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#### Letters to the Editor

# To drain or not to drain the infraperitoneal anastomosis after rectal excision for cancer<sup>★</sup>



## Sobre drenar o no drenar la anastomosis infraperitoneal tras escisión rectal por cáncer

To the Editor,

We have read with great interest a recent article by Denost et al. 1 published in *Annals of Surgery*. We would sincerely like to congratulate them, and we admire their effort in evaluating the effect of pelvic drainage after rectal surgery for cancer. However, we believe that their conclusions are not completely consistent with the results of the study, and we are concerned about the extent to which they may lead to negative consequences for patients.

Theirs is a superiority trial comparing drainage to no drainage, with statistically negative (non-significant) results, in which the main criterion for assessment was postoperative pelvic sepsis, including anastomotic leakage, pelvic abscess and peritonitis. According to such statistically negative results, the authors conclude that the use of pelvic drainage after excision of the lower rectum for rectal cancer does not provide any benefits for patients.

Generally, in any superiority trial with negative results, a negative conclusion must be made with great caution: the absence of evidence is not evidence of absence. Although the effect of drainage seems to be minimal for anastomotic leakage and peritonitis, we do not agree with such a definitive conclusion for the appearance of pelvic abscess. Thirty days after surgery, the authors found a difference in pelvic abscess of 3.7% (95% CI: -2.8 to 10.2%) against no drainage (P = .24). During initial hospitalization, this difference was 4.4% (95% CI: -1.2 to 10.1%, P = .010). Both confidence intervals can be easily calculated from the information in the article, although the authors have not reported them. Thus, in both situations, a

10% difference would be perfectly possible, and this difference is precisely what the authors consider to be clinically relevant. In addition, the probability<sup>3</sup> (confidence level) derived from their own data that more pelvic abscesses occur during hospitalization when drains are not used, compared to the use of drainage, is no less than 94%. It is clear that the authors have made a very frequent error of interpretation of a statistically non-significant result.<sup>2</sup> It is also clear that, in order to facilitate the interpretation of the main results of a study, they should be accompanied by confidence intervals, as stated in the Vancouver Recommendations, and conclusions should not rely on all-or-nothing interpretations of P values.

In conclusion, we believe that the results of the Denost et al. 1 trial do not demonstrate that the use of pelvic drainage does not produce beneficial effects to avoid pelvic abscesses after rectal surgery for cancer. Moreover, given their results, the inverse hypothesis could be perfectly posed. Therefore, this important research problem has yet to be resolved.

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# Should We Assume the New Definition of Sepsis in the Surgical Field?<sup>\*</sup>



### ¿Debemos asumir la nueva definición de sepsis en el campo de la cirugía?

To the Editor,

Recently, the Society of Critical Care Medicine (SCCM) and the European Society of Intensive Care Medicine (ESICM) reached a consensus that modified the definitions of sepsis and septic shock using a complex methodology based on 3 retrospective studies developed mainly in the United States, in addition to surveys that only used the Delphi method and a review of the literature.<sup>1</sup>

The most striking of these new definitions is the exclusion of systemic inflammatory response syndrome (SIRS) from the concept of sepsis. This would now be defined by a change  $\geq 2$  in the Sepsis-related Organ Failure Assessment (SOFA) or a modified Quick SOFA (qSOFA) with known or probable infection.<sup>1</sup>

The authors of the consensus mainly base this decision on a retrospective study in patients admitted to the ICU in situations of severe sepsis.<sup>2</sup> In these patients, one in 8 (12.5%) suffered from sepsis and multiple organ dysfunction without at least 2 SIRS criteria. However, it cannot be denied that in 7 out of every 8 cases (87.5%), at least 2 SIRS criteria were met, and were considered as such.<sup>3</sup> While it is true that SIRS is not a perfect tool, its usefulness has been well established. Given the high mortality of sepsis, a highly sensitivity screening tool, such as SIRS, should be given priority over specificity, which is somewhat higher with SOFA.<sup>4</sup> A directly proportional correlation between mortality and SIRS has been observed in several studies.<sup>5–8</sup> In addition, its use, as well as the definitions of previous sepsis and associated interventions, have significantly reduced overall mortality due to sepsis.<sup>2,6,9–12</sup>

The new consensus bases the definition of sepsis on organ dysfunction. The SOFA scale was designed to objectively identify established organ dysfunction in the context of sepsis in critical patients, <sup>11</sup> and this score does not include, for example, coagulopathy, one of the most frequent organ dysfunctions in septic patients. <sup>7,11</sup> Its use, despite being habitual in intensive care units, is anecdotal in other contexts. <sup>4</sup> Its lack of application outside the intensive care unit, such as surgical emergencies or surgery units, where cases of sepsis are usually diagnosed at their origin, as well as the dependence on these definitions of organ failure, a situation that occurs in severe sepsis and would prevent an early diagnosis, do not seem to advise its use in our setting.

This is why we concur with other authors who have also expressed their concern about this paradigm shift.<sup>3,4</sup> We believe that substituting a definition of sepsis—which, coupled with the homogenization of intervention packages, has led to an overall decline in mortality and lowered severe sepsis rates by 7%–16% and septic shock by 20%–25%, <sup>3,9,11,12</sup> and is widely extended and validated (higher precocity with lower mortality)—for another marginally used definition, without prospective studies in different types of patients, settings and regions to support this change, is a risky endeavor to which our patients should not be exposed.

"Good clinical care is grounded in common sense and carefully considered intervention, not in esoteric renderings of biology."—John Marshall $^{\rm 8}$ 

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