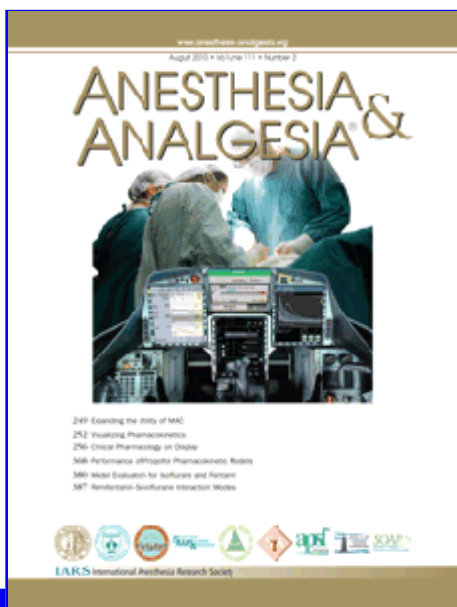


Retraction Watch

Tracking retractions as a window into the scientific process

Top German anesthesiologist's cardiac surgery paper retracted over "very serious misrepresentations"

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[Self-plagiarism](#) alert: A very similar version of this post is being published online in [Anesthesiology News](#), where one of us (AM) is managing editor.

A leading German anesthesiologist with more than 200 papers to his name has been accused of misrepresenting critical aspects of a paper — possibly including the data itself — published late last year in the journal [Anesthesia & Analgesia](#).

In a [retraction notice](#) published online today, Steven L. Shafer, editor-in-chief of the journal, writes that [Joachim Boldt](#) and his coauthors failed to obtain approval from an institutional review board, did not get patient consent and did not follow up as promised with volunteers in their study, reported in the December 2009 article, "[Cardiopulmonary Bypass Priming Using a High Dose of a Balanced Hydroxyethyl Starch Versus an Albumin-Based Priming System](#)."

In addition, the journal said, it has reason to suspect that data in the paper were fabricated, a possibility that is being investigated by German authorities. As the notice states:

it is possible that the study was never performed at all.

[Hydroxyethyl starch](#) is a colloidal solution—particles suspended in liquid—anesthesiologists administer to patients during surgery to keep their blood volume high, in order to maintain adequate delivery of nutrients to cells. So-called intraoperative fluid management remain an unsettled topic for anesthesiologists, who have taken to calling the controversy the "[Great Fluid Debate](#)."

Boldt, head of anesthesia at the Klinikum Ludwigshafen, a private hospital in Rheinland, has spent much of his career studying the safety and efficacy of colloids, Shafer says. Clinicians now may be left wondering how much, if any, of his work they can trust.

Boldt has disclosed receiving funding for his research from makers of hetastarch and other products including B. Braun, Baxter and Fresenius Kabi.* He also has received funding from Plasmaselect and Bernburg, as well as Edwards Lifesciences, which makes devices that allow clinicians to monitor fluids in surgery patients.

The paper in question reported on a study of 50 patients undergoing cardiopulmonary bypass (CPB). Some were given

hydroxyethyl starch and others received albumin.

According to the authors, "high-volume priming of the CPB circuit with a modern balanced HES solution resulted in reduced inflammation, less endothelial damage, and fewer alterations in renal tubular integrity compared with an albumin-based priming. Coagulation including platelet function was better preserved with high-dose balanced HES CPB priming compared with albumin-based CPB priming."

As Shafer says, the data in the paper simply looked too good to be true. From the retraction letter:

Shortly following publication the Journal received several letters from concerned readers that the variability in the cytokine assay was too low to be believed. Upon reviewing the results, we concurred with that assessment. We also believed that the variability in blood gas results reported in the paper was too low to be believable.

Shafer tells Retraction Watch that Boldt initially was cooperative and promised to help resolve the issue. However, he soon stopped cooperating, leaving Shafer to deal with the medical board, called LÄK, in Rheinland.

Earlier this week, nine months after he first raised questions about the paper, Shafer says he heard from the board. Again, from the retraction letter:

On October 25th I received notification from LÄK about their findings. Professor Boldt's manuscript describes IRB [institutional review board] review, written informed consent, prospective randomization, and a follow-up questionnaire. LÄK determined that there was no IRB approval, no informed consent, no randomization process, and no follow-up questionnaire as described in the study. These are very serious misrepresentations in Professor Boldt's manuscript. As a result, the entire manuscript is compromised, and is hereby retracted.

According to Shafer's letter, LÄK has asked for, but not received research data from Dr. Boldt's group that might help him refute allegations of fraud stemming from the retracted article. "LÄK has not reached a conclusion that the data were fabricated. This is still an open question, and LÄK is continuing its investigation," he wrote.

Even without fabricated data, those sins of protocol are certainly bad enough to get the paper pulled. But, the letter, continues, the issues might be far worse:

Professor Boldt has published more than 200 manuscripts in the peer reviewed medical literature. A shadow has been cast over that body of work based on a determination that the report published in *Anesthesia & Analgesia* is fraudulent. In the coming months and years we will work with LÄK to determine the veracity of all reports by Professor Boldt published in *Anesthesia & Analgesia*.

Shafer, who has notified other journals about the issues with Boldt's research and warned them to review his manuscripts, tells us his journal has published in the neighborhood of 40 articles by the researcher. The paper was cited five times, according to Thomson Scientific's Web of Knowledge, including [an editorial that accompanied it in *Anesthesia & Analgesia*](#) and another by Boldt in the [Journal of Cardiothoracic and Vascular Anesthesia](#).

If any more than a handful of those 40 papers were to require retracting, Boldt might eclipse the notorious [Scott Reuben](#) as the most significant fraudster yet detected in anesthesiology. Reuben, a Massachusetts pain specialist, was found to have fabricated data and committed other fraud that led to the retraction of at least 21 papers, many in *Anesthesia & Analgesia*, in early 2009. Reuben, who blamed his actions on mental illness, is now serving a six-month prison sentence for health care fraud.

His impact on the journals that published his research has not ended, however. Shafer says he spends several hours each week analyzing articles by the disgraced researcher that have not been retracted and handling other fallout from the case.

Dealing with Boldt's body of publications "could take years," Shafer says. Boldt "has published far more than Reuben. The data that Reuben fabricated supported the safety and efficacy of selective COX-2 inhibitors, drugs with a benign safety profile. Older colloidal solutions are known to interfere with coagulation and renal function and may contribute towards inflammation. Newer colloidal solutions appear to have addressed these limitations. However, some of that research was performed by Prof. Boldt. The safety and efficacy of modern solutions is potentially compromised by the finding of misrepresentations in his research."

That helps explain the penultimate paragraph of Shafer's retraction letter:

I apologize to our readership, and to the patients cared for by our readership, for the publication of a fraudulent report in *Anesthesia & Analgesia*. We will examine our editorial policies, the quality of our

peer review, and look for ways to detect fraudulent research in the peer review process.

Speaking of which, Shafer tells us the 2009 paper was reviewed by several cardiovascular anesthesiologists, none of whom caught the bogus data. Nor did Shafer himself suspect anything when he reviewed the report — including the parts about blood gases, an area of particular expertise for him.

That, he says, points to the difficulties reviewers and editors face in catching fraud before a manuscript is published. Quoth Shafer:

Things are only obvious once they're obvious.

We'll be following this story closely and hope to update soon with comments from Boldt, LÄK, and other journals where Boldt has published, including *Anesthesiology*, *Critical Care Medicine* and the *Journal of the American Medical Association*.

**Sentence edited 3 p.m. Eastern, 10/29/10 to clarify that Baxter's funding did not involve research into hetastarch.*

Written by amarcus41

October 28, 2010 at 3:44 pm

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