*the withdrawal of any neuromuscular blocking agents or reversal agents, even after sugammadex becomes available.*

François Donati PhD MD FRCPC
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## *Appraising the evidence in managing fibroproliferative acute respiratory distress syndrome*

To The Editor:

I write further to the appraisal of the "Best Evidence in Critical Care Medicine" article written by Drs. Ewanchuk and Jacka in the September 2007 issue of the *Journal*.[1] They correctly identify that routine use of methylprednisolone in patients with established acute respiratory distress syndrome (ARDS) does not improve outcome. However, they also reiterate the original article's conclusion that commencing the use of methylprednisolone more than 13 days after onset of acute respiratory distress syndrome "*had a significantly higher case fatality rate*".[2] A more detailed examination of the data may lead to a different conclusion.

The primary outcome of the study was 60-day mortality. In the placebo group the mortality rate was 28.6% [95% confidence interval (CI) 20.3 to 38.6%], and in the methylprednisolone group the mortality rate was 29.2 % (95% CI 20.8 to 39.4%). These mortality rates are similar to those reported in other studies of patients with ARDS.[3] In patients who were randomized between 14 and 28 days after onset of ARDS, the 60-day mortality rate in the methylprednisolone group ($n$ = 23) was 35% (95% CI 15.3 to 54.2%), and in the placebo group ($n$ = 25) it was 8% (95% CI 0 to 18.6%). While there was a statistically significant difference in the event rate between these two groups of patients, this outcome is due to a lower than would be expected mortality rate in the placebo group, as opposed to methylprednisolone directly increasing risk.

The mortality rate in the small group of patients who received placebo more than 13 days after the onset of ARDS, was far lower than that observed in other studies evaluating similar patients. It is difficult to reconcile that administration of a placebo more than 13 days after the onset of ARDS would in itself lead to a reduction of the expected mortality rate in this patient population. This is an example of problems that can arise from random error. In the trial published in the New England Journal of Medicine (NEJM), it appears that the low 60-day mortality rate observed in the placebo group was due to an effect of chance. Small samples increase the likelihood of misleading results through random error. It is surprising that this issue was not identified during peer review by the NEJM. This example serves as a gentle reminder for the readers to scrutinize the data when critically appraising an article. Guidance on this aspect of critical appraisal has been published.[4]

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*Accepted for publication November 5, 2007.*

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## *Reply:*

*We thank Dr. Daniel for his interest in our critical appraisal and in the role of steroids for the treatment of fibroproliferative acute respiratory distress syndrome (ARDS).[1]Dr. Daniel is correct in confirming that the central finding of the National Institute of Health (NIH) trial was that a statistically significant differ-*

*ence existed between the steroid and placebo groups, with this difference favouring placebo.*[2] *Given that the NIH trial was designed and powered to find a benefit in favour of steroids (if one existed), the converse finding of harm was surprising, and must be emphasized as the major observation of the trial.*

*The possibility that the mortality within the placebo arm was spuriously reduced due to the effect of chance alone exists, should be considered, and then summarily dismissed as irrelevant to the major issue. In a therapeutic trial, the protective caveat to which Dr. Daniel refers should be properly applied to the possibility of falsely attributing benefit to the therapy group due to random variation, rather than vice versa.*

*The analysis of the original authors and the peer review process of the New England Journal of Medicine remain correct: there is no support for routine administration of steroids as treatment in the fibroproliferative phase of ARDS. Clinician discretion remains appropriate as always.*

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## *Lumbar tattoos and lumbar epidural analgesia: unresolved controversies*

To the Editor:

In recent years body tattooing in unconventional sites has gained increasing popularity amongst young women.[1] Although the potential hazards of neuraxial procedures in patients with lumbar tattoos remain controversial[1–3] it may be prudent to avoid a hollow needle insertion due to possible tissue entrapment in its bore as the needle passes to the deeper structures through a tattoo. In their letter to the editor regarding lumbar tattoos and lumber puncture Kluger *et al.*[3] state: "*To date, however no, complication related to tattoo puncture during epidural anesthesia has been reported*". However, in 2004, Kuczkowski reported a 34-yr-old, healthy female at term who was in labour and requested labour analgesia.[1] Preanesthetic evaluation of her back revealed colourful tattoos covering her entire lumbar area. An epidural block was performed in a standard manner (one attempt at the L2–3 interspace) with an 18G Tuohy needle. Several hours after an uneventful delivery, the patient reported tenderness and burning in the lumbar area where the epidural catheter had been sited. There was tenderness localized at the L 2–3 interspace; however, due to the presence of a tattoo in this area no skin redness (irritation) could be determined. The neurological examination was normal and her symptoms resolved over the next 24 hr. The author speculated that a pigment-containing tissue core from a tattoo seemed a possible cause of deeper lumbar tissues irritation.

In another paper published in 2004 Vasold *et al.*[4] provided *in vitro* evidence that the tattoo colorants - industrial pigments, which have never been intended (and produced) by the chemical industry to be used in humans for ornamental purposes (but rather to stain consumer goods) may contain hazardous compounds (toxic and/or carcinogenic substances such as 2-methyl-5-nitroaniline, 2-5-dichloraniline and 4-nitro-toluene). Moreover, in 2005 Jack *et al.*[5] reported a case of axillary lymphadenopathy 30 years after a decorative tattoo, clinically mimicking metastatic melanoma. These new findings, which may not be known to many clinicians and their patients, may have implications for anesthesiologists performing labour epidural analgesia in patients with lumbar tattoos.

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