A NEW PROPOSAL FOR CHOICE OF VALUES OF PARAMETERS FOR RESTRICTED RANDOMIZATION RULES

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Because complete randomization in a small-sized experiment or in the early stages of a trial may result in severe imbalance the use of a restricted randomization rule are recommended. In general, by using these procedures treatments that have so far been assigned less frequently are given a higher probability of assignment with the aim of achieving a better balance.

The assignment should maintain a sufficient balance between the numbers receiving each treatment, yet should be sufficiently random to avoid selection bias. For restricted randomization rules this can be reached by suitable choice of values of parameters. But there is no obvious decision rule for optimising one's choice of the parameters. Our suggestion is to proceed as follows and to use the formulated condition below.

For the case of two groups, after n assignments n_A (number of patients assigned to group A) is a random variable for which the probability of imbalance AD_n, the absolute difference between the numbers of patients in these two groups, can be obtained. We endorse the generation of mildly unequal group sizes and specify that if a maximum tolerable imbalance d at the n-th stage only with probability pr can be exceeded, and d, n, pr are given, then values of parameters of restricted randomization rules can be determined.

We analyse and compare balancing properties of

- Biased Coin Design BCD(p) by Efron
- Urn Design UD (w, α, β) by Wei
- Big Stick Design BSD(a) by Soares & Wu
- Permuted Block Design PBD(b)

with respect to their final imbalance distribution and we propose suitable values for parameters p, w, α, β, a, and b of these procedures.

References:
Kundt G. A new proposal for setting parameter values in restricted randomization methods. Methods Inf Med. 2007;46(4):440-9.