Considering the Control Group

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THE "GOLD STANDARD" of research designs is the randomized control trial (RCT). When proposing an RCT the researcher divides patients into at least two groups of participants or subjects. The three defining features of an RCT include manipulation, control, and randomization.[1] Manipulation involves the researcher "doing something" to some of the subjects; these subjects are referred to as the treatment or intervention group. The control group comprises participants who do not get the intervention. In dividing the subjects into groups the researcher uses randomization; subjects are randomly assigned to the intervention or control group to avoid the researcher's bias. The purpose of an RCT is to determine if the intervention is superior or at least equal to the control condition. Although researchers tend to place a lot of emphasis on the intervention group, the control group is vitally important and often overlooked.

The control group typically receives no intervention or "usual care." An important consideration when determining the control group is to make sure that the only difference between the control group and the intervention group is the intervention being tested. Thus, researchers must carefully compare the control and intervention groups to detect any differences not related to the intervention.

One of the best ways for the perianesthesia research consumer to evaluate any differences between the groups is to identify a table provided by the researcher to compare demographic information. In the current issue of *JoPAN*, Chiodo et al[2] test the impact of music therapy on postoperative orthopaedic patients' satisfaction. The 25 patients in the control group received "standard care" whereas 25 patients received noise canceling headphones with music of their choice. However, there is no table of demographic information and the reader is not informed of any differences between the groups. Age, gender, or hearing ability could have been different between the groups, which would nullify any test of the intervention.

In the February 2019 JoPAN issue, In et al[3] tested the effects of postoperative postanesthesia care unit (PACU) parental visitation on children's delirium. The 47 children in the control group received usual care and were allowed parental PACU visits after 30 minutes. The 46 children in the intervention group were allowed immediate PACU parental visitation. The researchers clearly provide demographic information about the groups in Table 1. Unfortunately, the groups were not similar as there were more female children in the control group. The researchers determined that gender had a significant impact on the incidence of PACU delirium (Table 3). Thus, the reader is not sure if the intervention or gender impacted children's PACU delirium.

In this JoPAN issue, Wu et al[4] report an intervention study, in this issue of JoPAN, on the safety and feasibility of oral hydration. Water was withheld from the control group, also called the "conventional group," for the first four postoperative hours. Nurse assessment of the intervention group allowed for "early" oral hydration. The researchers clearly provide information in Tables 1 and 2 that there was no difference between the groups on key demographic characteristics including anesthetics and preoperative, intraoperative, and postoperative hydration. The reader can be confident that the intervention was the "active" ingredient in this study. However, it is not clear how much of a "dose" of water or the timing of the water ingestions within the first 4 hours was received by the intervention group. Similarly, it is not clear how much water the control group ingested because of their thirst at 4 hours.

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When determining the strength of the evidence provided by an RCT or intervention study the perianesthesia nurse must carefully consider the features of the control group. A description of the control group is vitally important to ensure that the intervention is truly responsible for the research findings.

References

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