

Clinical research in intensive care

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Clinical research encompasses epidemiology-based studies, which are the basis of the evidence-based medicine and physiological studies, which are the basis of the "rational"-based medicine. The first kind of studies usually implies a simple question (dead or alive?) and huge organization work.

The necessity for enrolling several hundreds of patients, however, carries, as side effect, the heterogeneity of the study population. As an example under the ARDS definition we enroll patients in which the lung recruitability is zero together with patients in whom lung recruitability is greater than 50 % of the lung parenchyma. In these two different kinds of patients we tested the PEEP effect and, not surprisingly, we failed to show any significant difference.

The ARDS Network showed the superiority of 6 versus 12 ml/kg ideal body weight ventilation, but we should remember that several other studies failed to show any difference in outcome when tidal volume was set at 6, 8 or 10 ml/kg. Although "evidence" requires two large studies to be established, the low tidal volume, after a single study, has become a dogma.

According to evidence the PEEP level is indifferent in outcome, but no intensive care doctor would use ZEEP.

The tight glyceemic control has been first magnified, then criticized and finally disproved.

In the last 30 years I saw cortison killed and resuscitated several times. Therefore, in synthesis, the whole process may be synthesized as follows: first we invent a name to define an ambiguous, heterogeneous and biologically different reality, as ARDS or sepsis; second,

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- 6** we pretend to show that a give maneuver or a given strategy is effective in syndromes which have been invented by physicians. Far more fascinating are, in my opinion, the physiological studies. These require more fantasy, imply more sophisticated questions and are feasible in a single centre.
- While the outcome studies are a simplistic and sometimes naïf attempt to prolong life through simple interventions, physiological studies are our attempt to discover the mechanisms underlying the diseases. However whatever research at whatever level is applied in a given ICU the worldwide experience show that the quality of care of the units rises.
- In Italy we have a fantastic participation of the units to research activity, ranging from epidemiology to physiology, from observation to intervention, from large studies to selected mono-centre activities. Overall quality is good but what is impressive is the enthusiasm and participation, even without any sponsor or financial support. This makes our Country an exception in the general panorama. Recently the scientific journal of our scientific society, *Minerva Anestesiologica*, was given 1.62 of impact factor. Greater than one of the scientific journals of Countries as France and Germany. I hope we will continue in such a way.