XIII. Research Design in the Structured Review of an Article

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The quality of information obtained according to the research design is integrated to the structured review in accordance with the causality model. For example, it is used in the article "Reduction in the incidence of post-stroke nosocomial pneumonia by using the 'Turn-mob' Program", whose design corresponds to a clinical trial. The aspects that have to be identified and analyzed include ethical issues, which are intended to safeguard the safety and respect for the patient; the random assignment, intended to generate groups with homogeneous baseline conditions, comprised by subjects with the same probability of receiving any of the maneuvers being compared and with the same pre-maneuver likelihood of adherence to them and the same chances of dropping out from the study for causes other than the maneuver. Other aspects include the relativity of the comparison, the blinding of the maneuver, the application in parallel of the comparative maneuver, the early termination and the analysis according to the degree of adherence. The analysis according to research design is supplementary to that performed on the basis of the causality architectural model and statistical and clinical relevance considerations

Key words
research design
clinical trial
causality
bias

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This text integrates the structured review of an article (Figures 1 to 3 from part VIII of this series), the characteristics of the research design and the resulting quality of the obtained information (parts IX and XII, also from this series).

We will use again the article "Reduction in the incidence of post-stroke nosocomial pneumonia by using the 'Turn-mob' Program" (published in J Stroke Cerebrovasc Dis. 2010;19:23-8), which aimed to demonstrate the efficacy of a mobilization program in bed in order to decrease the incidence of nosocomial pneumonia in patients with ischemic stroke. The research design used was the clinical trial; therefore, we will analyze its characteristics (Figure 4) and integrate them to the example based on the causality architectural approach described by doctor Alvan R. Feinstein.

Design Characteristics. Clinical Trial

Ethical Aspect

Although the first aspect that has to be analyzed is the ethical one, in view of its extension and distinct nature, it will be discussed in other article.

Randon Assignment

An element that defines the clinical trial is the *random assignment*. This is intended to generate groups with homogeneous baseline conditions in order to avoid susceptibility bias; to integrate in the groups subjects with the same probability of receiving any of the maneuvers being compared, and with the same pre-maneuver likelihood of adherence to them in order to avoid performance bias; to facilitate the blinding in the assessment of the outcome and, consequently, to reduce the diagnostic detection bias. Randomization also distributes the subjects between the groups with the same probability of dropping out from the study for causes other than the maneuver, thereby reducing transfer bias.

As for the Turn-mob program, it was randomly assigned and achieved balanced groups at the baseline state, except for chronic pulmonary obstructive disease, which could have favored the experimental maneuver. Thanks to randomization, groups were generated with the same likelihood of adherence to the maneuver, although in this study, adherence to the standard maneuver was never verified, whereby it is possible that it was total absence of mobility of the patient. As for the assessment of the outcome, it is not specified if it was performed by a second assessor without any knowledge of the group the patient

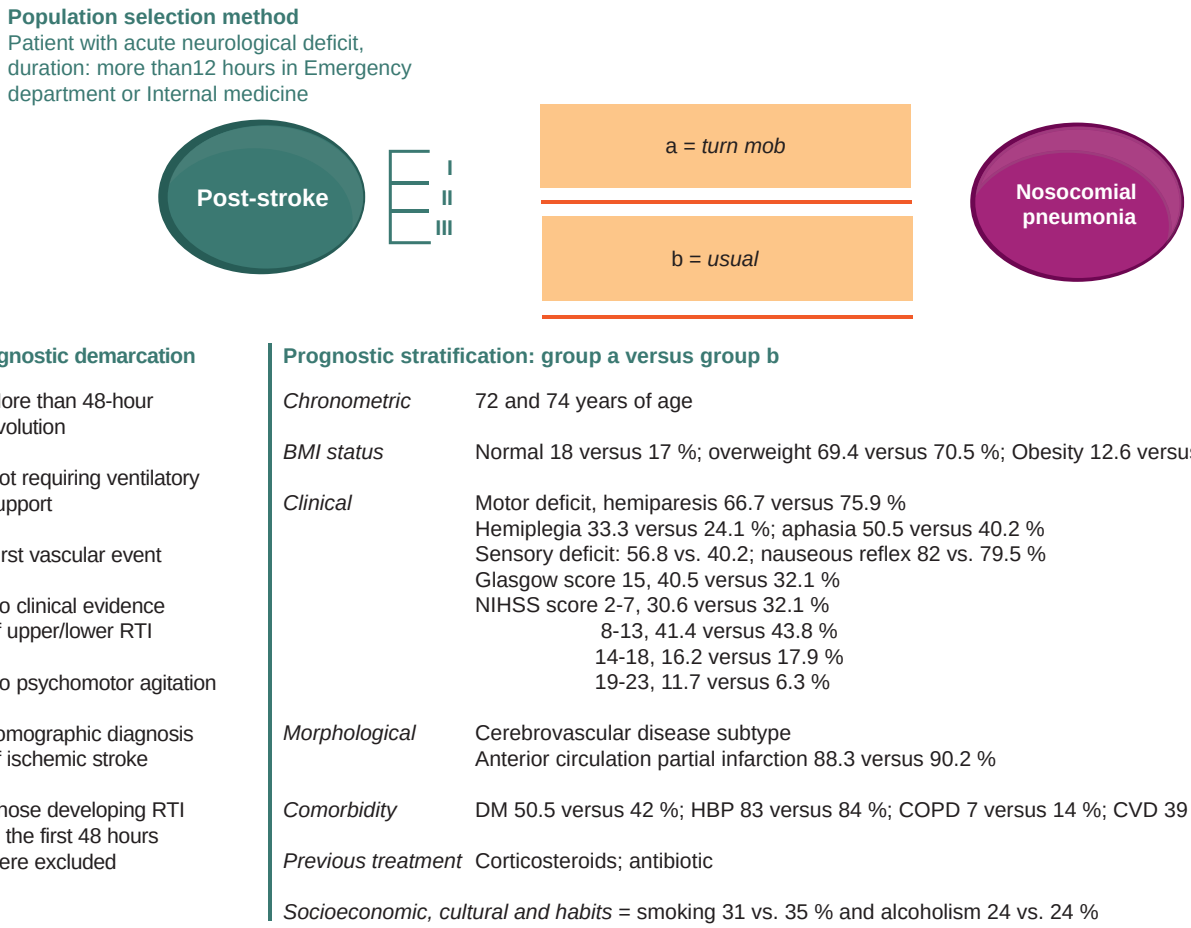

Figure 1 Characteristics that have to be considered at baseline state: diagnostic demarcation (scope of research, stroke definition, selection criteria) and prognostic stratification (variables that impact on the outcome regardeless of the maneuver). In the Turn-mob program, although randomization was able to balance groups characteristics, except for chronic obstructive pulmonary disease (COPD) —discretely higher in group *b* (14 versus 7 %, p = 0.088) and may impact on the final result—, it is not possible to observe the effect of each one of the maneuvers depending on different risk factors and, thus, the result must be attributed mainly to average characteristics of the population

belonged to. Finally, no losses are observed that might have caused transfer bias.

Relativity of the Comparison

Although the Turn-mob program was planned as an effectiveness study by comparing the new against the standard maneuver, it could have turned out to be an efficacy analysis since the possibility exists for the comparative maneuver to be precisely not applying any action.

Blinding

Blinding of the maneuver was impossible in the Turn-mob program and, although a second assessor of the outcome could have been promoted, this is not mentioned. Therefore, there was the likelihood of diagnostic detection bias.

Parallel Comparative Maneuver

The requirement of performing a comparative maneuver in parallel (during the same calendar days) was covered and was met by preventing differences in the diagnostic or stratification demarcations (in order to avoid inadequate assembly and prognostic susceptibility biases), differences in accesibility to peripheral maneuvers (to avoid performance bias) and differences in outcome diagnosis criteria (which reduces the possibility of detection bias).

Early Termination

There was no presence of adverse events due to the maneuvers. Nor were there early differences in the outcome. Should events or differences have been present, these might have stopped the Turn-mob program.

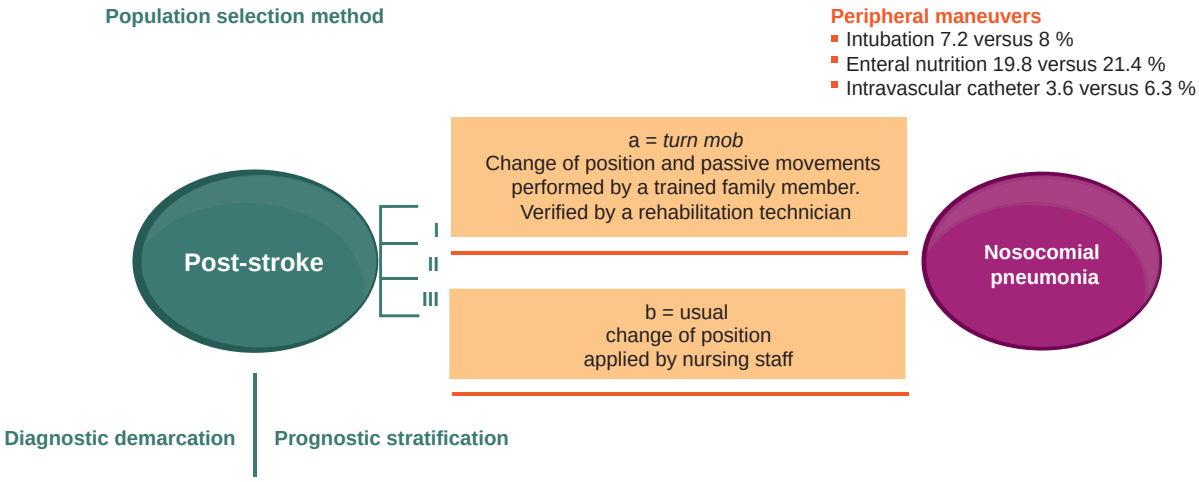

Figure 2 Characteristics that have to be considered during the application of the maneuver: quality of application of the principal maneuver (Turn-mob compared with usual position changes) and verifying that peripheral maneuvers are applied similarly in both groups. Although there was no difference in peripheral maneuvers, the application of the Turn-mob program was inicially standardized and verified day by day. Conversely, usual treatment was never standardized or its aplication verified on a daily basis; therefore, there is no guarantee that it was carried out; furthermore, when the patient was discharged to home, nursing support ceased to exist. This could represent more the result of applying the program against no action than superiority of the Turn-mob program over the usual treatment

Analysis According to Adherence

The last aspect is the analysis according to adherence, which shows clearly that the Turn-mob program was carried out in the intent-to-treat modality, since all patients were assessed in each one of the groups they were assigned, regardless of whether in the group with the standard maneuver they received it or not, as it could have been the case, with the consequent performance bias.

Final Comments

As we can observe, the analysis of a research article or work according to the design used is complementary to the analysis made on the basis of the causality architectural model; on the other hand, statistical and clinical relevance considerations will have to be taken into account. Without any doubt, the performance of a structured analysis requires time and knowledge and with no doubt it is more enrichening than just

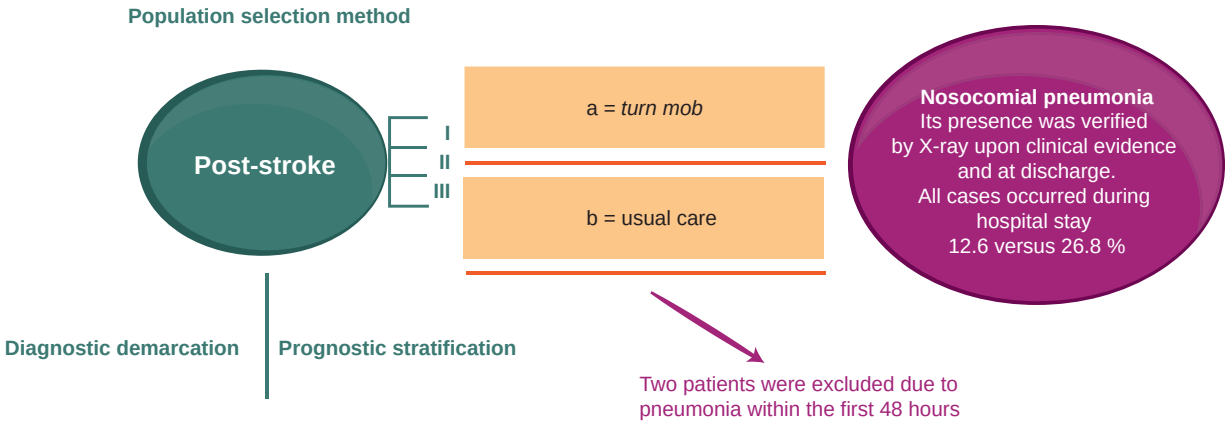

Figure 3 Characteristics that have to be considered in the outcome: there is no possibility of having diferentially detected nosocomial pneumonia, since all patients underwent chest X-rays at discharge or upon the slightest clinical suspicion. Similarly, there is no problen due to patient losses; only 2 cases were excluded out of a total of 225 and due to the presence of pneumonia wlthin the first 48 hours of hospital admission

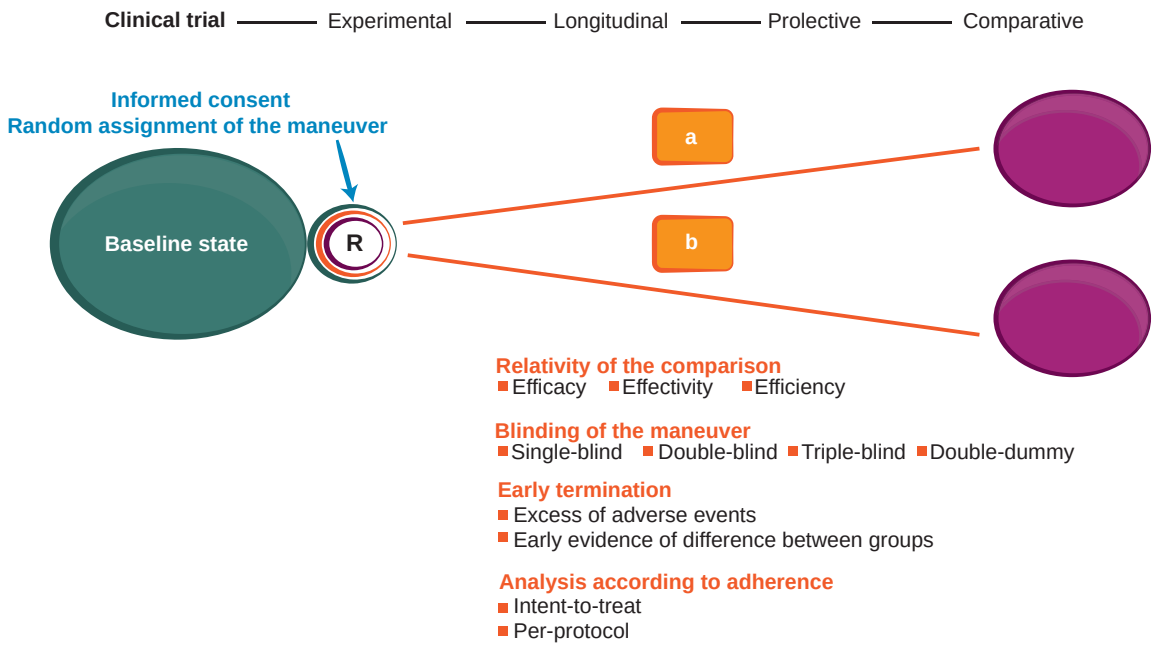

Figure 4 Clinical trial characteristics in paralell to clinical reasoning

accepting a foreign and superficial quality judgment, as it is pretended in the classification by level of evidence. On the other hand, keep in mind that although every article specifically tries to answer one question, it happens to contain a large amount of useful information for the clinician, such as epidemiological and clinical aspects of the pathology under study.

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