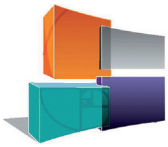
Anaesth Crit Care Pain Med 38 (2019) 571–572



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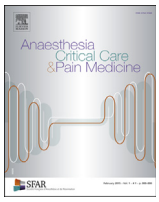

Editorial

ICU diary: Should we turn the page? More liberal visiting policies: Must the door stay closed?

ARTICLE INFO

Keywords:
Post-intensive care syndrome
ICU diary
Family-centered care

For more than a decade, the interest in "improving living in the ICU" [1] kept growing. We can only welcome this awareness of the importance of our patient's quality of life, during and after their stay in ICU, perfectly complementary with the aim of decreasing mortality even more. It is now well established that stay in ICU can be experienced as a real aggression, a break in the patients' life course. A post-intensive care syndrome (PICS) can appear, including the psychological component with delirium, depression, anxiety, acute stress reactions and post-traumatic stress disorder (PTSD). This PICS per se can ultimately alter their future quality of life. Different therapeutic strategies have been tested to improve the in-ICU patient's experience and to prevent the psychological consequences. Among them, one can quote the implementation of a dated clock with date and week day in the room to facilitate the orientation in time; to limit the loudness of the alarms by making a proposal to the patients of headphones or earplugs; to favour electric switches with dimmers to vary luminous intensity and to respect the rhythm day/night. Mindfulness meditation techniques may also be taught.

To illustrate this interest, the *Journal of the American Association* published in the issue of July 16, 2019, two articles about two specific therapeutic actions aiming to reduce the PICS, not only in patients but also in their relatives, who can be as much or even more impacted than the patients themselves.

The first of these actions concerns the ICU diary. The ICU diary, set up in intensive care in the 90s, is filled out by clinicians and relatives during the ICU stay. To date, it is the only strategy that aims at helping patient to rebuild their history during the ICU stay, in case of consciousness disorders.

Through a multicenter (35 French ICUs), randomised clinical trial, Garrouste-Orgeas et al. [2] questioned the interest of the ICU diary to reduce the incidence and intensity of PTSD in adult patients ventilated more than 48 hours and in their relatives. PTSD was assessed by an IES-R score $>$ 22 (range, 0–88, the higher score, the more severe the PTSD). Three months after ICU discharge, 51.6% of patients included in the study could be evaluated (164 in the diary group and 175 in the control group). The incidence and the intensity of PTSD were similar in the two groups: 34.3% and median (IQR) IES-R score 13 (6–27) in the control group *vs.* 29.9% and 12 (5–25) in the diary group. Anxiety and depression scores, assessed by HADS scale were also similar between the two groups. The relatives' results were similar (45.0%, IES-R score 20 (10–37) and HADS score 14 (9–22) in the control group *vs.* 47.7%, IES-R score 20 (11–35) and HADS score 14 (9–20) respectively in the diary group).

The authors concluded that the use of an ICU diary did not significantly reduce the prevalence of PTSD symptoms at 3 months.

The second of these therapeutic actions consisted in promoting the family-centred care by extending the opening of the ICU unit to the relatives [3]. RG Rosa et al. [4], through a cluster-crossover randomised clinical trial, compared the usual restricted strategy (less than 4.5 h/day) to a flexible hourly range of visits (up to 12 h/day) on the incidence of delirium. The trial was conducted in 36 Brazilian ICUs, which until then applied a restricted policy visitation. Delirium was diagnosed by CAM-ICU score, measured during 12 h, found positive at least once during the stay. The final duration of visits was 1.4 h in the "restricted visitation" group *vs.* 4.8 h in the "flexible visitation" group. The incidence of delirium was similar in the two groups (20.1% *vs.* 18.9%, respectively).

Finally, these two trials have invalidated the main hypothesis about specific therapeutic actions (ICU diary and flexible relatives' visitation) to reduce the psychological consequences of the ICU stay. The publication of these two articles demonstrates the awareness of publication bias that aims at promoting the publication of positive results. In recent years, medical journals with high impact factors are no longer reluctant to publish well-designed negative studies to better understand and reduce medical overuse through initiatives guided by the principle that less is more. Up to now, these publications have been primarily concerned with studies about withdrawal studies, which are the systematic, structured elimination of low-value practices that are no longer supported by the best available evidence, because they are unnecessary, costly, or do not improve outcomes. Here, the two studies published by the *Journal of the American Association* are studies of implementation, whose initial hypotheses, finally disavowed, were to test the benefit of a new intervention. These publications prove that editorial policies continue to evolve in the

https://doi.org/10.1016/j.accpm.2019.10.015

right direction: actually, more and more journals, such as the *British Medical Journal*, are committed to evaluating research projects and publishing the results of selected projects, whatever they are. The message is clear: writing the manuscript and submitting to a high impact factor journal the negative results of a well-conducted study is not a waste of time!

While we can welcome the easier publication of negative studies, we must nevertheless remain vigilant concerning the interpretation of these negative results: as the Scottish philosopher D. Hume, at the origin of scepticism, asserted, it is possible to prove the existence of a fact but it is impossible to prove its non-existence: one can have consecutively observed ten thousands swans, all white, one cannot conclude that no swan is black! Failure to show that the diary can reduce the incidence and/or intensity of PTSD of patients hospitalised in ICU, ventilated for more than 48 hours, and/or of their relatives, should not lead to conclusion that the diary is never effective in achieving this aim. Firstly, in this study, the number of patients required was made with a hypothesis of an expected PTSD rate of 40% and finally measured at 34% in the control group; the β risk acceptable to erroneously conclude that the diary is not effective in reducing the PTSD rate was arbitrary set at 20% by the authors. Would the null hypothesis have been rejected if the patients in the control group had a higher PTSD rate and/or if the β risk had been set at 10% (90% power), imposing a greater number of patients to include? And what if selected patients were with a history of psychiatric symptoms, risk factors associated with developing a post-ICU PTSD? Or if the contents of the diary had been standardised according to instructions? It would be even more erroneous to conclude that there is no interest in setting up a diary for these patients and/or their relatives, knowing that the authors have investigated the only psychological component of PICS of these patients and their relatives. The danger lies in extrapolating only one aspect of the intervention that one wished to implement, at the risk of discrediting it definitively in all its aspects. As a proof, one of the secondary benefits common to both published studies is to have confirmed that relatives were at least as impacted as patients by the stay in ICU. Garrouste et al. diagnosed a PTSD in 21% of patients *vs.* 46% of relatives, and a HADS median score of 9 in patients *vs.* 14 in relatives, 3 months after ICU discharge. Similarly, the Brazilian study showed relatives' median HADS scores ≥ 10, compatible with a diagnosis of anxiety and depression syndrome.

Thus, before definitively giving up the use of a diary or extending the hourly range of visits by relatives, it is interesting to assess the potential beneficiaries other than the patients themselves, whether they are their relatives and/or caregivers. Although the French study was unable to prove a benefit of the diary on the incidence of PTSD among relatives, the Brazilian study showed a decrease in relatives' anxiety (7.0 *vs.* 6.0 respectively, $P < 0.001$) and depression (5.0 *vs.* 4.0 respectively, $P = 0.003$) scores when they were permitted with an extended time for their visits and an increase in their satisfaction index. To be unable to prove that the flexible family visitation does not decrease the prevalence of delirium in ICU patients should not lead to the conclusion that opening the doors of the ICU unit has no interest! In both therapeutic strategies, it would be unfortunate to throw the baby with the bath water!

Therefore, should family members be considered as a new group of "patients", whose caregivers would also be responsible for? In paediatric ICU, the child is inseparable from his ubiquitous parents, and the child-parents-caregivers triad is de facto the paradigm that imposes family-centred care. Because it is unthinkable to exclude parents from caring for their child, it appears necessary to the caregivers to offer them support. Regarding adult ICU, the medical literature is enriched with studies that demonstrate the benefits for patients of the concept of family-centred care, which promotes the involvement of relatives in the care of patients [5]. If this model of family-centred care tends to be recommended, will the ICU caregivers not have to consider these caregiver relatives as new patients themselves, for whom it will be necessary to propose specific therapeutic interventions too? Then, the primary outcomes of clinical trials, investigating new therapeutic actions to prevent PICS, could involve more the relatives than the patients themselves.

Disclosure of interest

The author declares that he has no competing interest.

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