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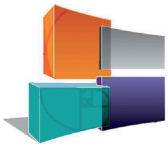

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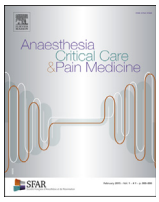

Editorial

The EPOCH trial: A non-resolved dilemma between ambition and pragmatism?

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Postoperative morbidity and mortality are disproportionate in high-risk patients. Among them, patients undergoing abdominal surgery have a risk of mortality exceeding 10% for emergency laparotomy [1]. Taking into account the wide variation of standards of care between hospitals for these patients, and the success of small studies describing the effects of quality improvement (QI) programmes on their survival, the Enhanced Peri-Operative Care for High-risk patient (EPOCH) group implemented a large national QI programme in 93 hospitals across the UK, based on two interventions: a bundle of 37-element care pathway and a quality improvement programme designed to support the application of the care pathway for patients undergoing emergency abdominal surgery [2]. In a stepped-wedge cluster randomised trial including 15,873 patients recently published in The Lancet, Peden et al. failed to demonstrate a 90-day mortality reduction in the QI group while they were expecting to decrease mortality from 25% to 16%. Both the usual care and QI groups had a 90-day mortality of 16% and did not differ on secondary outcomes, including 180-day mortality, length of stay and readmissions [2]. This study is particularly impressive by its ambition and complexity, with a large number of centres, a huge number of interventions to implement (10 preoperative, 16 intraoperative and 11 postoperative) and the heaviness of the accompaniment necessary for the implementation of the QI programme and its follow-up. The negative results of this study deserve to be analysed and put into perspective.

A stepped-wedge cluster randomised design was chosen to control contamination bias in the usual care group of the EPOCH study [3]. Clusters were formed on the geographical proximity of hospitals but did not integrate the interventions of the bundle of care already set up in each centre. It was difficult to determine which interventions mattered most, but clinical processes and practices that were the focus of improvement, such as those with an impact previously demonstrated on postoperative outcomes or the ten defined by the authors as key components of the care pathway might have been considered to perform a baseline comparison between clusters. It was also surely challenging to evaluate pre-existing relationships between staff leading execution of QI programme in the different hospitals, but the authors acknowledged that implementation of change was slower when existing relationships within the perioperative team were weaker. If the improved practices but also support and training for the QI programme were concentrated among centres with the longest duration in the usual care setting, the heterogeneity of centres distribution within clusters may have contributed to the negative results of the study. Because of the stepped-wedge cluster trial design, the duration of the QI intervention varied between clusters and could be as brief as 10 weeks (including an initial five-week period where the data collected were excluded), leading to difficulties to implement complex and time-consuming resources, such some included in the programme. Whether no evidence was found that the longer the QI programme had been adopted, the higher was its effectiveness; we cannot exclude that a too short timeframe of QI programme implementation may have contributed to limit its impact on postoperative mortality.

The number of patients included over the 85 weeks of the study period was lower than expected, as well as the estimated mortality of patients (16% vs. 25% in the analysis of UK National Health Service registry data ending April 2011 and used to sample size calculation), thus contributing to a reduction of power and to the absence of effect on the primary endpoint. One explanation concerning the reduction of expected mortality in the usual care group may be related to the implementation of a number of evidence-based standards of care, which when delivered led to substantial improvement in patient outcomes [3–5]. The progressive application of these elements along time in the UK may have initiated a background trend to improve the survival. The patient-level process measures concerning the ten key components of the care pathway in the usual care group revealed a high average rate of implementation, between 47% and 90%. It is, for example, important to note that nearly half of the centres in the EPOCH study used goal-directed fluid therapy during surgery while in France, in a contemporary study also performed in high-risk surgical patients, this only affected 10% of the centres [6]. Another possibility is that EPOCH patients were not as severe as those in the NHS registry, half of the patients having isolated intestinal obstruction in the former study.

One of the major information of the EPOCH trial and probably the main explanation for its negative results may be found in the process evaluation, which was fully detailed in another report [7]. The

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delivery of the EPOCH intervention at the site level was evaluated by a 37-item online questionnaire administered at the end of the study period. It was designed to allow QI leads in each centre to describe which elements of the pathway they achieved, the rate of change and their eventual success. Only a fifth of respondents said they had attempted full pathway intervention. Of the potential 37 pathway components, there were only 11 interventions from the clinical pathway that more than half of the teams attempted to improve, and only half of the trial cohort reported using five or all six of the QI strategies designed to enable pathway implementation [7]. Finally, at the national level, there were only modest improvements among measures reflecting key processes of care within the pathway. Was the EPOCH trial intervention too ambitious? We can reasonably ask the question when considering recent reports on postoperative outcomes of smaller-scale QI programmes for patients undergoing emergency abdominal surgery [1,4]. These studies involved the implementation of smaller evidence-based care bundles (5–6 interventions) in a more reduced number of hospitals reporting a reduction of postoperative mortality. An underlying question raised by the weak implementation of the multi-component QI interventions in the EPOCH study concerns the capacity of centres to conduct the change in terms of time, resources and organisational support in addition to their regular clinical commitments. The multiplicity of centres may have contributed to amplify the impact of these elements and lead to an unsuccessful study.

Should we doubt the relevance of the QI programme used in the EPOCH study? Certainly not! We can only question certain points of the method employed in this study. The EPOCH trial was resolutely ambitious if not pragmatic, and remains particularly important despite its negative results, as it highlights some prerequisites for the successful delivery of complex QI interventions on a very large scale.

Disclosure of interests

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Authors' contributions

All authors were responsible for drafting the manuscript and approved the submitted version.

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