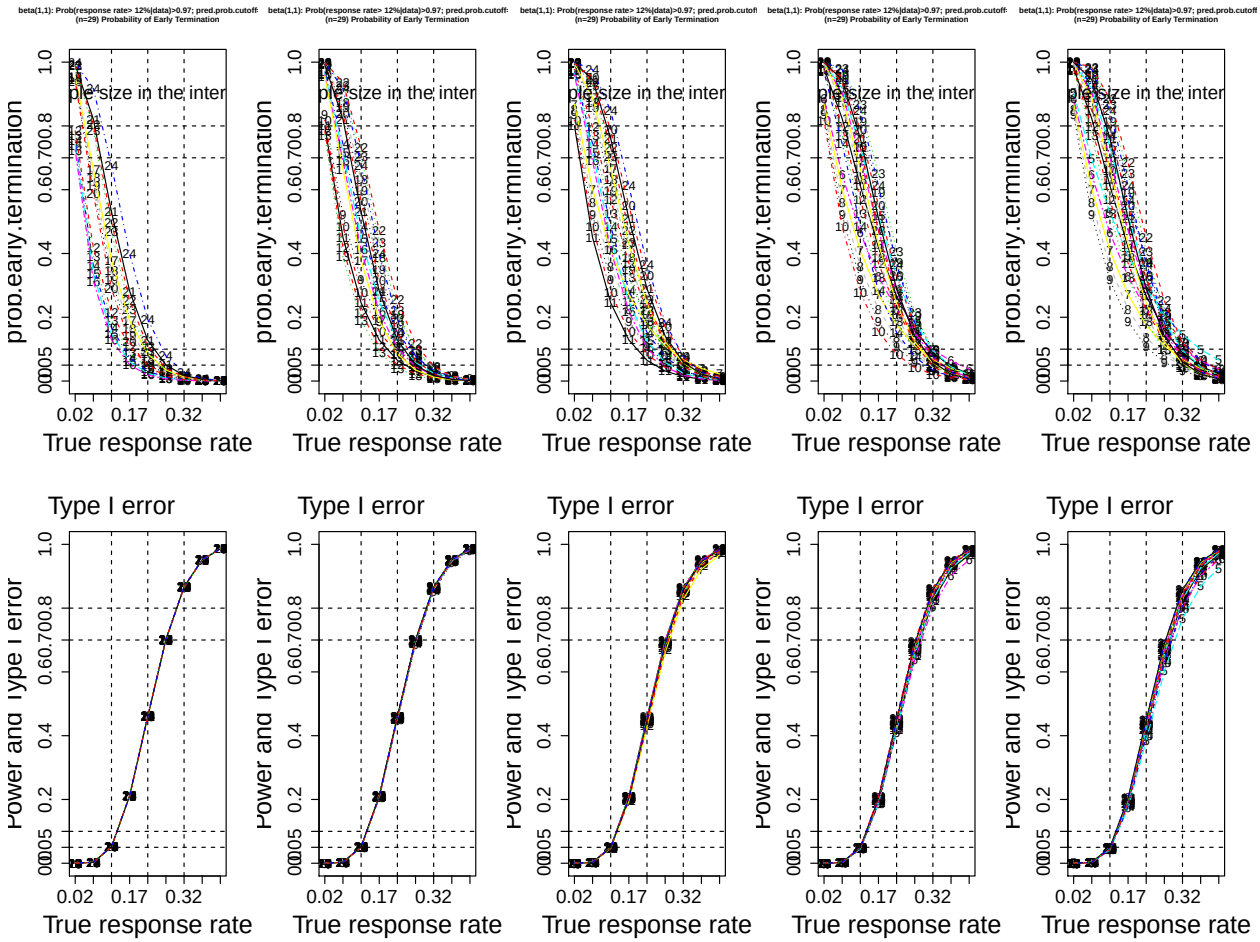
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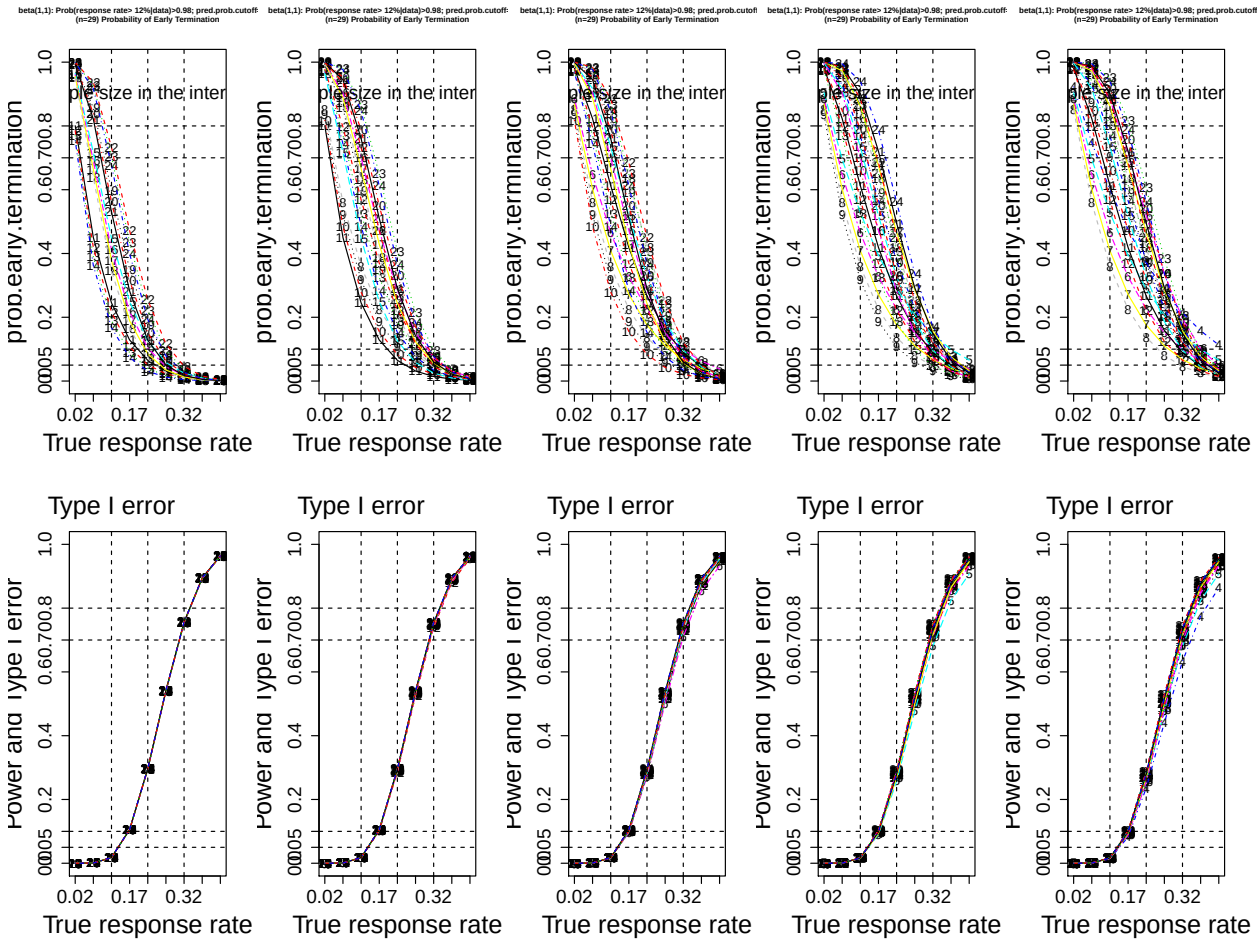
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prob.early.termination
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Power and Type I error
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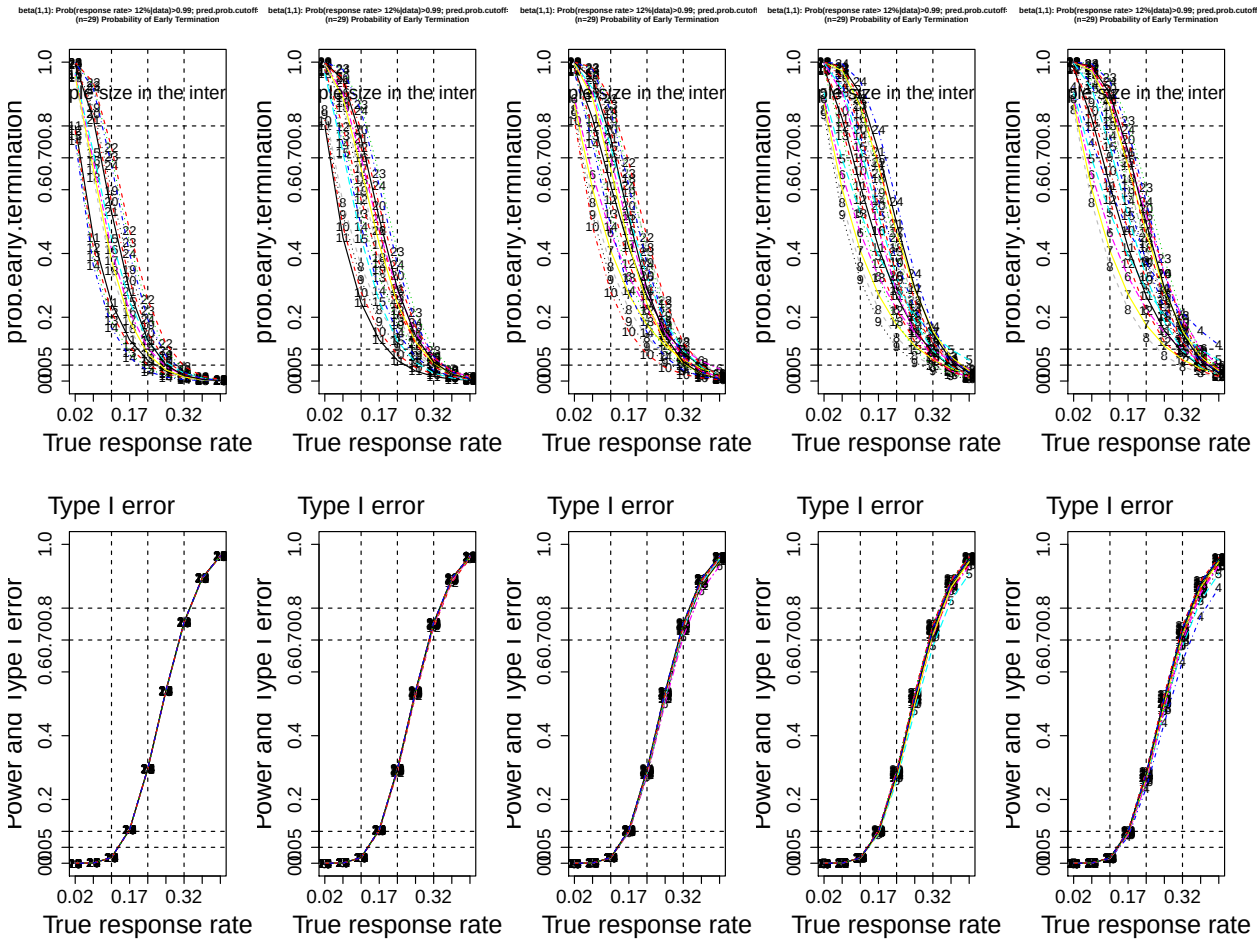
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prob.early.termination
Type I error
Power and Type I error
True response rate
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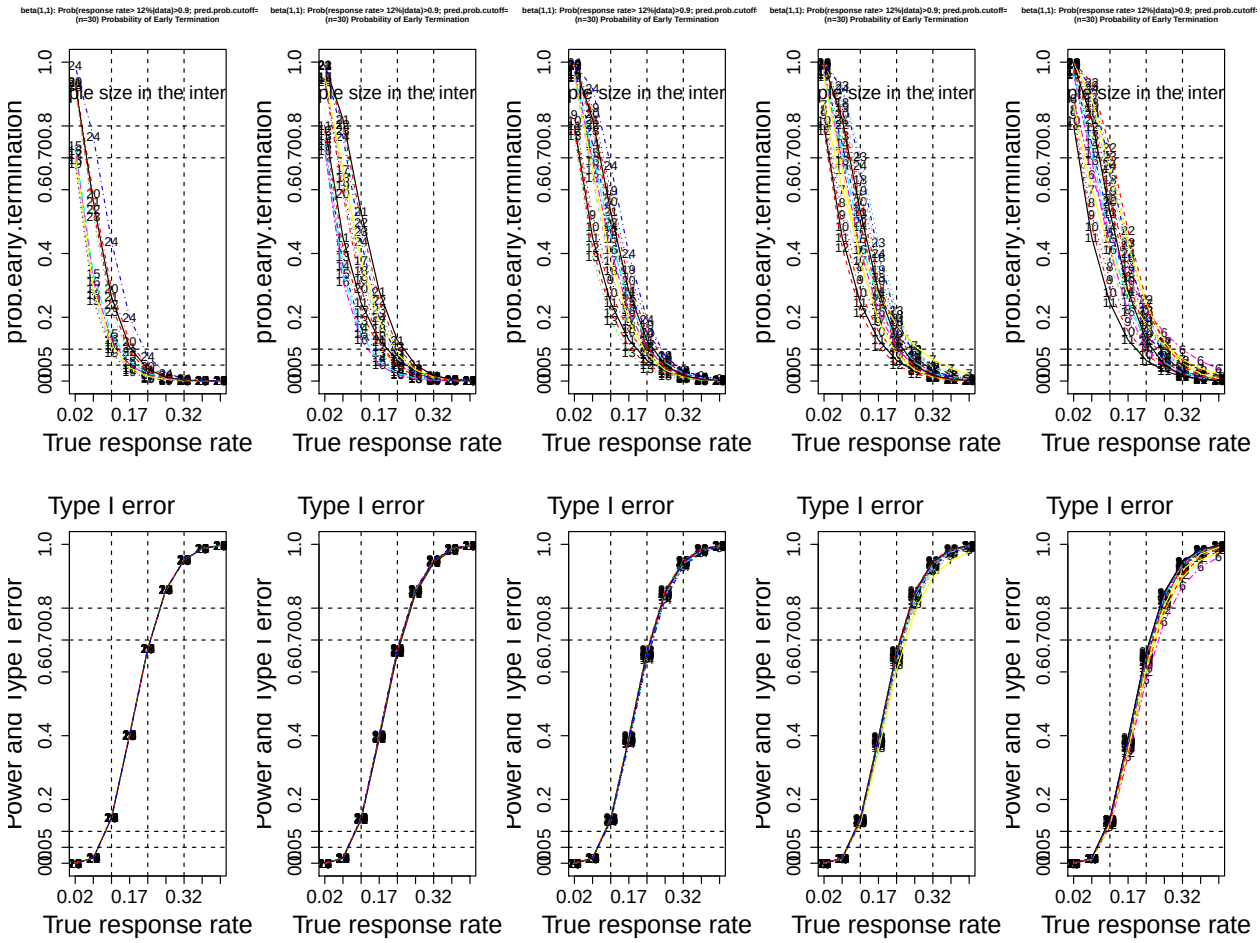
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Power and Type I error
True response rate
Type I error
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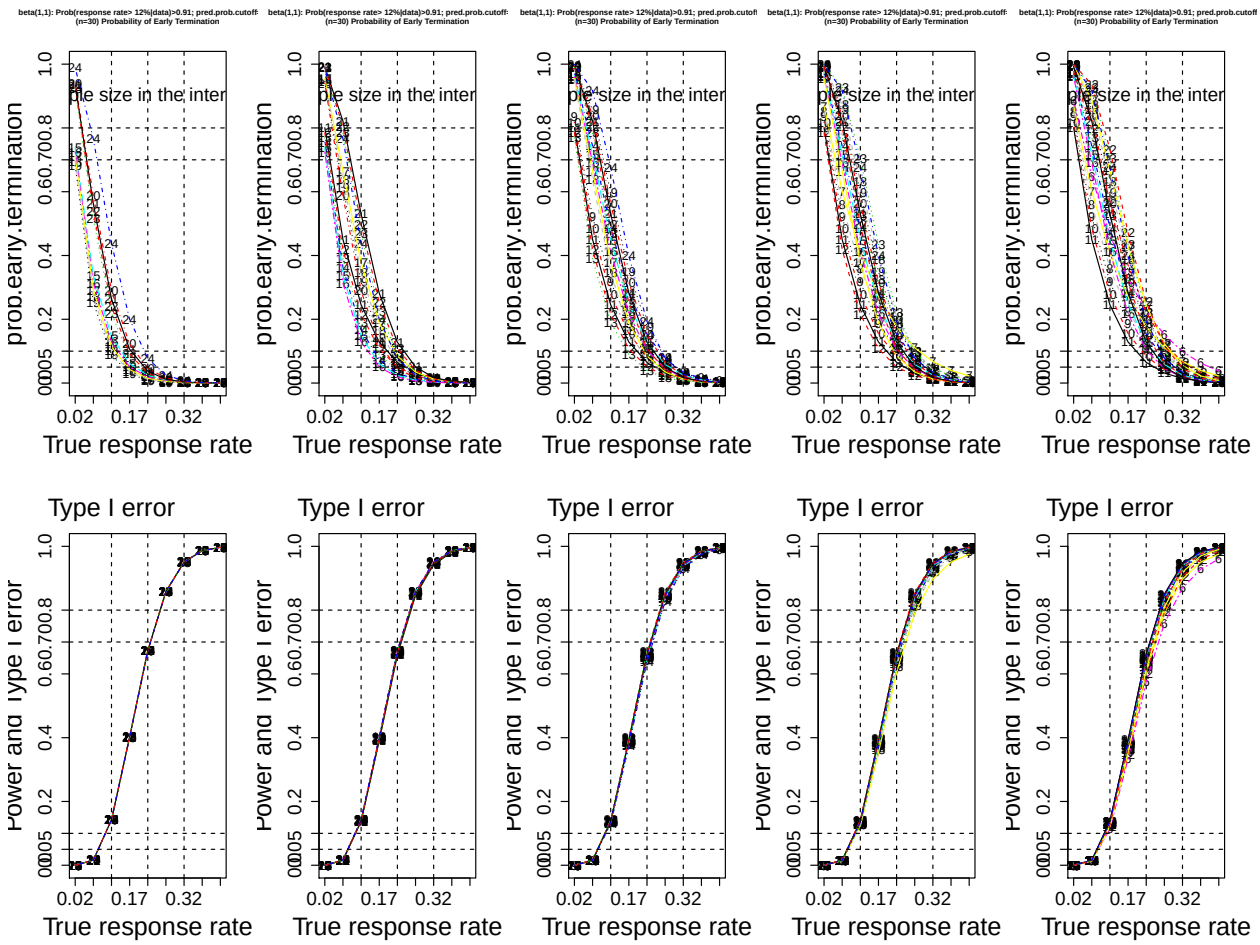
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prob.early.termination
Type I error
Power and Type I error
True response rate
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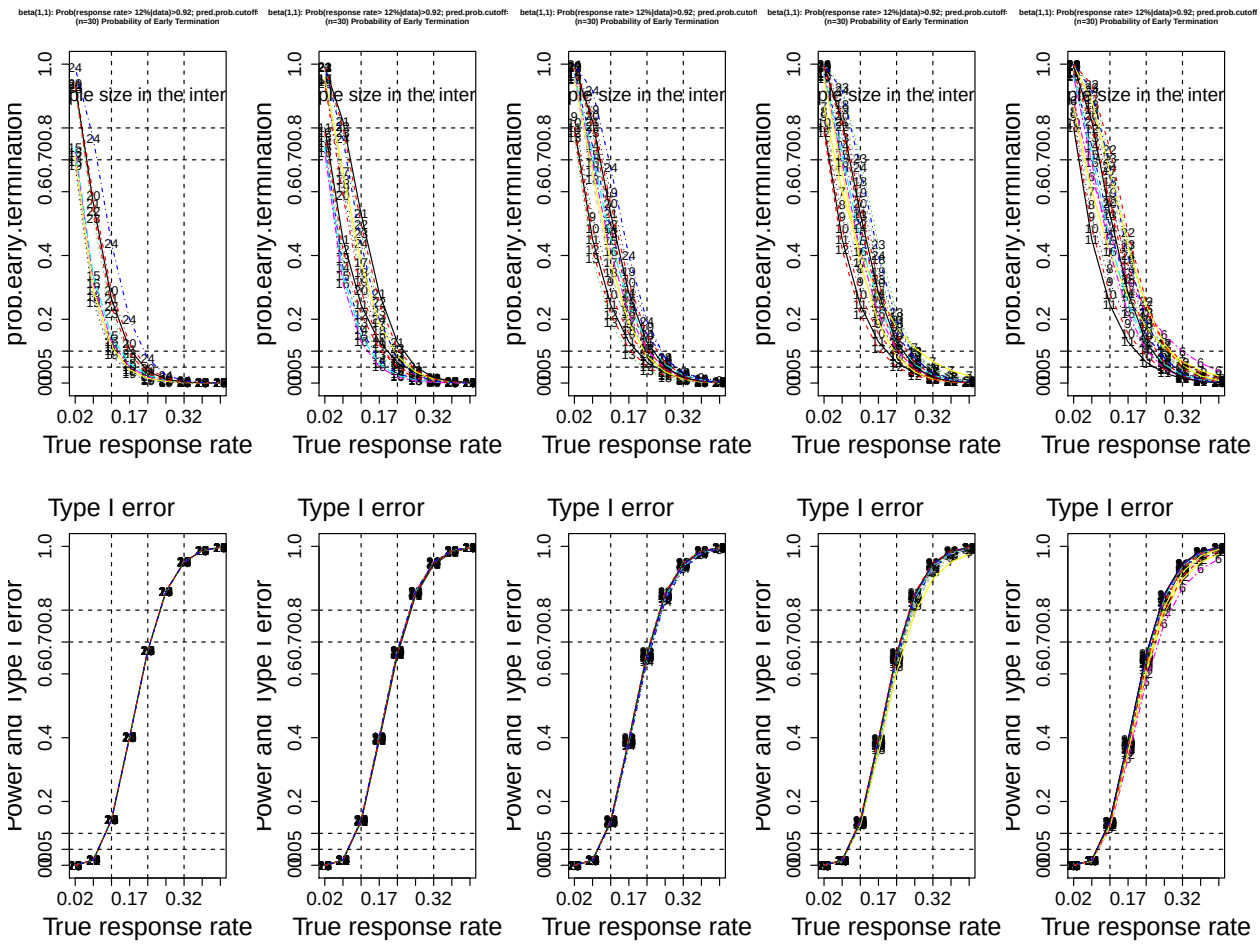
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(n=30) Probability of Early Termination
prob.early.termination
Power and Type I error
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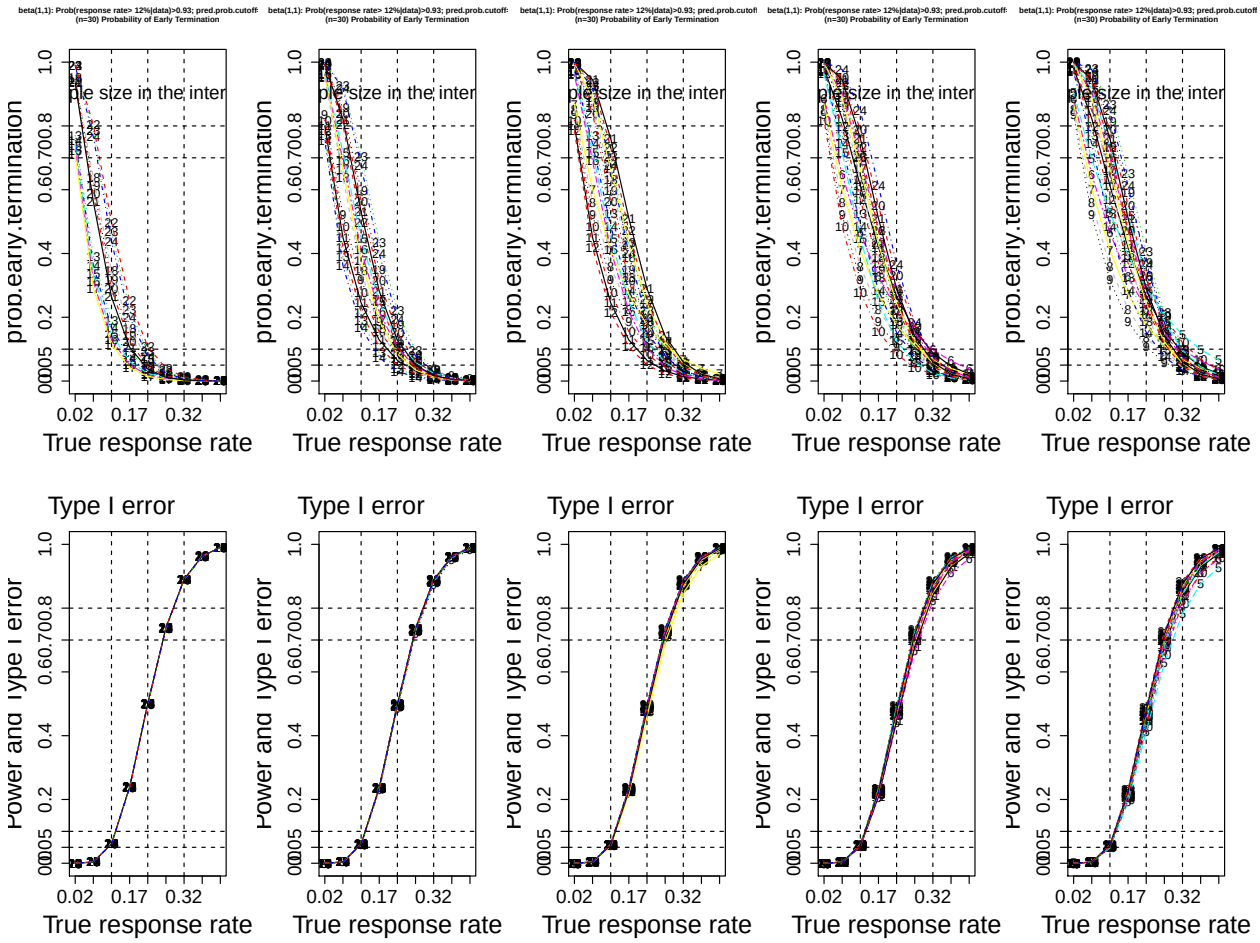
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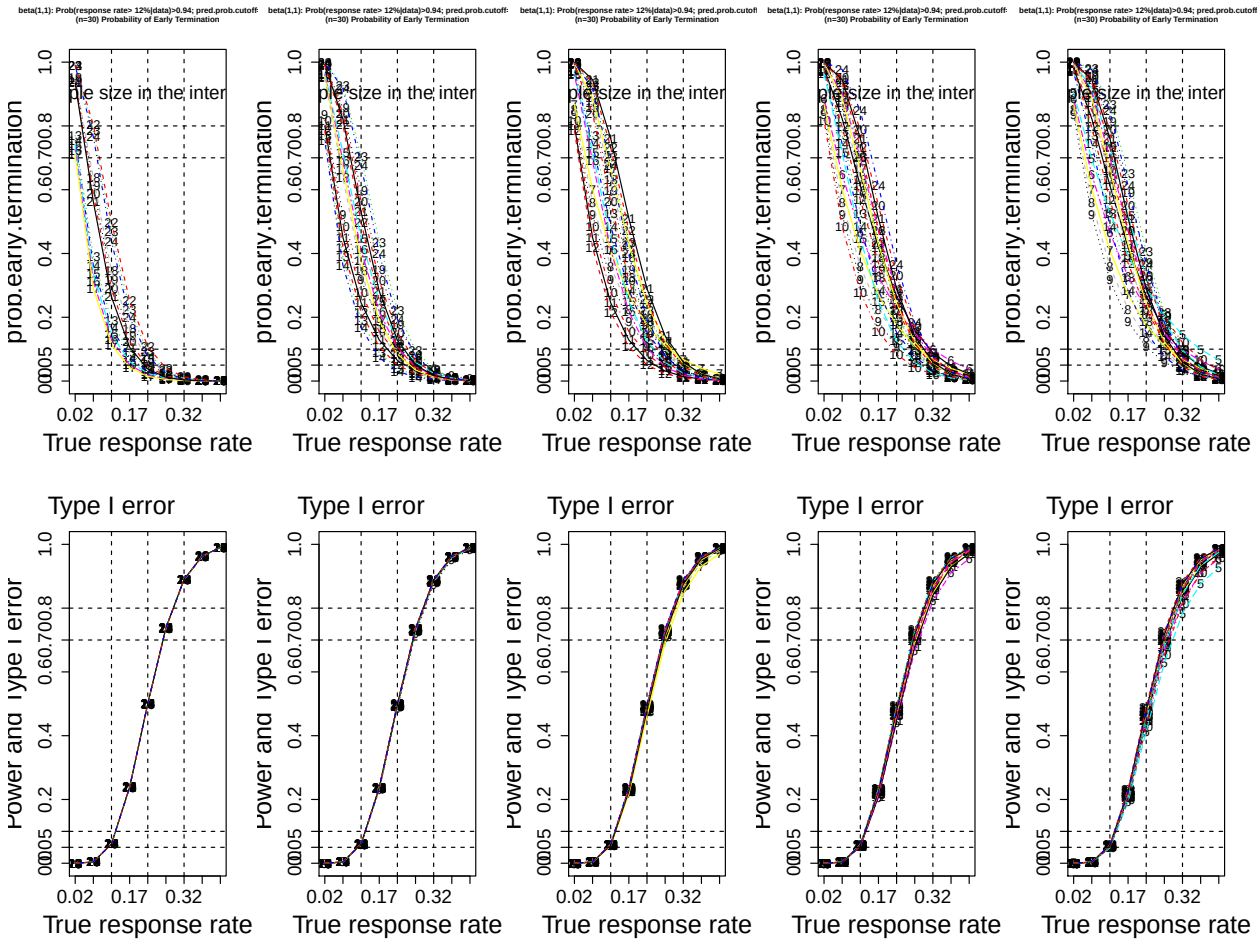
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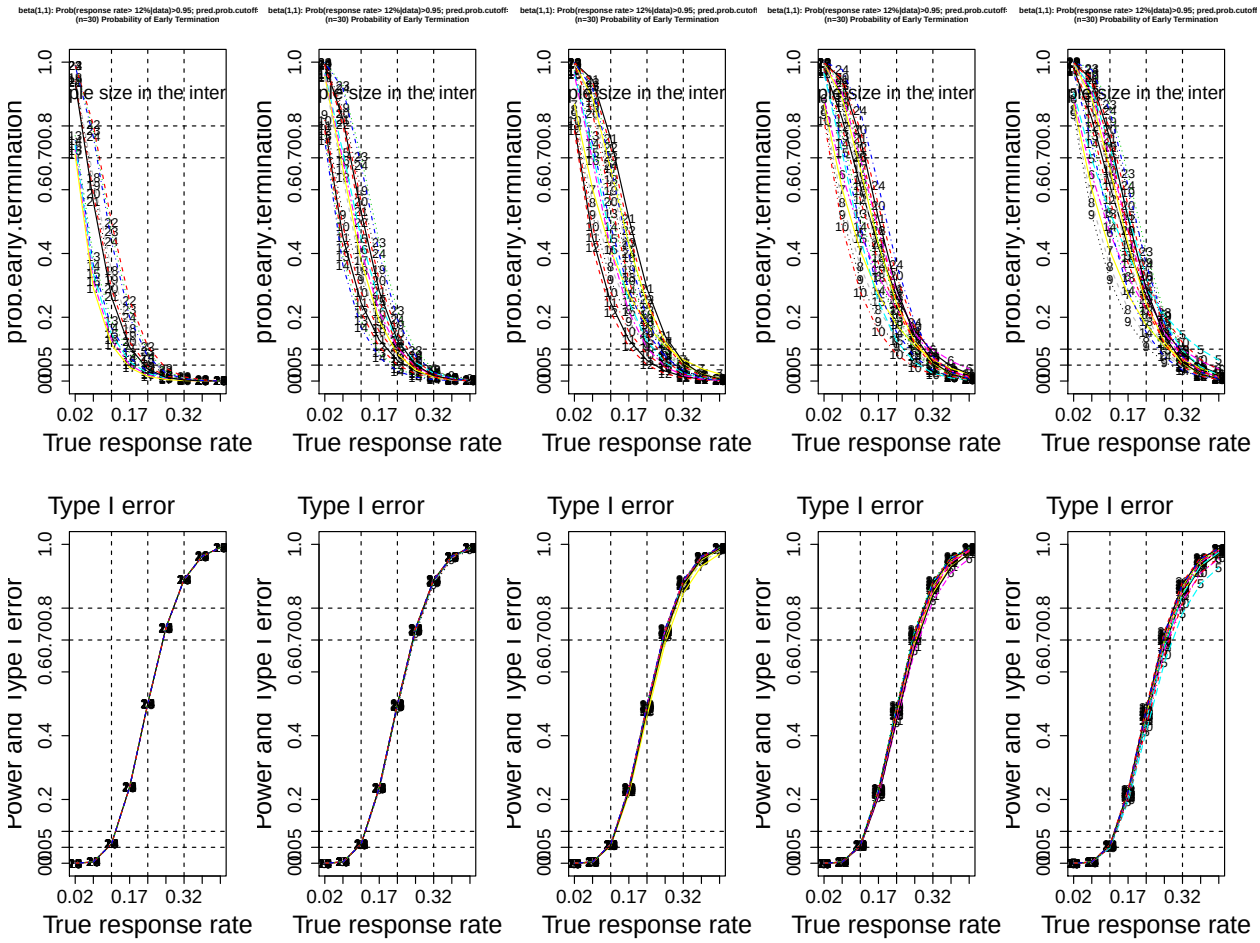
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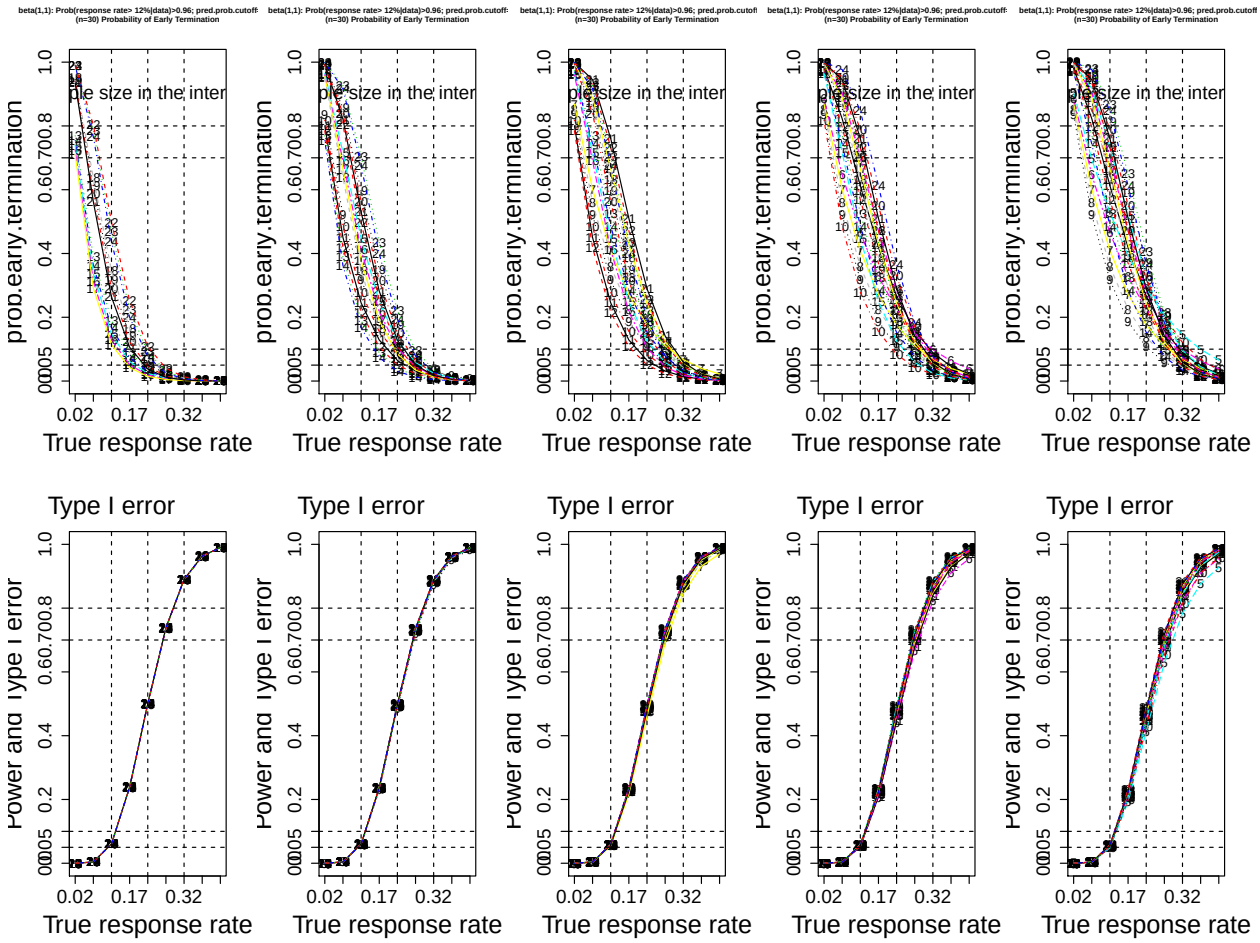
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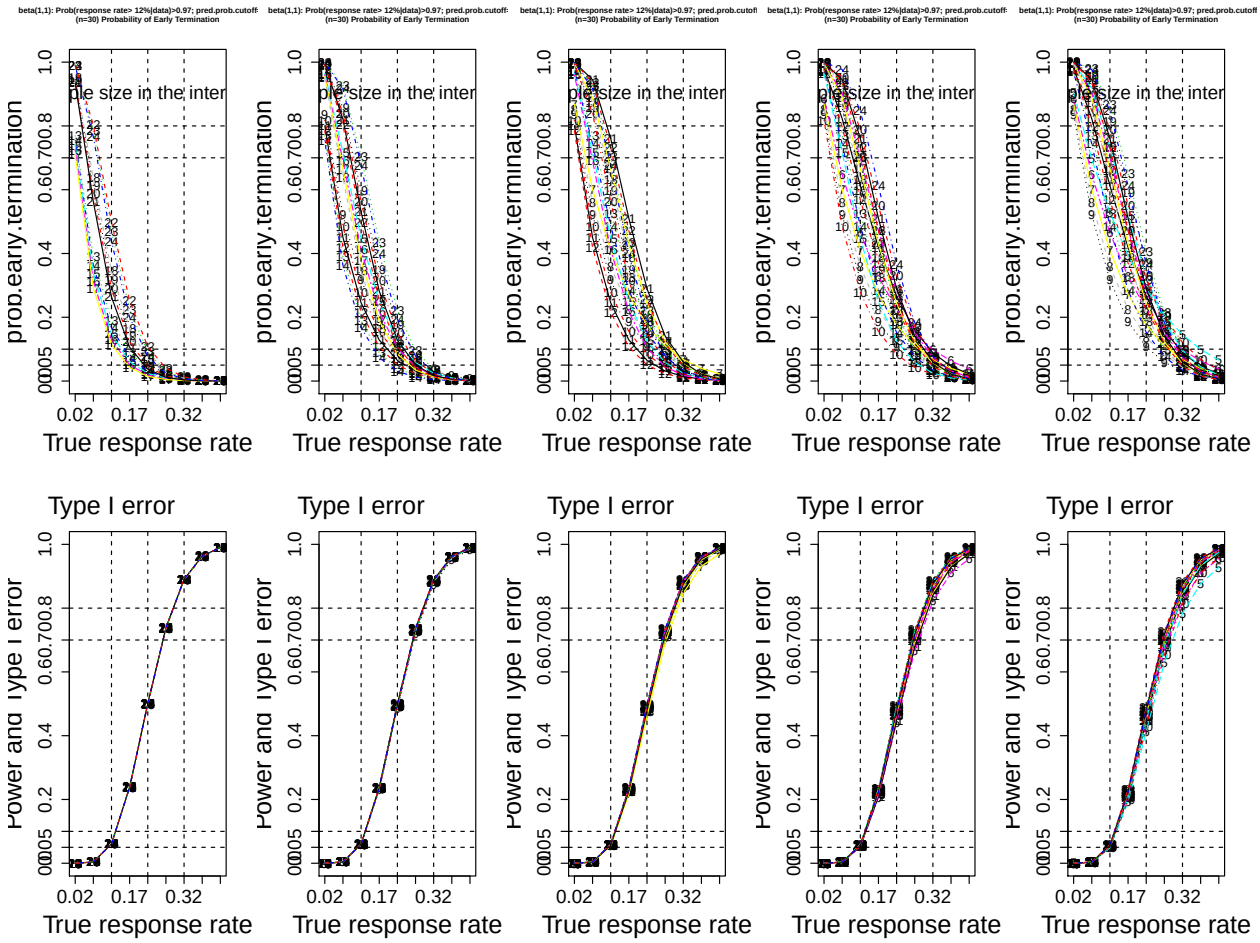
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prob.early.termination
Power and Type I error
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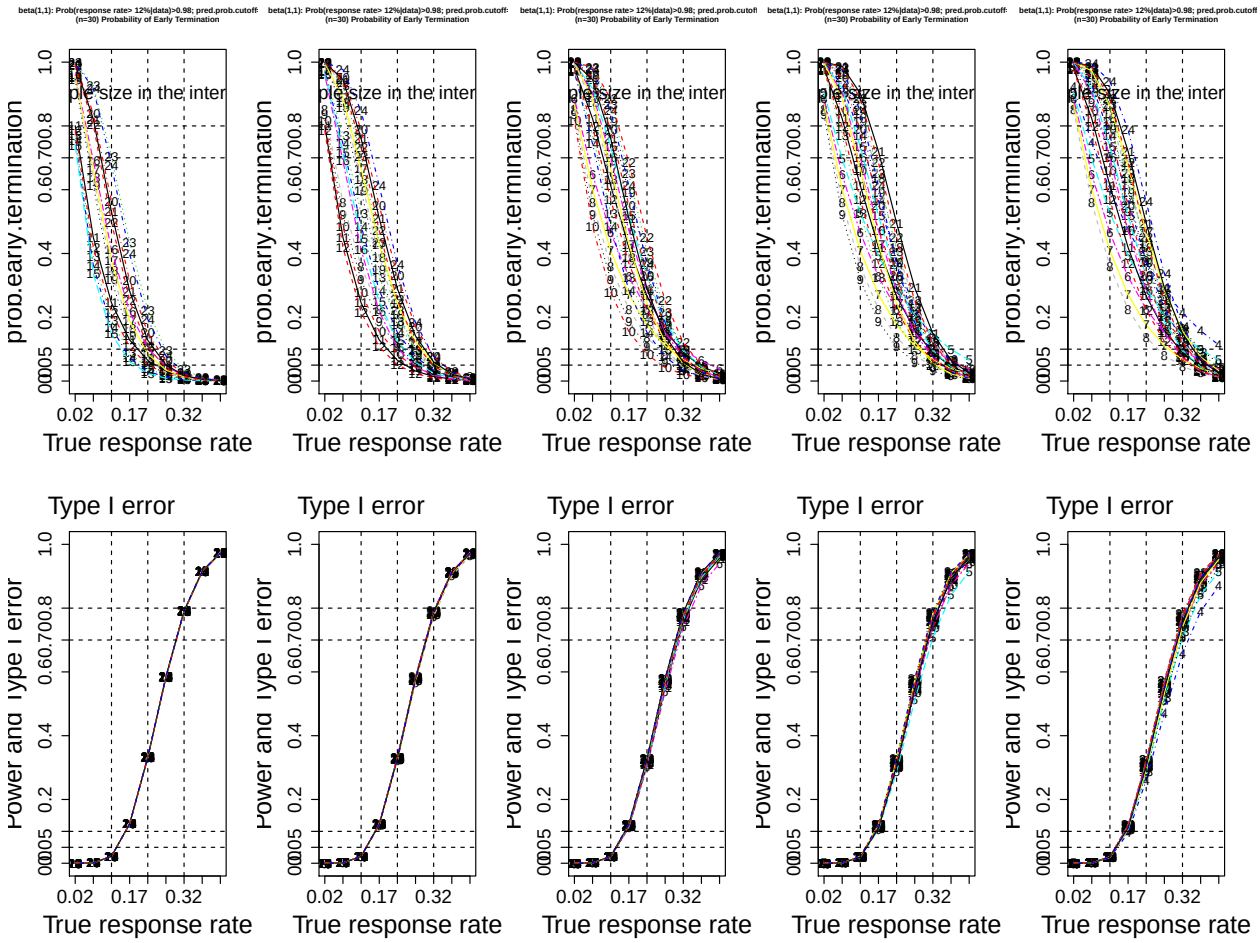
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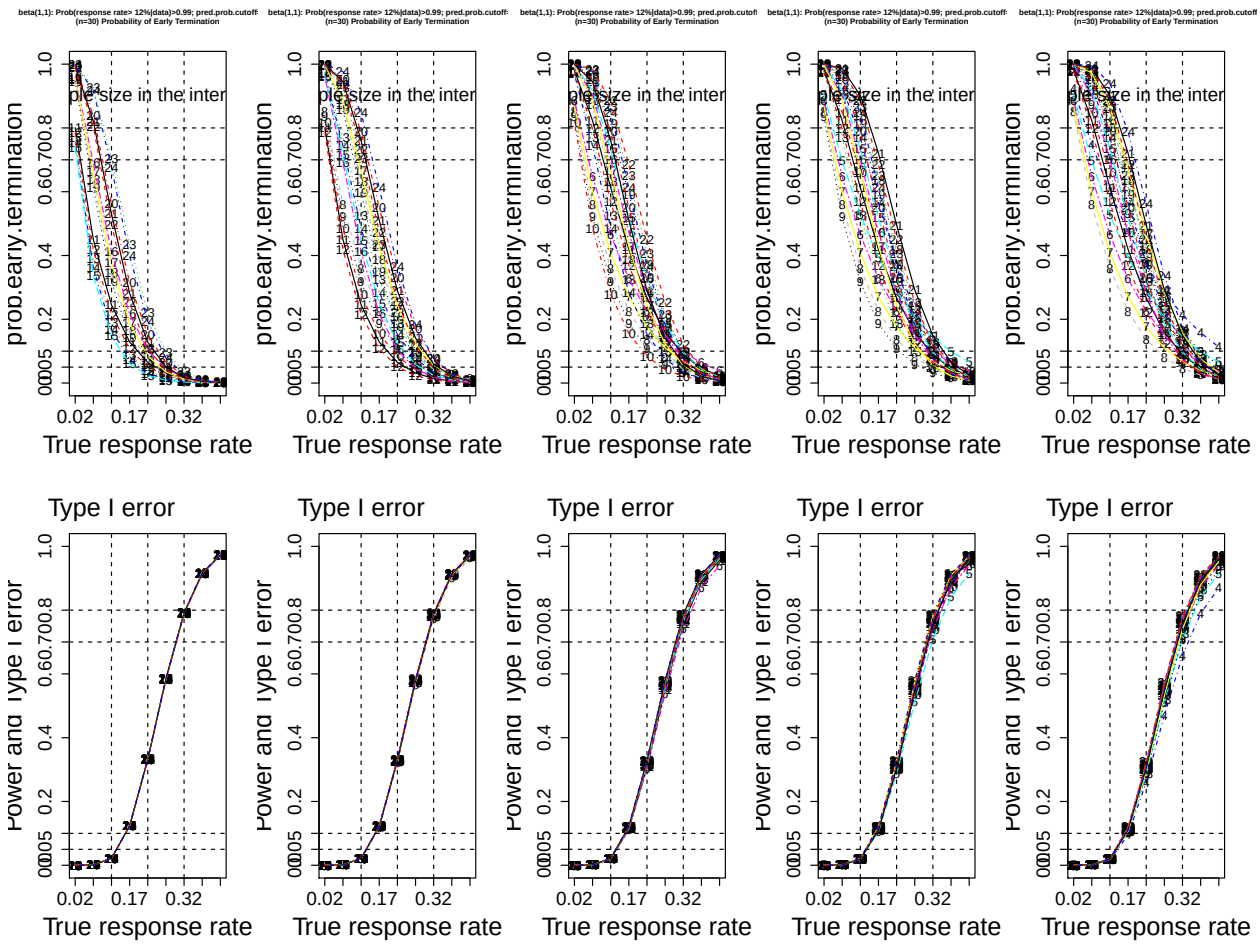
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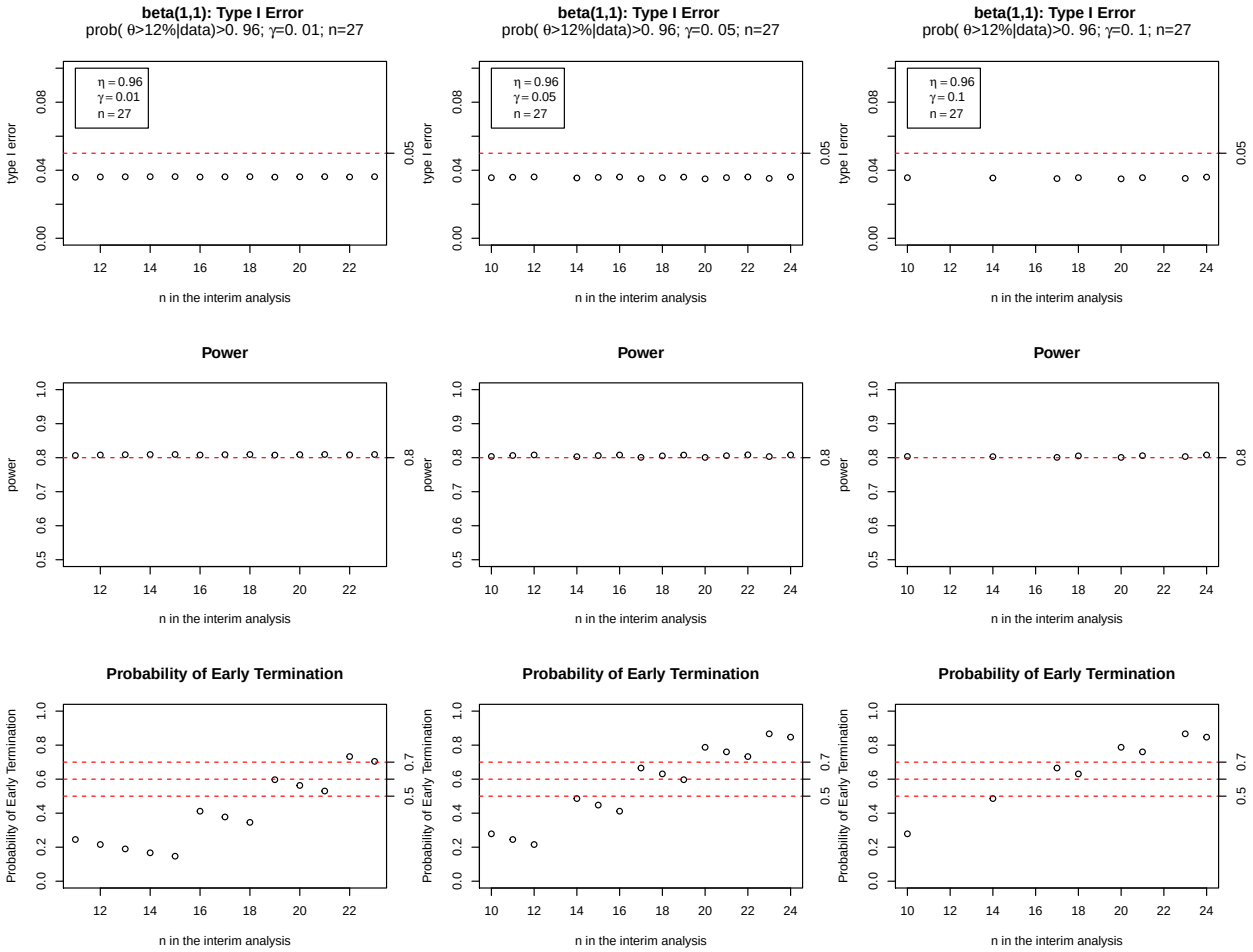
beta(1,1): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 01; n=27
η = 0.96
γ = 0.01
n = 27
type I error
n in the interim analysis
beta(1,1): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 05; n=27
η = 0.96
γ = 0.05
n = 27
type I error
n in the interim analysis
beta(1,1): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 1; n=27
η = 0.96
γ = 0.1
n = 27
type I error
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Probability of Early Termination
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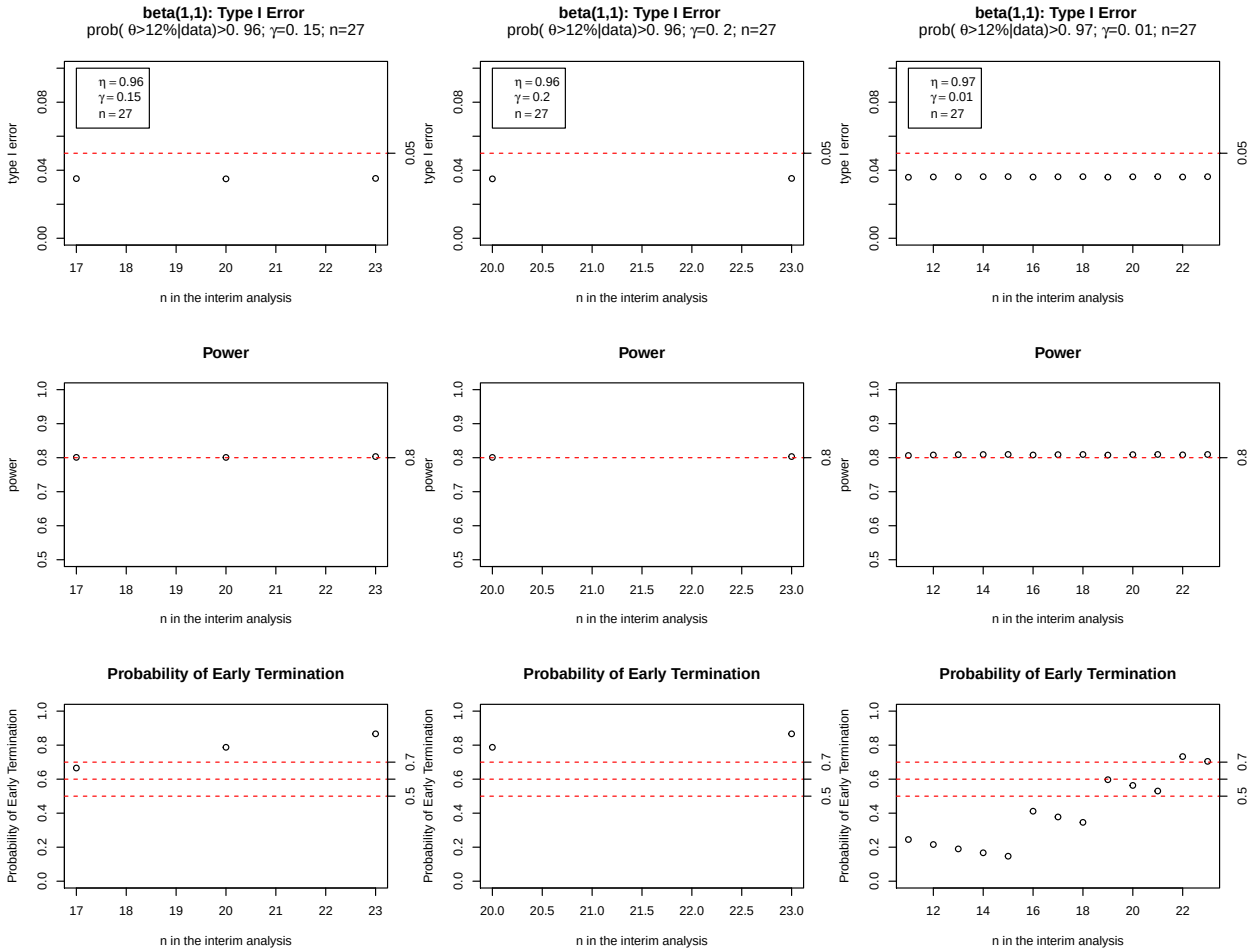
beta(1,1): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 15; n=27
η = 0.96
γ = 0.15
n = 27
type I error
n in the interim analysis
beta(1,1): Type I Error
prob(θ>12%|data)>0. 96; γ=0. 2; n=27
η = 0.96
γ = 0.2
n = 27
type I error
n in the interim analysis
beta(1,1): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 01; n=27
η = 0.97
γ = 0.01
n = 27
type I error
n in the interim analysis
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Probability of Early Termination
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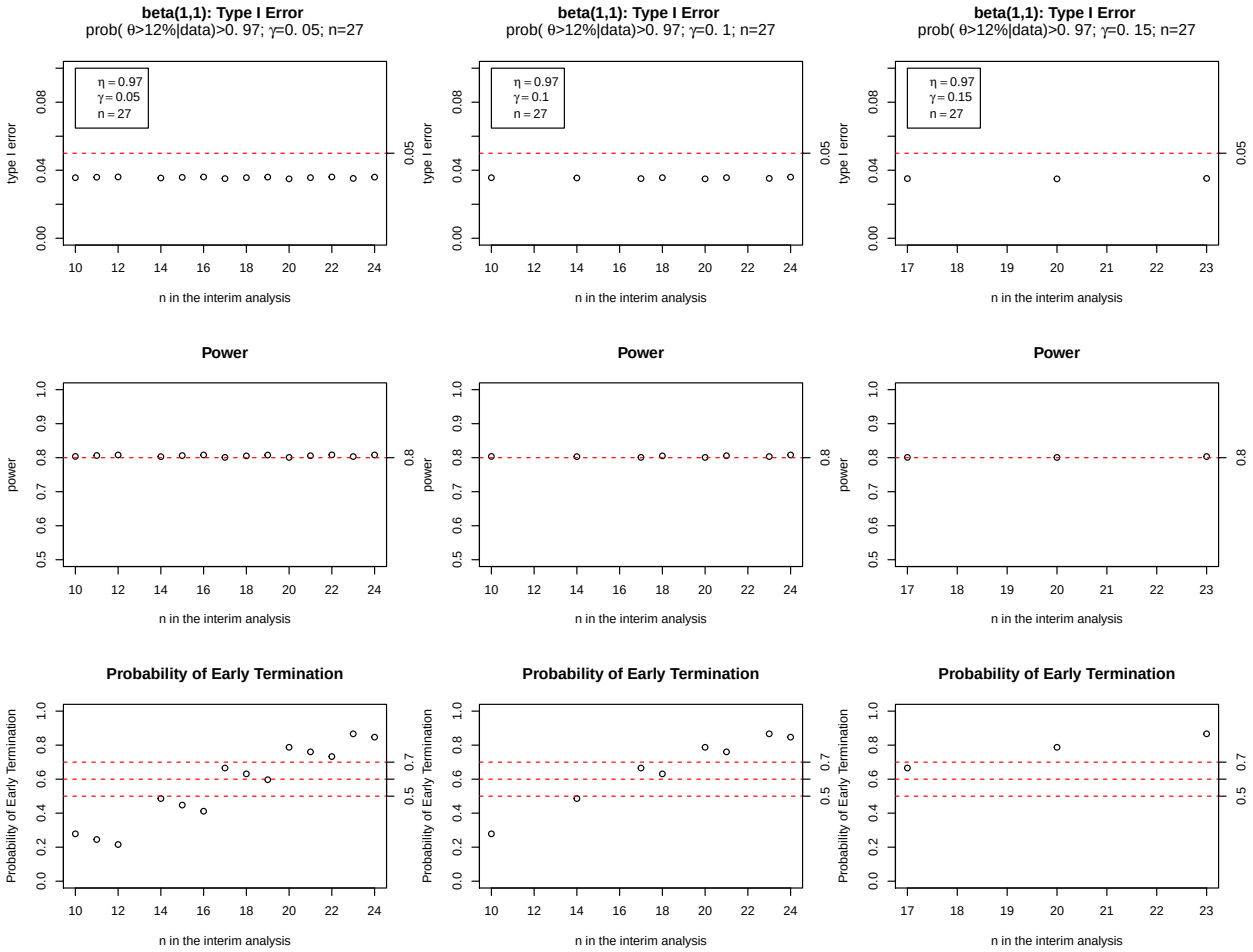
beta(1,1): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 05; n=27
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γ = 0.05
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type I error
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beta(1,1): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 1; n=27
η = 0.97
γ = 0.1
n = 27
type I error
n in the interim analysis
beta(1,1): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 15; n=27
η = 0.97
γ = 0.15
n = 27
type I error
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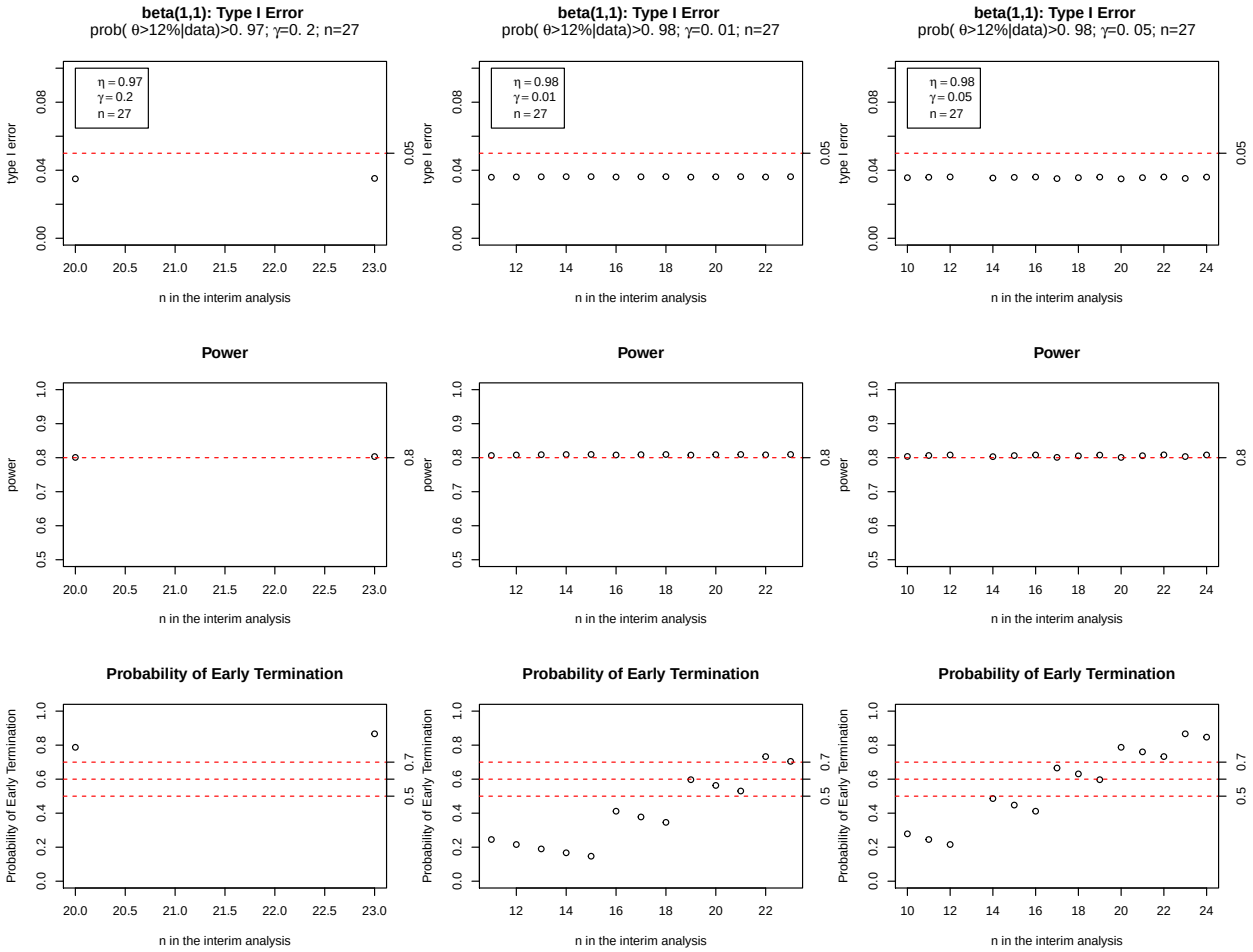
beta(1,1): Type I Error
prob(θ>12%|data)>0. 97; γ=0. 2; n=27
η = 0.97
γ = 0.2
n = 27
type I error
n in the interim analysis
beta(1,1): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 01; n=27
η = 0.98
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n = 27
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beta(1,1): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 05; n=27
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γ = 0.05
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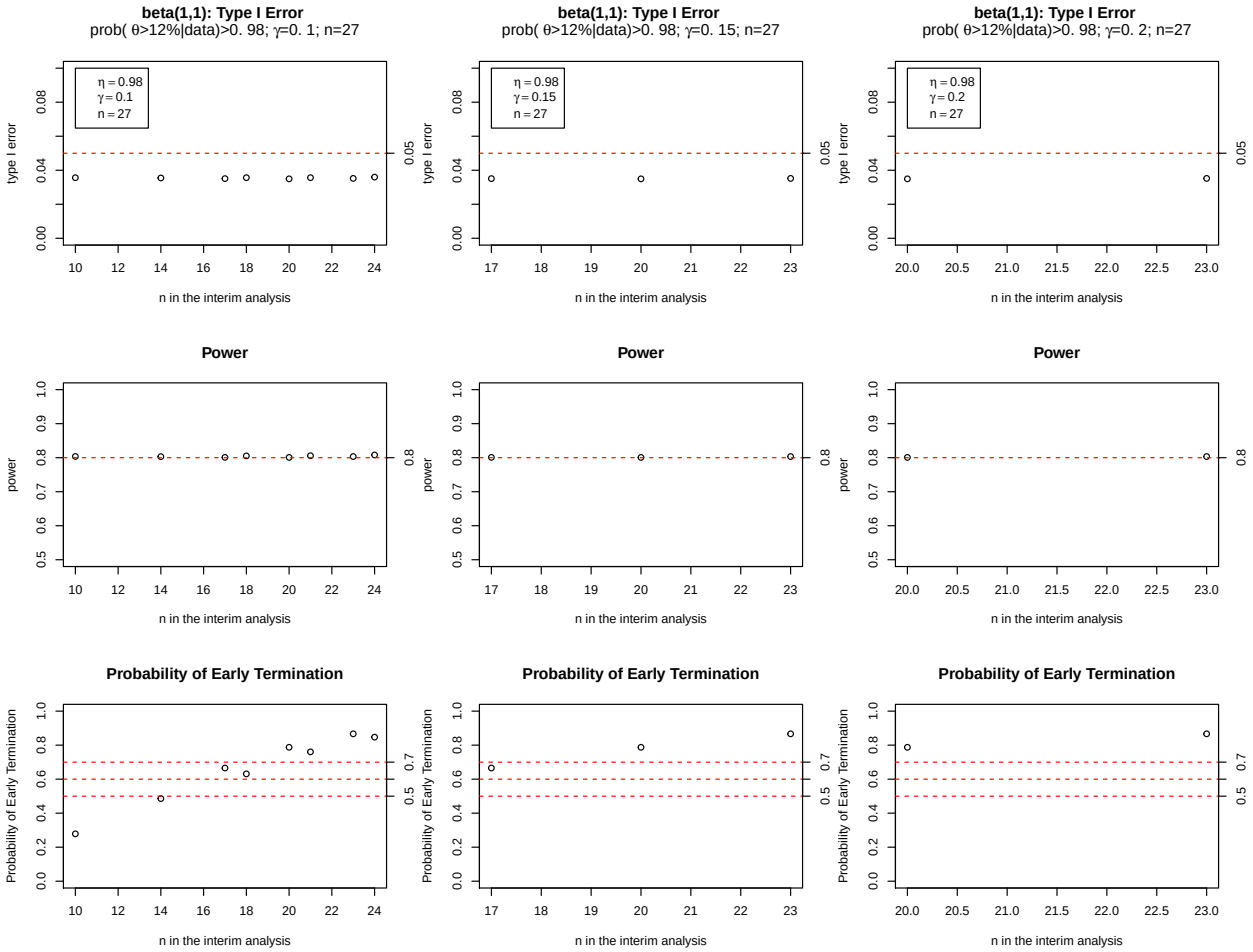
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type I error
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beta(1,1): Type I Error
prob(θ>12%|data)>0. 98; γ=0. 15; n=27
η = 0.98
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beta(1,1): Type I Error
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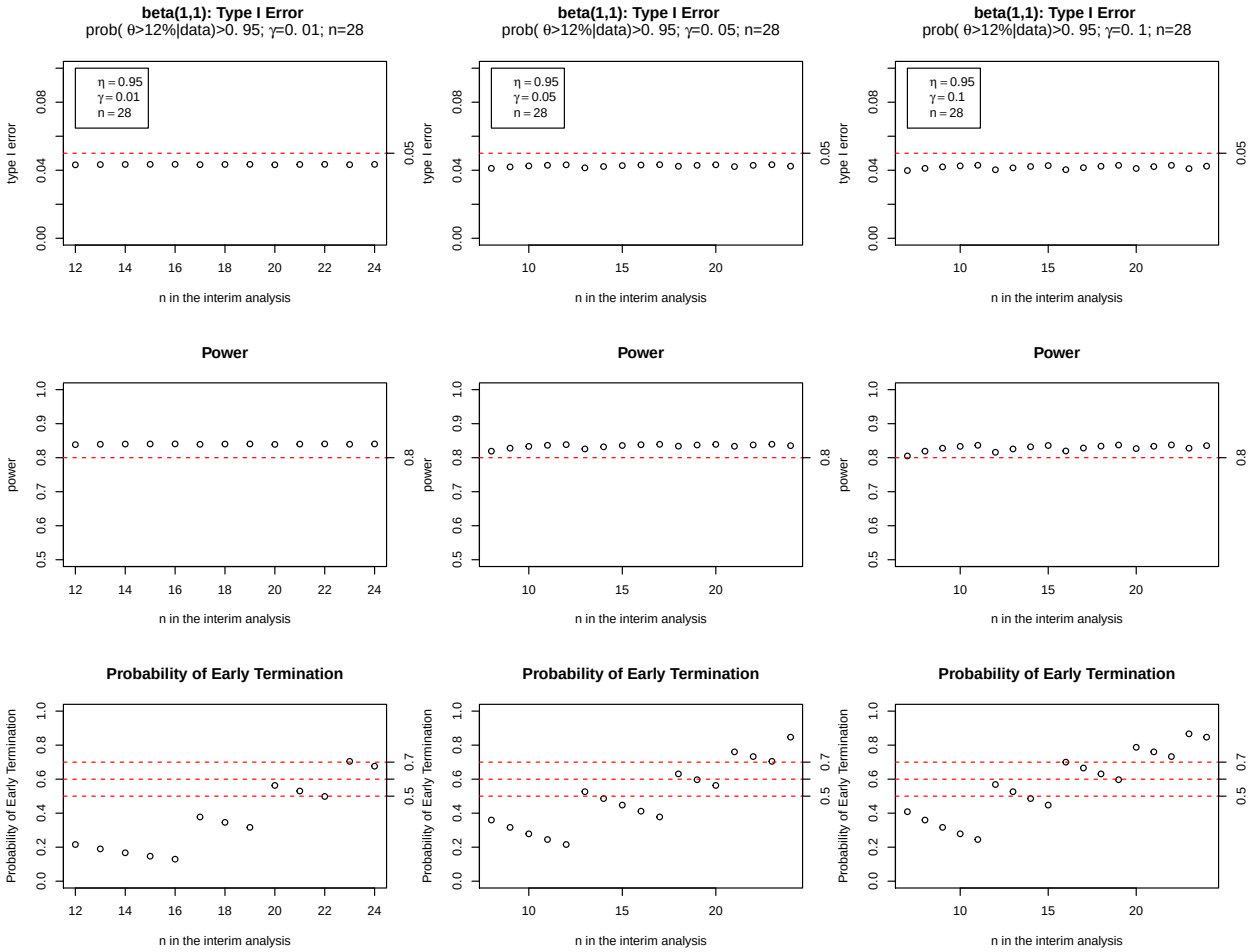
beta(1,1): Type I Error
prob(θ>12%|data)>0. 95; γ=0. 01; n=28
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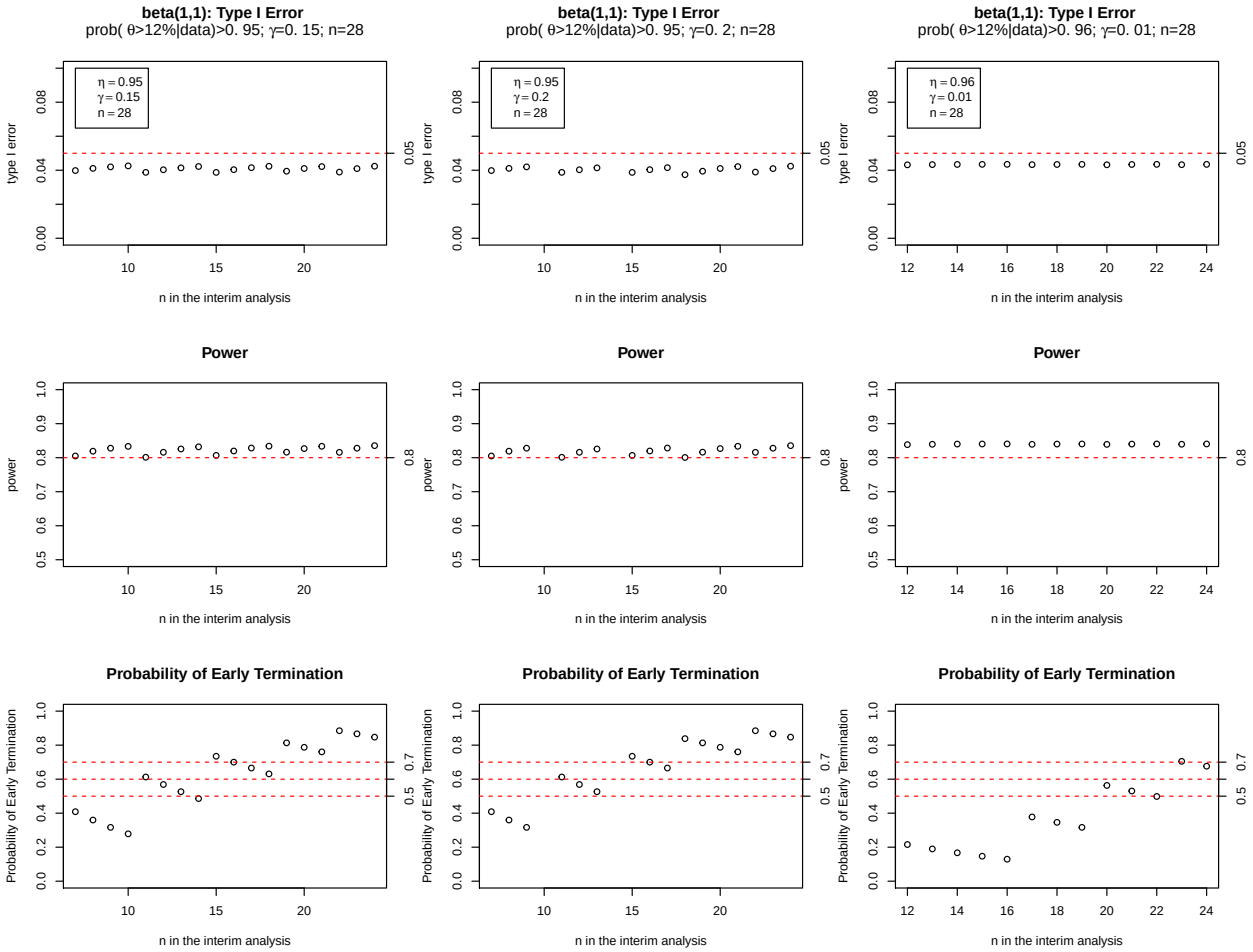
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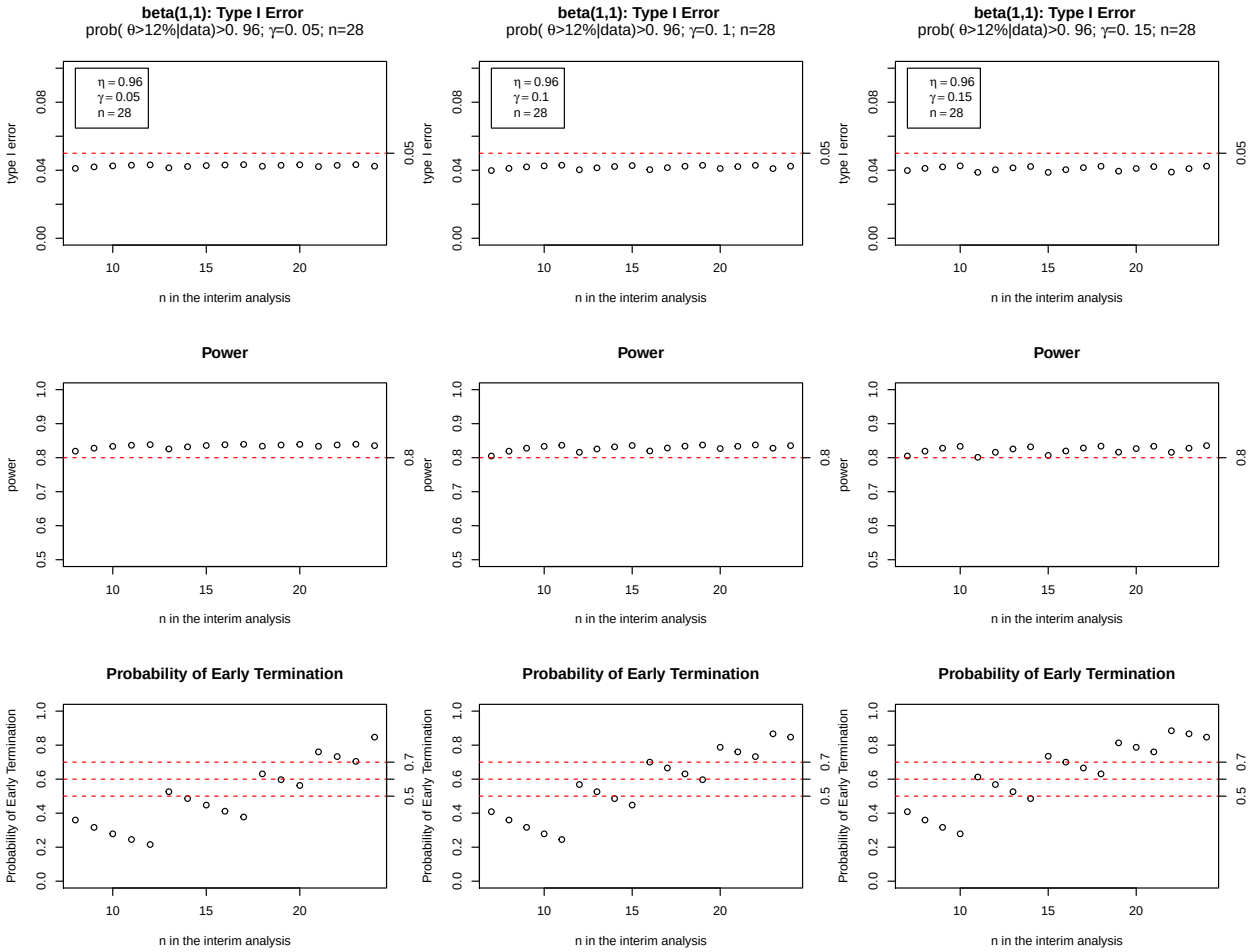
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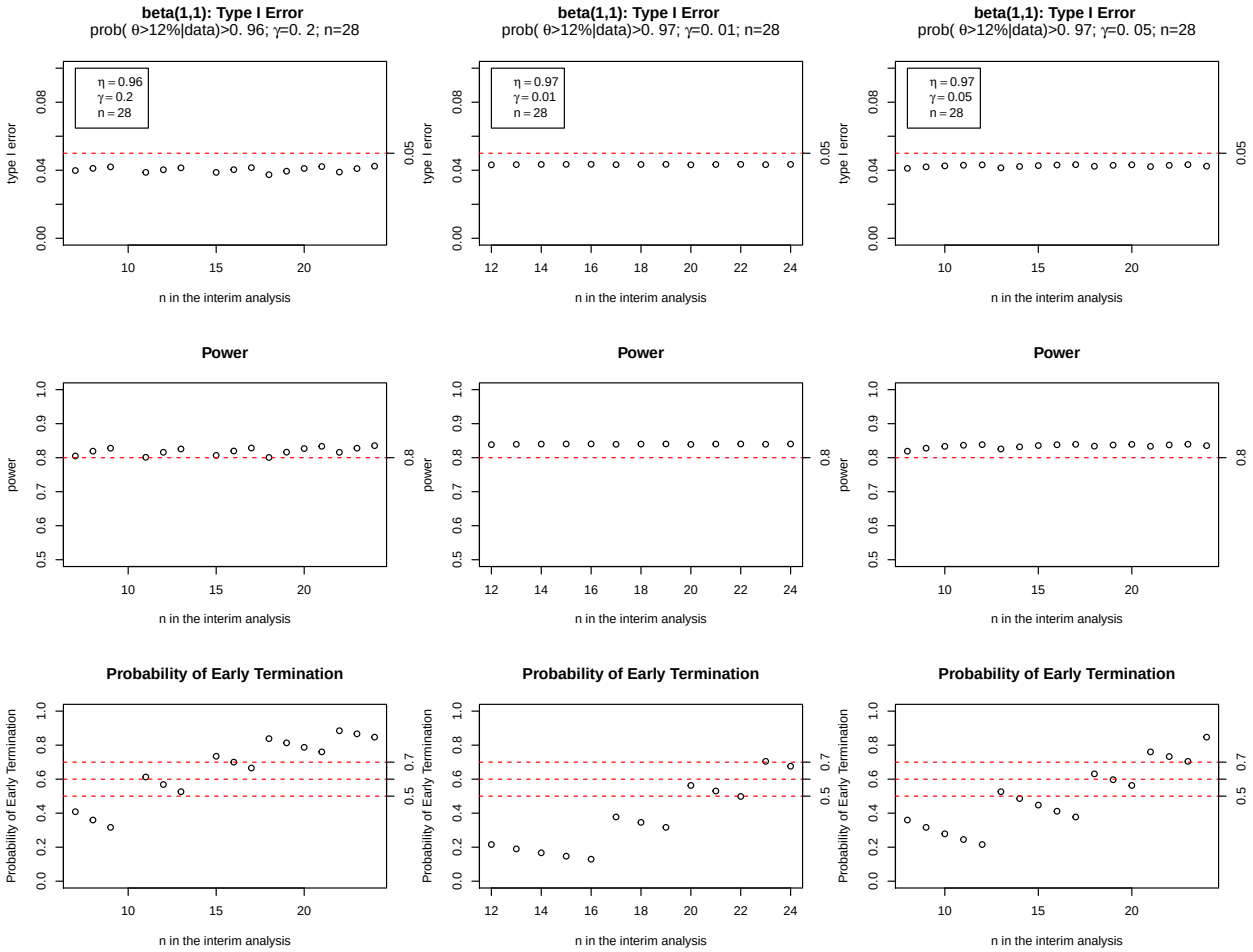
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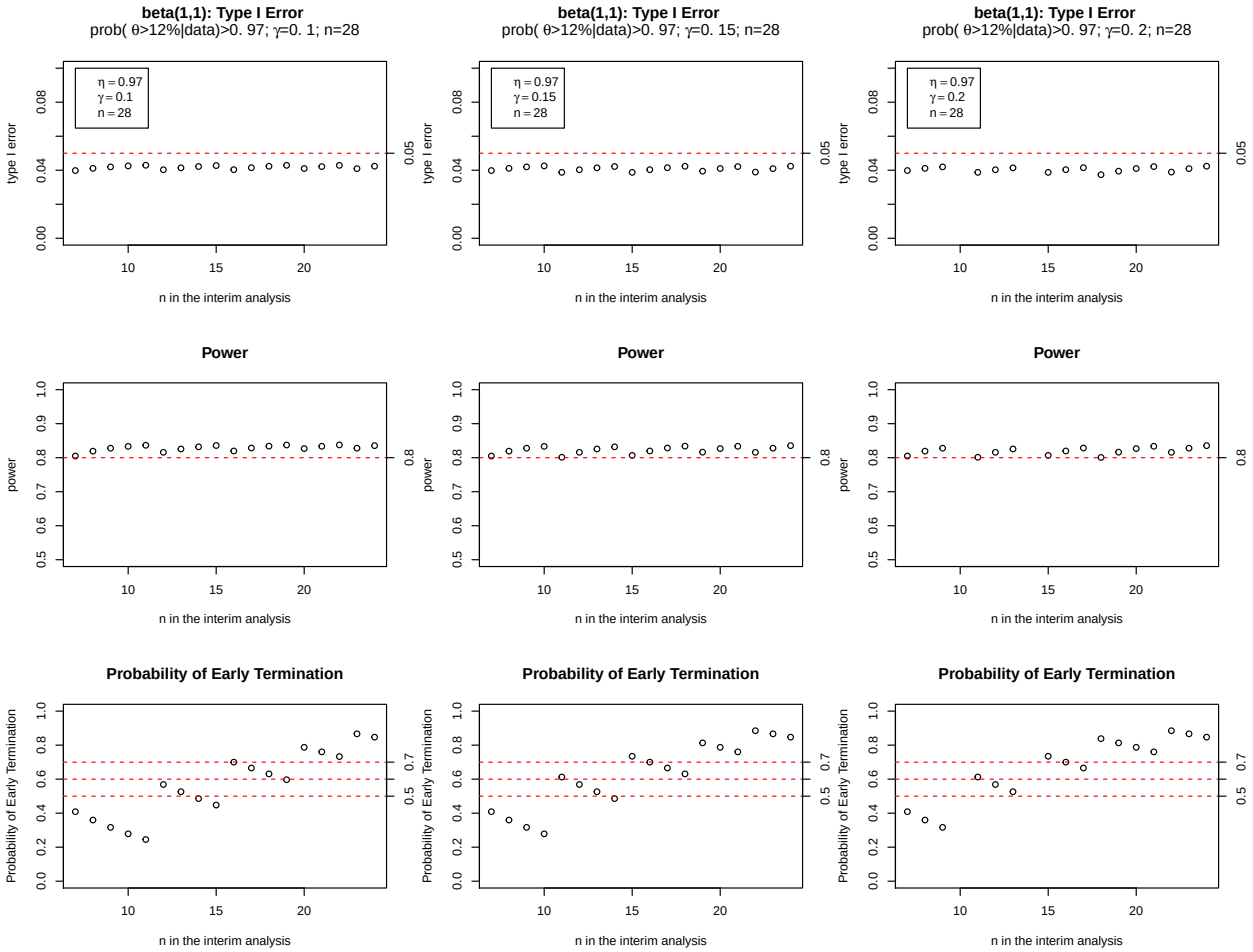
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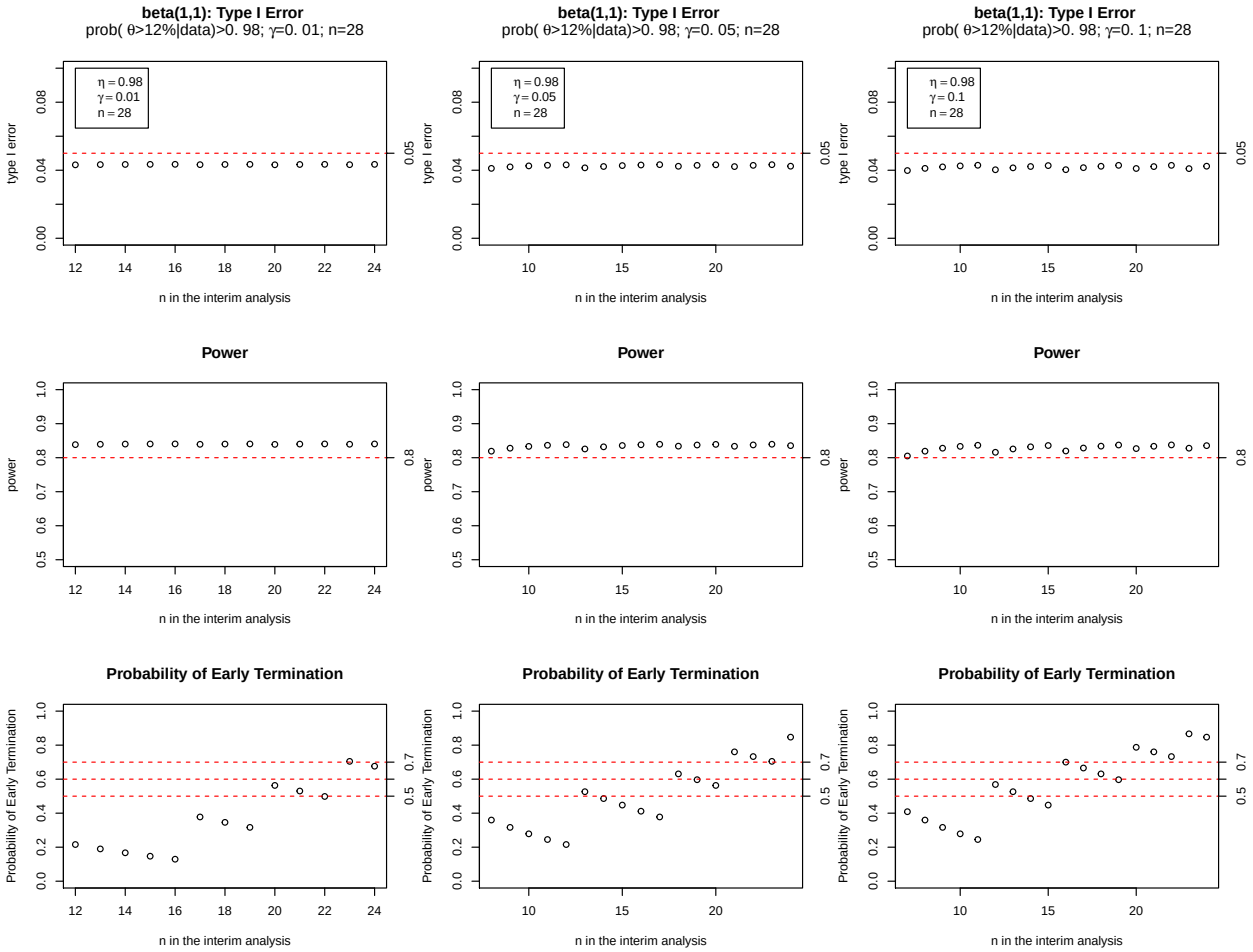
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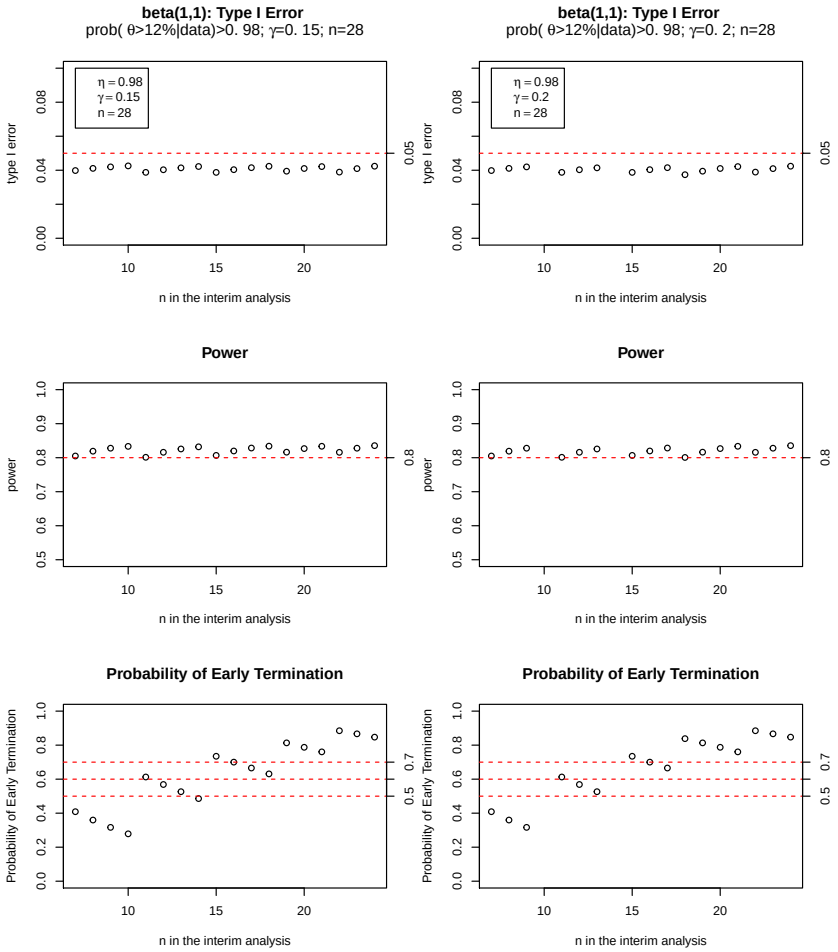
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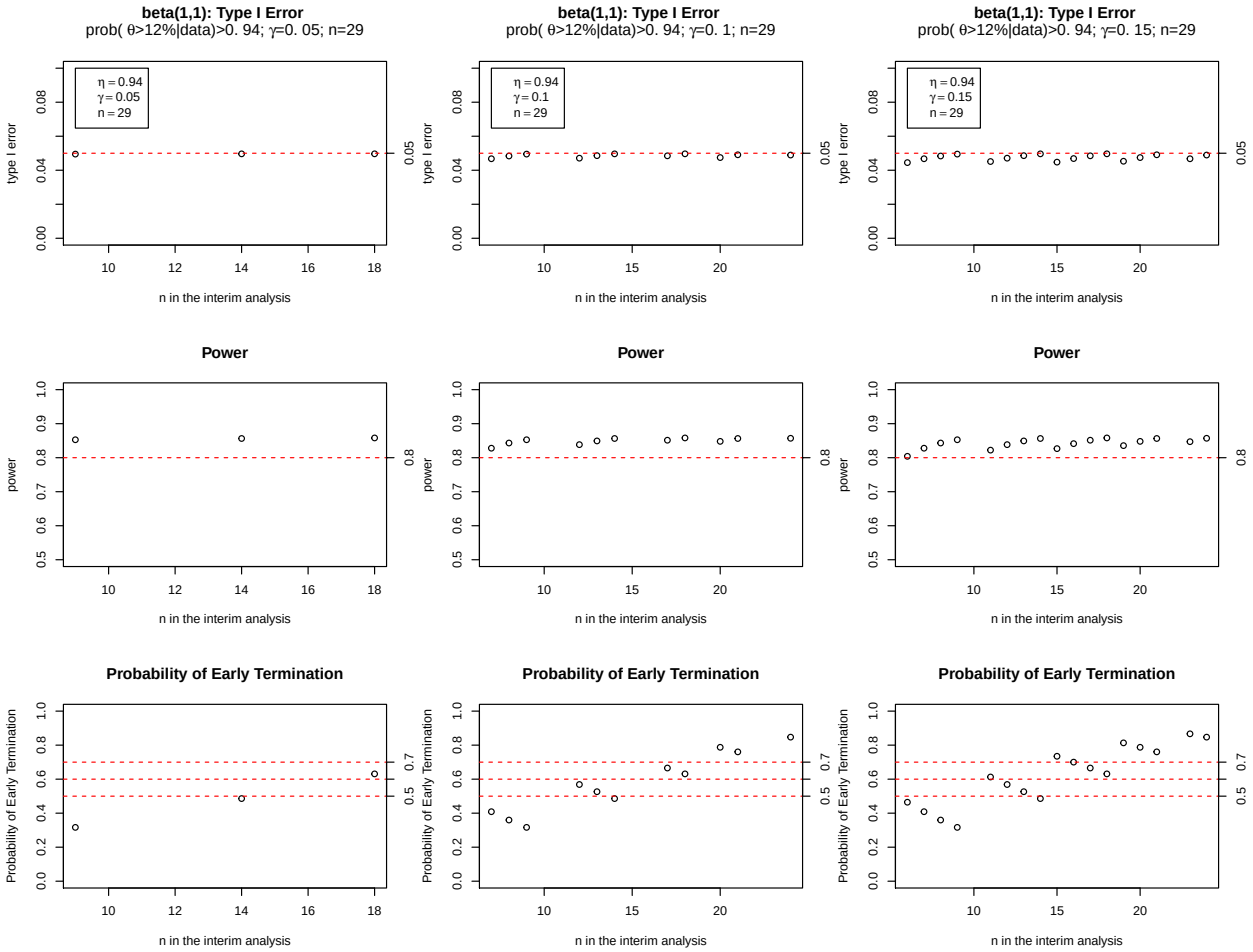
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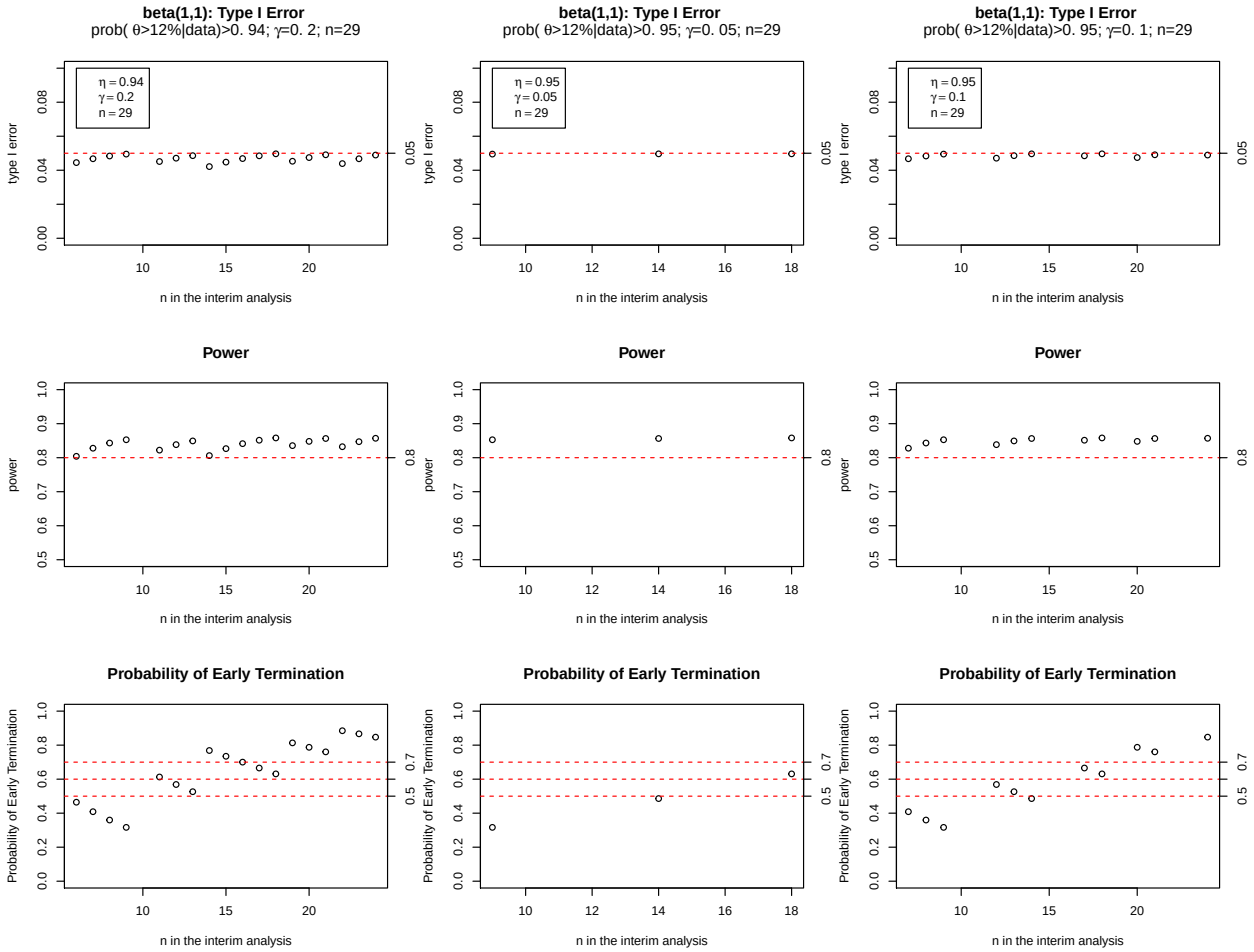
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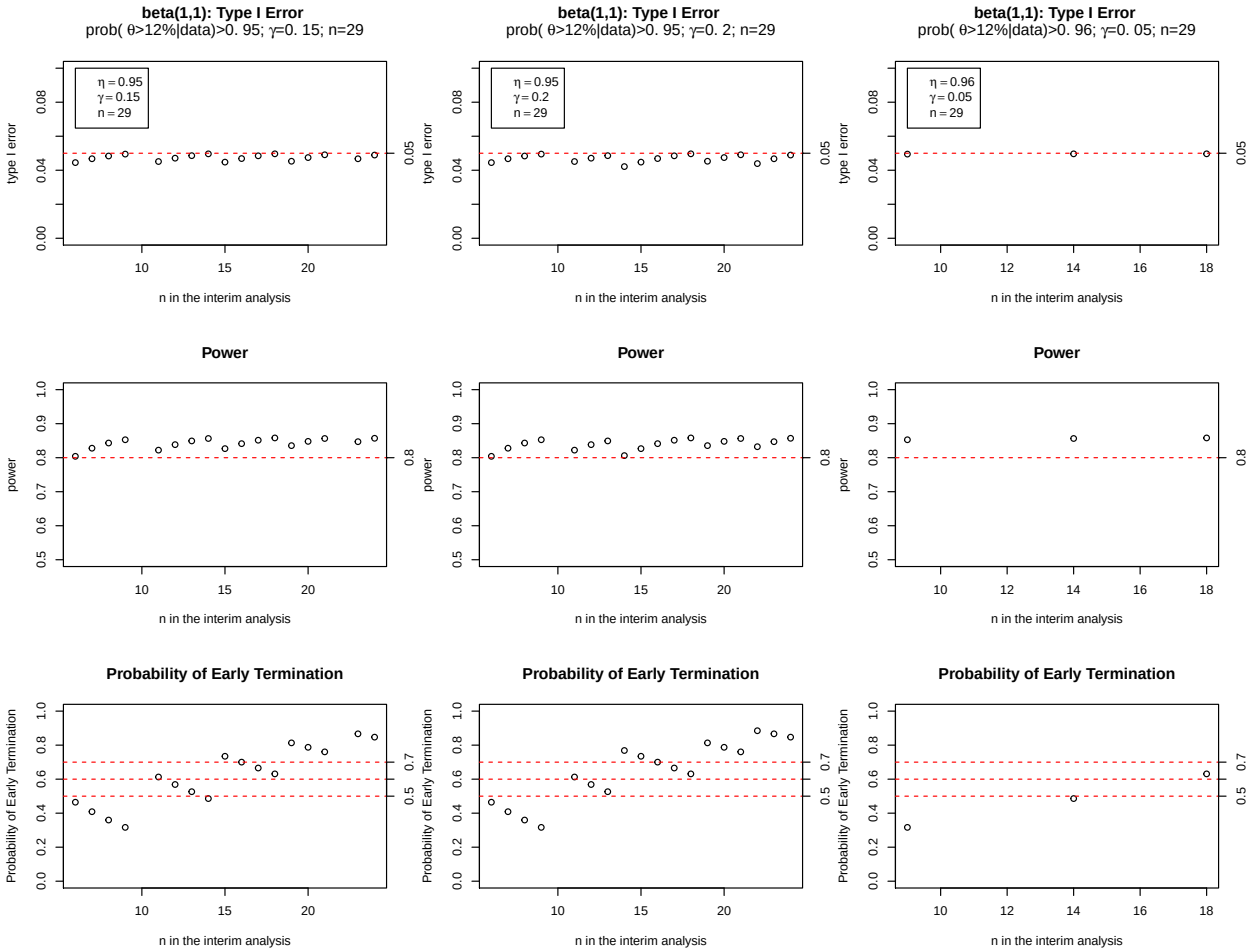
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type I error
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Probability of Early Termination
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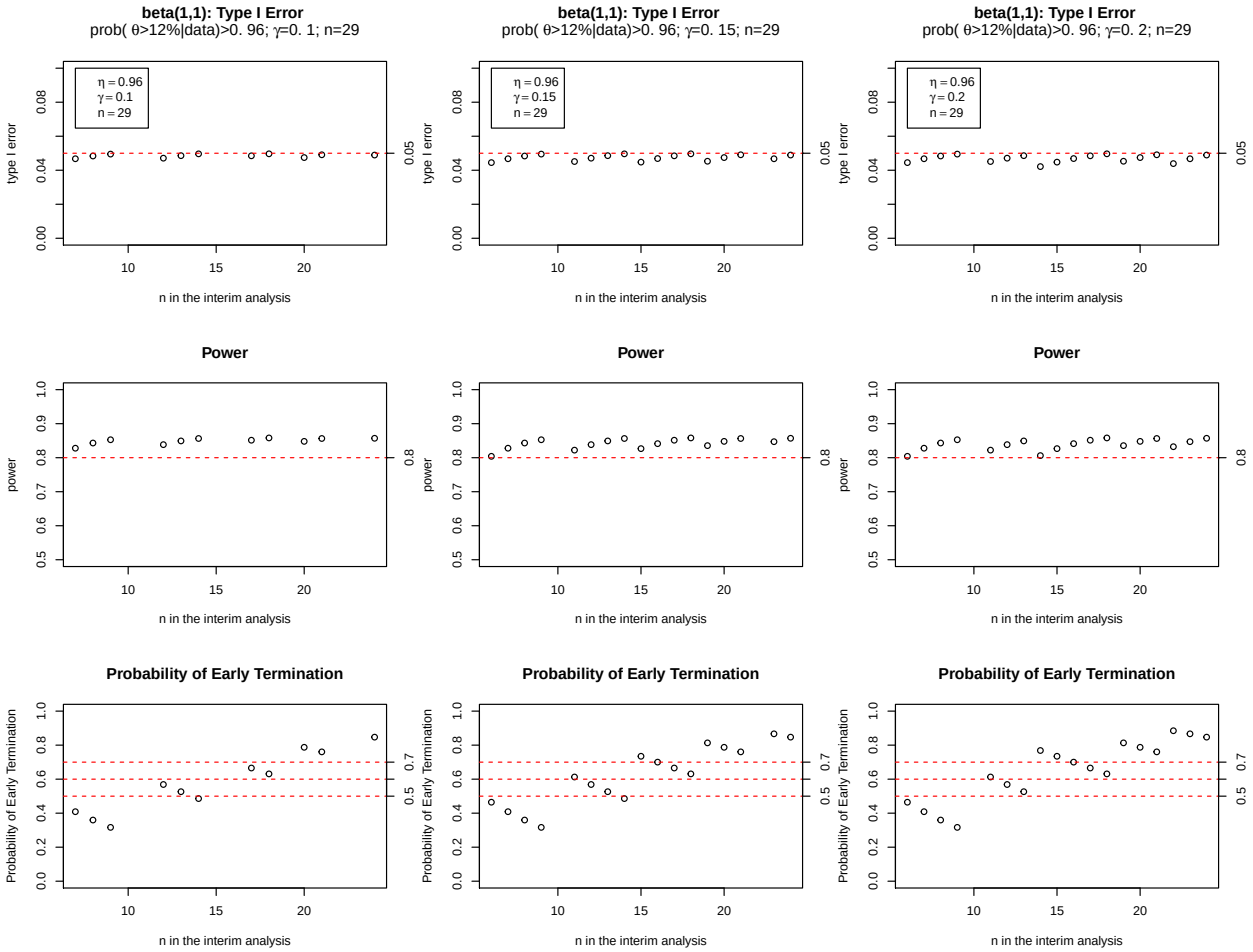
n in the interim analysis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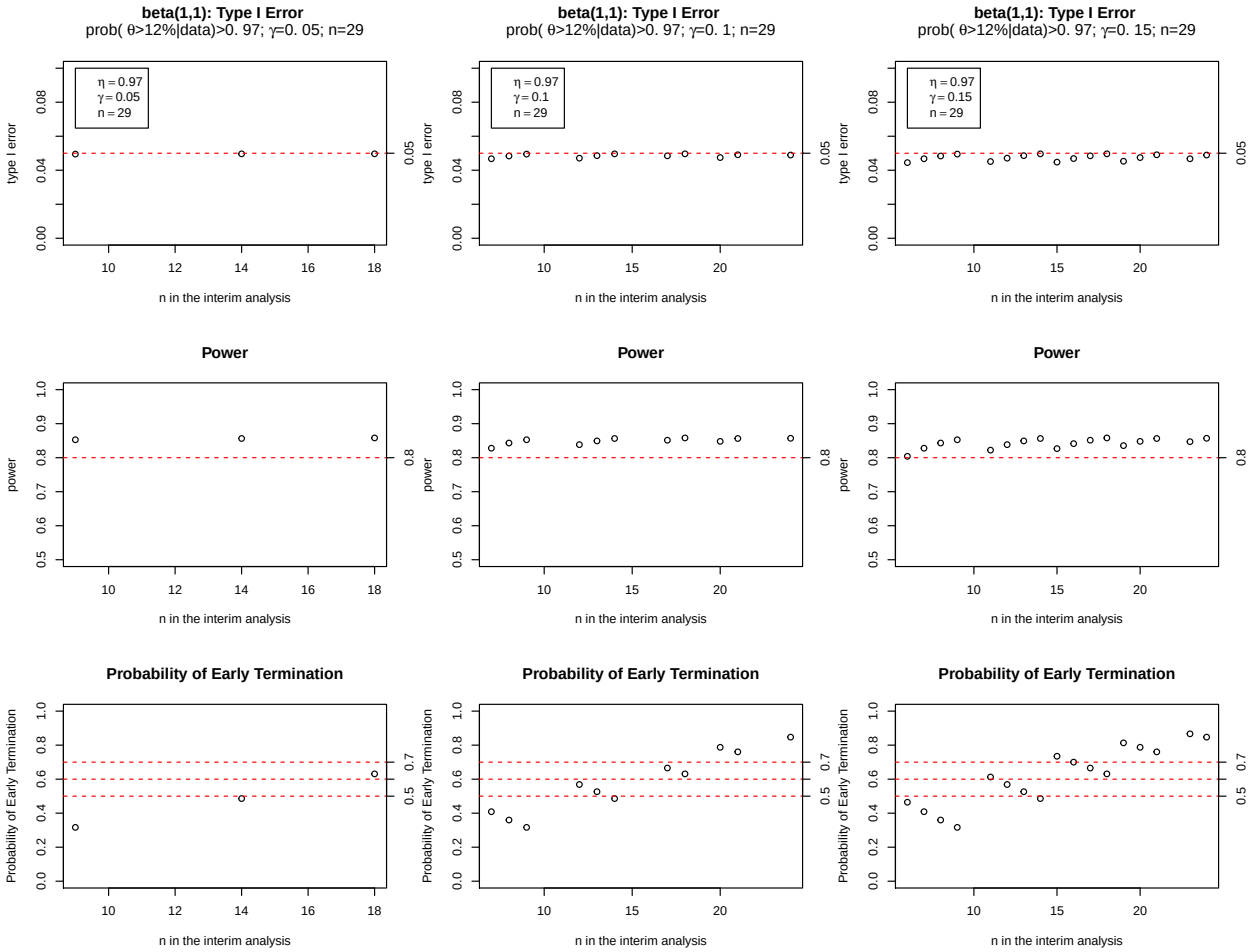
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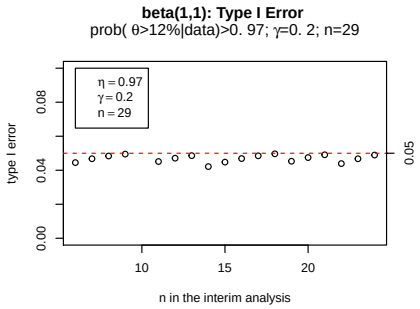
beta(1,1): Type I Error
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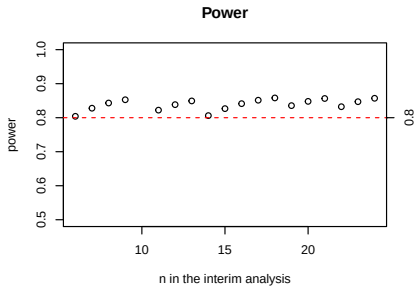
n in the interim analysis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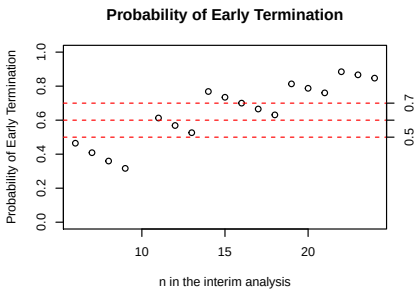
n in the interim analysis


Probability of Early Termination
Probability of Early Termination
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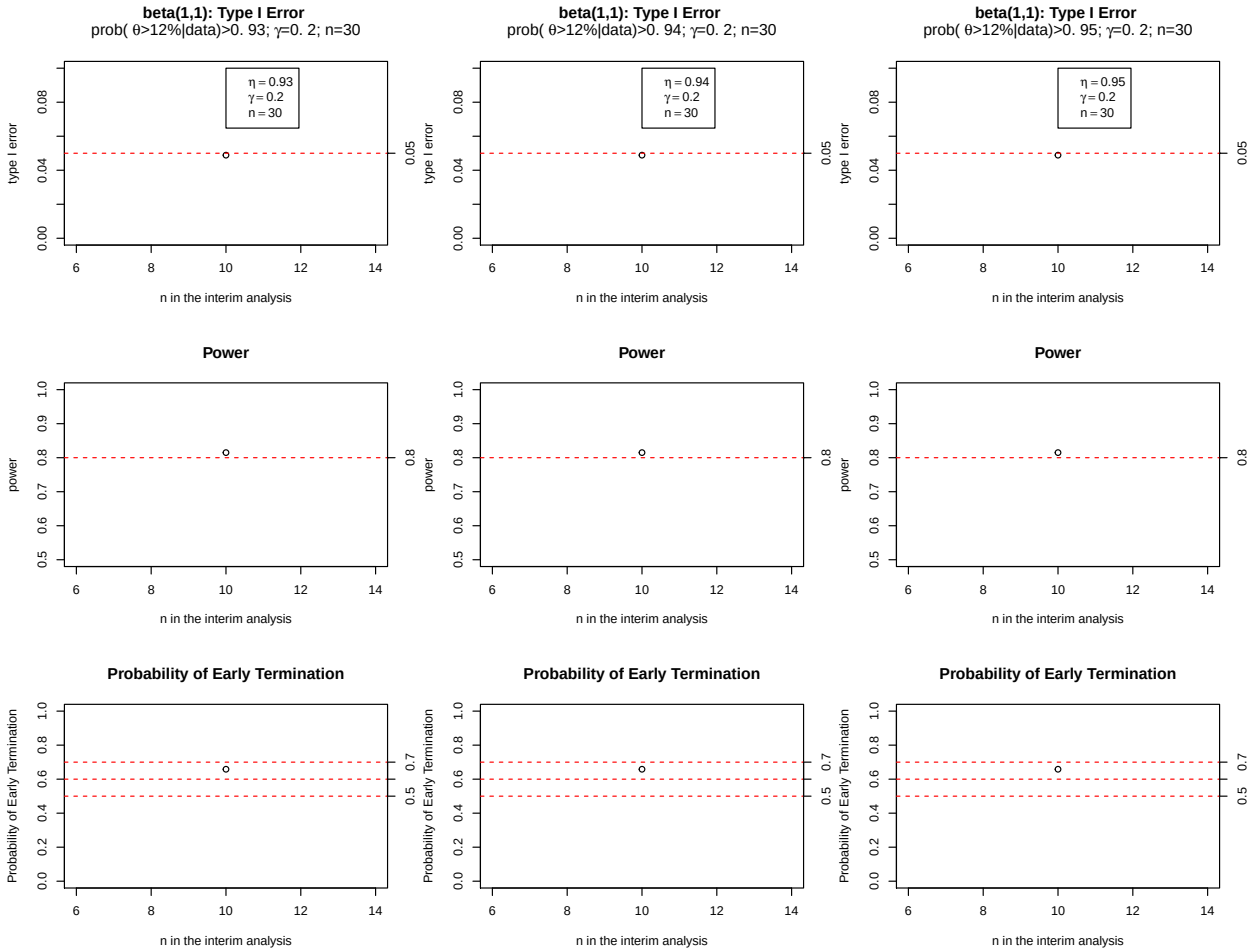
n in the interim analysis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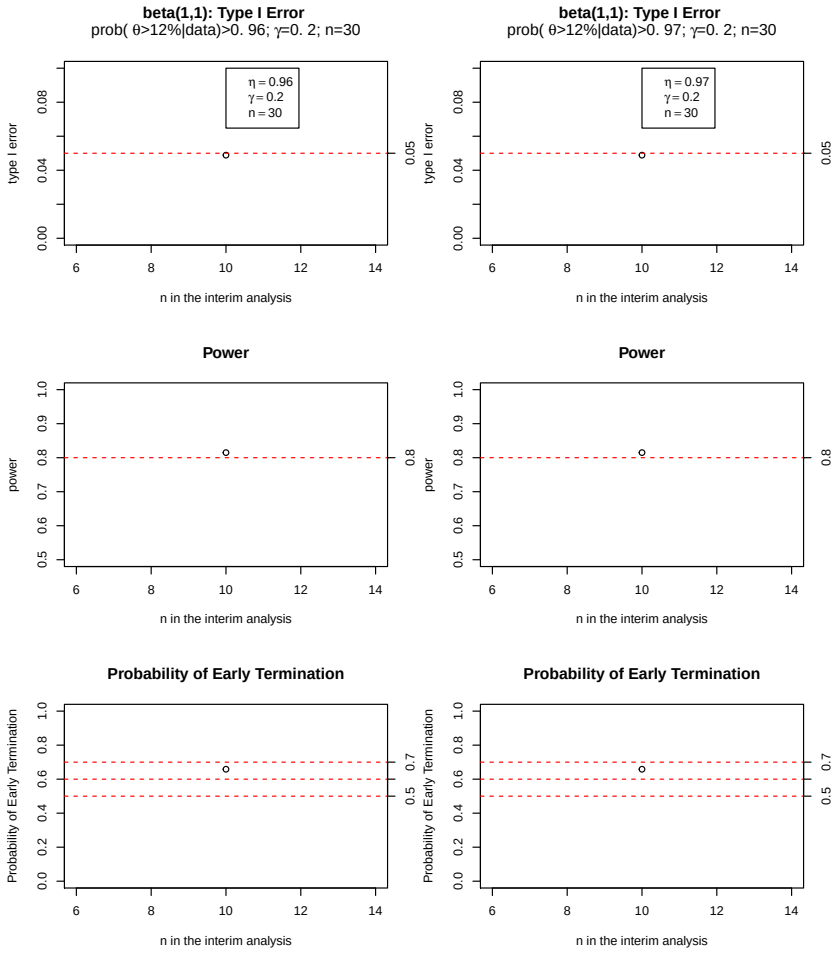
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