Expression of Concern

Online posting to the Canadian Journal of Anesthesia

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To our readers:

In 2011, the Canadian Journal of Anesthesia received an article submission entitled: "Effects of colforsin daropate on hypercapnic depression of diaphragmatic contractility in pentobarbital-anesthetized dogs". The authors were Yoshitaka Fujii, MD and Aki Uemura, MD from the First Department of Anesthesiology, Toho University School of Medicine. At the time of article submission, we were aware of ongoing concerns regarding Dr. Fujii’s work that extended as far back as 2000. A Letter to the Editor by Drs. Kranke et al. published in Anesthesia & Analgesia raised concerns about the implausibility of data from a large number of articles published by Dr. Fujii across a number of journals, including the Canadian Journal of Anesthesia. We were also aware of an ongoing analysis of 169 randomized controlled trials being undertaken by Dr. John Carlisle, the results of which were recently published in Anaesthesia. This unique article provides overwhelming statistical evidence that “the distribution of continuous and categorical variables reported in Fujii’s papers, both animal and human, are extremely unlikely to have arisen by chance and if so, in many cases with likelihoods that are infinitesimally small.”

As a result of an internal investigation in the Department of Anesthesia at Toho University, it was determined that the article submitted to the Canadian Journal of Anesthesia in 2011 had no ethical approval but also that the data had been fabricated. These events resulted in the launch of a more extensive review by the Investigating Committee of the Faculty of Medicine at Toho University. The results of the university Discipline Committee were released on March 8, 2012:
“Since all of Dr. Fujii’s clinical studies that appeared in these 9 publications [below] were conducted at
Ushiku Aiwa General Hospital, which has no relation to his research activity in Toho University, the
investigation committee contacted the head of the hospital. As far as the head of the hospital knows, there
was only one clinical study listed by Dr. Fujii as having been conducted at the hospital. The other eight
clinical studies were conducted without any ethics committee’s approval, and this was judged sufficient to
decide that 8 of his publications (No. 2 to 9) should be retracted since they did not conform to the global
standard of ethics for clinical studies. After the investigation, the committee asked Dr. Yoshitaka Fujii and
his co-author, Dr. Michiyo Itakura, to explain the whole circumstances. Dr. Fujii admitted that the clinical
studies were done without any ethics committee’s approval. Dr. Itakura, however, was not involved in this
misconduct. Dr. Yoshitaka Fujii sent letters of retraction to the affected journals. We organized a
disciplinary committee and decided that a disciplinary dismissal was appropriate for Dr. Fujii effective from
February 29, 2012. Dr. Fujii has already been dismissed from Toho University.”

Below is the list of nine publications in which it was determined that Dr. Fujii did not receive ethical
approval:

1. *Fujii Y, Itakura M.* Efficacy of the lidocaine/flurbiprofen axetil combination for reducing pain during


3. *Fujii Y, Itakura M.* A prospective, randomized, double-blind, placebo-controlled study to assess the
   antiemetic effects of midazolam on postoperative nausea and vomiting in women undergoing laparoscopic

4. *Fujii Y, Itakura M.* Reduction of postoperative nausea, vomiting, and analgesic requirement with


The announcement by Toho University follows a joint effort by editors-in-chief of a number of anesthesia journals. I extend my personal thanks to Dr. Steven Shafer, Editor-in-Chief of *Anesthesia & Analgesia*, and Dr. Steven Yentis, Editor-in-Chief of *Anaesthesia*, both of whom have played pivotal roles in pursuing the question of possible scientific misconduct of Dr. Fujii’s work. While none of the nine articles on the above list was published in the *Canadian Journal of Anesthesia*, the egregious ethical misconduct that has already been confirmed and the overwhelming concerns of scientific misconduct now cast a shadow of serious doubt relating to every one of the articles that Dr. Yoshitaka Fujii has ever published. Accordingly, it is important that we provide a complete list of articles written by Dr. Yoshitaka Fujii that were published in the *Canadian Journal of Anesthesia*:


The editors of the affected journals will jointly contact the Deans of the Faculties of Medicine of the six universities from which Dr. Fujii published his work to alert them of these concerns and to request that they provide unequivocal evidence of Institutional Review Board approval and data veracity regarding all of the studies cited in the Carlisle article. This review will be complex as it involves a number of institutions. In the absence of the aforementioned documentation, it is possible that many or all of the affected articles may be retracted in due course.

In general, health practice and policy is rarely changed based on the results of a single primary study. More often, change happens after a systematic review or practice guideline (resulting from a systematic review). In the case of Dr. Fujii, it will also be important to ascertain whether any of his primary research has been included in systematic reviews, as the results could be potentially misleading until such time as they can be re-analyzed without the problem primary studies.

We deeply regret the shadow of serious doubt that has been cast over such a large body of scientific literature. I have previously expressed my personal views regarding scientific misconduct. In a recent editorial, Dr. Elizabeth Wager, Chair of the Committee on Publication Ethics, explored the challenging and complex issue concerning who is responsible for investigating suspected research misconduct. As stated by Dr. Wager in her recent editorial, “Research misconduct is hard to prevent because it represents a systems
failure, so its causes and solutions are multifactorial. Similarly, systems for investigating misconduct appear to be difficult to establish, fund and monitor…unless we establish better methods for investigating misconduct, researchers and clinicians will be left with lingering doubt about the purity and therefore trustworthiness of the evidence they rely on to make decisions.”

Donald R. Miller, MD
Editor-in-Chief
Canadian Journal of Anesthesia

References


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