

An open letter to the sultans of variability

Concerned response to a "Notice relating to fetal monitoring products" addressed to "whom it may concern" from March 14, 2019

From

Martin Daumer (1, 2, 3) & Christian Lederer (1, 2)

1. Trium Analysis Online GmbH, Munich, Germany

2. SLCMSR e.V. - The Human Motion Institute, Munich, Germany

3. Technical University of Munich, Department of Electrical Engineering, Munich, Germany

To

Whom it may concern (in particular the editor of AJOG, DGGG guideline committee, BfArM)

Munich, 3.4.2019

We have received a letter, including several attachments, dated March 14, 2019, from Peter Cashin, Managing Director Huntleigh Healthcare limited, on March 19th 2019. The subject was "Notice relating to fetal monitoring practice" and it was addressed "To whom it may concern". Huntleigh informs about the intention to circulate the letter and the attachments within 14 days to the "wider market place".

We respond with an open letter "To whom it may concern" (in particular the editor of AJOG, DGGG guideline committee, BfArM) - and to interested recipients of Huntleigh's information package linked to the "Notice relating to fetal monitoring practice".

We would like to start by confirming that in general we highly respect the outstanding pioneering contributions of Drs. Dawes and Redman to the field of electronic fetal monitoring.

We've carefully read and discussed Peter Cashin's letter and the attached letters from Dr. Richard Liwicki, Deputy Director, Research Services, Oxford University, Dr. James Pardey, first author of the "AJOG Paper" 2002;186:1095-1103, Dr. Adam Stoten, COO Oxford University Innovation, and Professor Emeritus Chris Redman, Oxford University, "co-inventor" of the "hidden variable" Dawes/Redman STV.

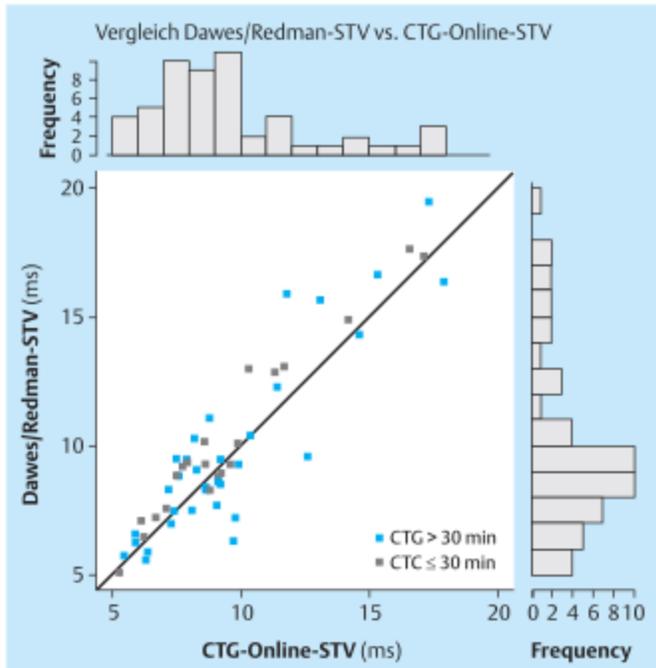
We came to the following two main conclusions.

1. Evidence for scientific misconduct

- It is a well known problem in science in general and in the medical science in particular that articles get published in peer-reviewed journals, although the authors do not provide enough details such that the reviewers and the editors can make an informed decision about the validity and credibility of the results. This is one of the reasons for the disturbing fact that “most published research findings are false” (Ioannides 2005, <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124>). In many cases the authors do not hide important details on purpose, but suppress them because of limitations of space. In some cases, however, authors hide important details on purpose for other reasons. We noted with interest that in the case of the AJOG paper the lead author acts as a whistle blower and has the infrontery (in German: “entblödet sich”) to openly admit that “significant information was deliberately omitted from this paper to ensure that the Dawes-Redman CTG analysis could not be reproduced by 3rd parties.” .
- We wonder what the editor of the AJOG will do when she/he will see this involuntary confession of what we think is severe scientific misconduct.

2. Evidence for a clinical risk linked to the use of Dawes/Redman STV

- Our product “Trium CTG Online” offers computerized CTG analysis following the FIGO concept and is distributed by GE Healthcare.
- The core algorithm of our CTG analysis system, the “delayed moving windows - DMW” algorithm to calculate the baseline of the FHR has been patented. As a matter of principle the patent assignee, in this case Trium, gets a time-limited exclusive right for commercial exploitation in return for a publication that must contain all the important details of the invention.
- In our computerized CTG analysis we follow the overall direction of the international FIGO guidelines. We agree with FIGO who does not find enough evidence to justify the inclusion of any form of short term variability in the alarm classification.
- Using the DMW algorithm we’ve used the partial information about a trivial standard measure of variability in the AJOG paper from 2002 to do a straightforward implementation of a measure for short term variability to be displayed in CTG Online as supplementary information without any link to the alarm conditions.
- This “CTG-Online-STV” was compared, in collaboration with researchers and clinicians from the Marien hospital of the Universität Witten/Herdecke and from the Friedrich-Ebert-Krankenhaus, Neumünster, to the “Dawes/Redman-STV”. The methods and the results, in particular Fig. 2, are published in Schiermeier S., Westhof G, Daumer M, Scholz M, Hatzmann W - Geburtsh Frauenheilk 2006; 66: 752 – 755 © Georg Thieme Verlag KG Stuttgart · New York · DOI 10.1055/s-2006-924385 · ISSN 0016-5751:



It is obvious that there is strong correlation between the two variables, although it is also obvious that the two variables are not identical. We leave it up to the reader/user to judge to what degree and in what context this similarity should be regarded as “equivalent”.

- We have noticed with interest that Huntleigh has knowledge about “significant weaknesses in the 2002 version which” - allegedly - “have been addressed in the latest release.” Huntleigh also states that these significant weaknesses “may present a clinical risk”. We are not aware of any related field safety notes.
- The field would benefit, given the past experience, from a publication about when these significant weaknesses have been discovered, what is their nature, how they have been addressed and corrected and the evidence that the modifications are a true preventive action and improvement. An independent validation of the existence of a substantial additional predictive value of the “corrected Dawes/Redman STV” for fetal acidosis would be desirable. The publication should give access to raw data and algorithms, ideally publically or at least to independent knowledgeable third parties.
- We are concerned and feel obliged to inform the responsible German guideline committee of the German Society for Obstetrics and Gynecology DGGG and the German BfArM about this important potential safety issue.

