February 15th, 2013

Notice of Retraction

The articles in Table 1 by Yoshitaka Fujii were retracted in 2012. At that time, the articles in Table 2 were still under review by the University of Tsukuba. The University of Tsukuba has completed its review, and based upon their findings, and further to the Expression of Concern* posted online on March 13th, 2012, and the Editors-in-Chief Request for Determination of April 9, 2012†, and further to the Canadian Journal of Anesthesia Notice of Retraction of 17 articles by Dr. Yoshitaka Fujii, dated September 6th 2012,‡ the following 16 additional articles are hereby retracted as a result of:

1. overwhelming evidence of fabrication relating to the fact that the distributions of many variables reported by Dr. Fujii in these studies are exceedingly unlikely;¹² and

2. the inability of Dr. Fujii’s institutions to attest to the integrity of the studies and/or the data conducted under their auspices, as set out in the Joint Editors-in-Chief Request for Determination of April 9, 2012.†

There are now 33 articles retracted from the Journal, written by Dr Fujii. The University of Tsukuba has affirmed the validity of three articles³⁴ five published in the Journal by Dr. S. Takahashi, for which Dr. Fujii was a coauthor. In addition, Tokyo Medical and Dental University has affirmed two other articles published in the Journal, one by Dr. T. Ebata⁶ and the other by Dr. Y. Saitoh,⁷ for which Dr. Fujii was a coauthor. These five articles shall remain part of the unimpeached medical literature.

We extend our sincere appreciation to the universities in Japan for their review of the status of Dr. Fujii’s research, and to the investigating committees for their review of his research findings.

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

* http://www.springer.com/medicine/anesthesiology/journal/12630
‡ http://www.springer.com/medicine/anesthesiology/journal/12630,
References

**TABLE 1**  Articles written by Dr. Yoshitaka Fujii retracted in 2012

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TABLE 2  Articles written by Dr. Yoshitaka Fujii that are retracted, based upon review by the University of Tsukuba

September 6th, 2012

**Notice of Retraction**

Further to the Expression of Concern* posted online on March 13th, 2012, the 17 articles listed in Table 1 by Dr. Yoshitaka Fujii are hereby retracted as a result of:

1. overwhelming evidence of fabrication relating to the fact that the distributions of many variables reported by Dr. Fujii in these studies are exceedingly unlikely;1,2 and

2. the inability of Dr. Fujii’s institutions to attest to the integrity of the studies and/or the data conducted under their auspices, as set out in the Joint Editors-in-Chief Request for Determination of April 9, 2012.*

The University of Tsukuba has affirmed the validity of three articles3-5 by Dr. S. Takahashi for which Dr. Fujii was a coauthor. In addition, Tokyo Medical and Dental University has affirmed two other articles published in the Journal, one by Dr. T. Ebata6 and the other by Dr. Y. Saitoh,7 for which Dr. Fujii was a coauthor. These five articles shall remain part of the unimpeached medical literature.

Another 17 articles listed in Table 2 by Dr. Fujii remain under review by the University of Tsukuba. These articles are considered compromised until they are assessed by the University. Articles in Table 2 that are not affirmed as valid by the University of Tsukuba will be retracted.

Kobe University was mistakenly listed as one of the responsible institutions in the initial Joint Editors-in-Chief Request for Determination Regarding Papers Published by Dr. Yoshitaka Fujii. Kobe University has never been associated with Dr. Fujii.

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

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References

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Table 2: Articles written by Dr. Yoshitaka Fujii that are indeterminate

Expression of Concern
Online posting to the Canadian Journal of Anesthesia
Release Date: March 13, 2012

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:


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


Editors-in-Chief Statement Regarding Published Clinical Trials
Conducted without IRB Approval by Joachim Boldt

March 4, 2011

To our readers:

Landesärztekammer Rheinland-Pfalz (“LÄK-RLP”), the State Medical Association of Rheinland-Pfalz, Germany serves as the Institutional Review Board (IRB) for clinical research at Klinikum Ludwigshafen, where Dr. Joachim Boldt’s recent research was conducted. On February 25, 2011, LÄK-RLP provided the involved journals with the results of their evaluation of the status of IRB approval for research conducted by Dr. Boldt dating back to 1999. LÄK-RLP determined, to the best of its ability, the status of IRB approval for 102 articles published by Dr. Boldt.

Table 1 lists 88 articles for which LÄK-RLP was unable to verify IRB approval. Table 2 lists 12 articles for which LÄK-RLP was able to verify IRB approval. Table 3 lists 2 articles for which LÄK-RLP determined that IRB approval was not necessary.

The undersigned Editors-in-Chief of medical journals affected by these findings will retract the articles in our respective journals that are listed in table 1. Formal retraction notices will appear in each journal.

The retraction of the articles in Table 1 for lack of IRB approval means that the research was unethical, and that IRB approval for the research was misrepresented in the published article. It does not mean that the research results per se are fraudulent. Klinikum Ludwigshafen has commissioned an investigating committee to systematically assess the veracity of the findings presented in Dr. Boldt’s articles against patient and laboratory records. We will communicate to our readers any finding of data fabrication, falsification, or misrepresentation identified by the investigating committee at Klinikum Ludwigshafen.

We, the undersigned Editors-in-Chief, on behalf of our Editorial Boards, affiliated societies, and publishers, extend our appreciation to LÄK-RLP for their review of the status of IRB approval for Dr. Boldt’s research and to the investigating committee at Klinikum Ludwigshafen for their ongoing review of his research findings.

Amendments:

1. March 4, 2011: LÄK-RLP has verified IRB approval for Boldt J, Schöllhorn T, Münchbach J, Pabsdorf M. A total balanced volume replacement strategy using a new balanced hydroxyethyl starch preparation (6% HES 130/0.42) in patients undergoing major abdominal surgery. Eur J Anaesthesiol. 2007;24:267-75. This article was moved from table 1 (articles without documented IRB approval) to table 2 (articles with documented IRB approval).
On behalf of our respective journals,

Lars S. Rasmussen  
Editor-in-Chief, *Acta Anaesthesiologica Scandinavica*

Steven M. Yentis  
Editor-in-Chief, *Anaesthesia*

Hugo Van Aken  
On behalf of the Editorial Board, *Anästhesiologie Intensivmedizin Notfallmedizin Schmerztherapie*

Steven L. Shafer  
Editor-in-Chief, *Anesthesia & Analgesia*

James C. Eisenach  
Editor-in-Chief, *Anesthesiology*

Charles S. Reilly  
Editor-in-Chief, *British Journal of Anaesthesia*

Donald R. Miller  
Editor-in-Chief, *Canadian Journal of Anesthesia/Journal canadien d'anesthésie*

Joseph E. Parrillo  
Editor-in-Chief, *Critical Care Medicine*

Bernd Zwissler  
On behalf of the Editorial Board and his CoEditor-in-Chief, Rolf Rossaint, *Der Anästhesist*
March 4, 2011

Martin R. Trautner
Editor-in-Chief, European Journal of Anaesthesiology

Massimo Antonelli
Editor-in-Chief, Intensive Care Medicine

Joel A. Kaplan
Editor-in-Chief, Journal of Cardiothoracic and Vascular Anesthesia

Jörg Wiltfang
Editor-in-Chief, Journal of Cranio-Maxillo-Facial Surgery

George B. Stefano
Editor-in-Chief, Medical Science Monitor

Davide Chiumello
Editor-in-Chief, Minerva Anestesiologica

Wolfgang R. Mayer
Editor-in-Chief, Vox Sanguinis
Table 1: Articles without evidence of IRB approval as determined by LÄK-RLP

*Acta Anaesthesiologica Scandinavica*


*Anaesthesia*


*Anästhesiolgie Intensivmedizin Notfallmedizin Schmerztherapie*

Triem JG, Röhm KD, Boldt J, Piper SN. [Comparison of a propofol-based anesthesia regimen using optimated-target-controlled-infusion (OTCI) and manually-controlled infusion (MCI) technique]. Anästhesiol Intensivmed Notfallmed Schmerzther. 2006;41:150-5


*Anesthesia & Analgesia*

Boldt J, Brosch Ch, Röhm K, Lehmann A, Mengistu A, Suttner S. Is albumin administration in hypoalbuminemic elderly cardiac surgery patients of benefit with regard to inflammation, endothelial activation, and long-term kidney function? Anesth Analg. 2008;107:1496-503


**Anesthesiology**


**Annals of Thoracic Surgery**


**British Journal of Anaesthesia**


Boldt J, Suttner S, Brosch C, Lehmann A, Mengistu A. Influence on coagulation of a potato-derived hydroxyethylstarch (HES 130/0.42) and a maize-derived hydroxyethylstarch (HES 130/0.4) in patients undergoing cardiac surgery. Br J Anaesth. 2009;102:191-7


Piper SN, Röhm KD, Boldt J, Faust KL, Maleck WH, Kranke P, Suttner SW. Inspired oxygen fraction of 0.8 compared with 0.4 does not further reduce postoperative nausea and vomiting in dolasetron-treated patients undergoing laparoscopic cholecystectomy. Br J Anaesth. 2006;97:647-53


**Canadian Journal of Anesthesia/Journal canadien d'anesthésie**


**Critical Care Medicine**


**Der Anästhesist**


**European Journal of Anaesthesiology**


**Intensive Care Medicine**


Journal of Cardiothoracic and Vascular Anesthesia


Journal of Cranio-Maxillo-Facial Surgery


Medical Science Monitor


Minerva Anestesiologica

The Thoracic and Cardiovascular Surgeon

Vox Sanguinis
Table 2: Articles with IRB approval verified by LÄK-RLP


Table 3: Articles that do not require IRB approval as determined by LÄK-RLP

