## The Importance of Timing in Medical Science

## Reflections, with Own Experiences, upon an ignored Topic

New projects are almost always incidentally caused (when finally evaluated fruitful in hind sight). This essay, or project, was initialised by following the advice of a friend, Francis Dumont, to read a book by Jonathan Haidt [1], with the subtitle 'Finding modern Truth in Ancient Wisdom' (the main title was not so attractive to me). His book related to a provocation described just initially, in short: in 1992, Dr. Haidt was after several decades' intermission finding himself on a mountain ride. The road was narrow and his horse was on the wrong side, facing a deep fall into the valley by a further detour to the right. This danger was suddenly amplified as the road turned left. For a few seconds, Dr. Haidt thought he was facing death, expecting the horse to proceed straight away. The book was only possible to be written thanks to the horse turning left by itself - and we must be extremely grateful for that. The author then realized that his own fear was related to the fact that he was being used to drive cars and if born 150 years ago, he would not have reacted that way. Horses don't commit suicide but cars do go over the edge if you don't tell them not to do so. I remember my own group excursion on horseback in my youth; my horse also didn't commit suicide but it decided to run through the lake (perhaps 1 meter deep only there, but very impressive and humidifying! And when we went back, it wanted to show the other (horses) another masterpiece and we went in first - I was impressed while still alive. The horse is presumably dead now, and as I swore her eternal loyalty, I never rode again.

Dr. Haidt mainly seeks examples among old and ancient philosophers for prediction of, what contemporary researchers believe they found anew. My current topic here is another: How can you find something new, if you do not miss it why nobody made available to you? Or how could it be new, if it was already available? And how can a new invention find support when the users want to use the old principles for almost parallel (but improvable) principles and products? In my clinical career as anaesthetist and emergency physician, I found a number of examples and ran into some myself with interesting principles, generally being lost while wrongly used. The tendency has increased in later years, for spectacular reasons still ignored among the physicians. The fact that new drugs and principles have indeed survived until registration partially relates to other factors better not discussed here. My lawyer says, we cannot afford it – being right does not necessary imply that you win a lawsuit.

I want to mention some examples from my time as an emergency physician, a topic well developed in some European countries but virtually unknown in the United States. I enjoyed this field particularly because it was in development at the time and it was still possible to apply logic where others would adopt to strict guidelines. If you pressed upon an artery and bleeding stopped, you could claim that there was a causal connection. Today, you can let it bleed because there is no double-blind study available to confirm that your impression was correct and the measure has any impact on survival – and today's physician generally believes in that sort of nonsense.

So, while we are at the bleeding, it leads us to the *first claim*: **'If you use a method wrongly, a controlled study will show it to be of no clinical advantage.'** I had experienced many ugly fatalities among severely traumatised patients. Fortunately, I can also proudly refer to successes, but the worst was a patient, responsible after an accident, who then later died – could this not really have been prevented? If it could, you had committed a serious error – enough for many not to search very wide.

With the potential enemy of a malpractice-fearing physician, the police and general attorney, we performed a study of fatal traffic accidents in our county in 16 years [2]. The majority of the 430 cases died instantly, to which you may add the patients with cardiac

<sup>1.</sup> Jonathan Haidt: The Happiness Hypothesis. Finding modern Truth in Ancient Wisdom. Basic Books, NY, 2006 (ISBN 0-475-02801-6).

<sup>2.</sup> Schou J, Ginz HF, Herion H-P, Huck D, Blum R, Fehlmann R, Ummenhofer W. Abdominal haemorrhage – a preventable cause of death after field stabilization? Resuscitation 2000;43:185-93.

arrest exerted to cardiopulmonary resuscitation (CPR), an almost always fruitless, ritual measure when performed after a traumatic incident. 43% of the victims were admitted to hospital, of whom 5% had received prehospital CPR and the remaining 38% had not. Going into further details, I studied the 60 fatalities in my own responsibility. Of these, 27 (45%) patients died within the hospital; almost half of these cases (13/27) had been conscious at some time after the accident and of these, 7 (7/13) died from intra-abdominal bleeding within 4 hours after admission. The same cause of death was found in 3 of the 14 comatose patients. Pleural drainage was carried out in 4 patients and unrecognised pneumothoraces or spinal injuries did not occur. Medical anti-shock trousers [MAST] were not available for us at the time. The most negative conclusion of this small study was, that when everything else is taking care of [3], it might have been possible to save about half of the patients who died after an accident, after which they had been responsible for some time (thus excluding severe cranial trauma) – provided there was a method for control of internal bleeding.

There is such a method and, to my belief, we also found the proof of its value. Moreover, it is possible to cite a number of reasons, why this had not led to approval in a widely cited controlled study of MAST [4], although the double-blind physicians will never accept my arguments. That bleeding can be stopped by pressure is an observation that can be followed back to the 18<sup>th</sup> Century and is a fact, to which the vascular surgeon does not need particular scientific arguments for being convinced. We acquired a special model of MAST, in which a ball is pressed on the abdomen but the pressure is generated only by the tension of the velcron fibres in the surrounding garment. The previously responsive patient would need anaesthesia in advance, since any pressure on the stomach is then very painful, when MAST is indicated, but since the patient with a bleeding belly was never prepared for dramatic interventions, it was anyhow advantageous to carry out intubation before applying pressure to a possibly full stomach, and in the meantime, assistants could squeeze the legs (accessing blood to the remaining body and later contrasting the effect of abdominal compression to create stasis to the legs). The IV line - generally a small challenge to the anaesthetist - was the vehicle for anaesthesia, not (just) for volume substitution.

Using this principle, we managed rather soon to save the life of three patients (two of them published [5]) with ruptured aortic aneurysm, diagnosed in the hospital, and bring them to Operation in the University Hospital of Basle. Then follows in Sherlock Holmes' deduction, not the conclusion of a randomised, double blind study, that if it is possible to control bleeding from a ruptured aortic aneurysm with MAST, then most other abdominal bleeding sources should also be an appropriate target.

Now to the other side, why did they discredit the method? Actually, they showed that it was detrimentally used (which is correct), mostly others made other deductions (generally wrong). In the USA, a sensible doctor does not take the risk of performing out-of-hospital emergency therapy (even the in-hospital aspect may be crucially delayed until all forensic details have been cleared). If you know too much, the lawyer may complain that you did not use your knowledge to the benefit of the patient. Instead, programmes have been developed which paramedics should follow like Pavlov's dogs, once they have recognized an inductive sign. That is safe - for the paramedics, at least - but one may wonder, how these programmes found their way to European emergency physicians. They have immediately adopted ALS and ATLS fully and switched off any thoughts that individual cases may profit from a different therapy. Let them protest to this conclusion, if they care (a discussion medium is not available), but this is my second *claim*: `Prehospital randomised studies have brought wrong conclusions through oversimplification.' In addition, such studies are basically unethical for lack of informed accept of participation, something you can never demand in an acute case. The opposite side finds it unethical not to perform 'research' in the prehospital scenery, to which they add their opinion that only randomised studies are to be considered research [6].

<sup>3.</sup> Schou J. Major interventions in the field stabilization of trauma patients: what is possible? Eur J Emerg Med 1996;3:221-4.

<sup>4.</sup> Mattox KL, Bickell W, Pepe PE, Burch J, Feliciano D. Prospective MAST-study in 911 patients.. J Trauma 1989 29:1104-12

<sup>5.</sup> Schou J, Hauser E, Schreiner W. Use of non-pneumatic antishock garments for ruptured abdominal aortic aneurysm. Eur J Emerg Med 1997;4:169-71.

<sup>6.</sup> Schou J. Prehospital research and clinical decision-making. Eur J Emerg Med 1998;5:74.

What makes the American concept of MAST even worse, is the use often without previous intubation, the delay associated with searching for an IV line, too high and too low pressures used in the pneumatic chambers – and, quite paradoxically, delay in operation after admission (the patient appears stable). Within this chaos derives the impression that MAST is disadvantageous to the patients (which it indeed is when used wrongly).

A grotesque example of the power behind ATLS is the spine-board vs. the vacuum mattress in the care of traumatic spine injury. If the spine was straight like a flagstaff, it could be regarded kind of stabilization to force it down to something absolutely flat. The spine board is as flat and hard as the floor in your house, and patients – even without a back trauma – confirm it as utterly unpleasant. Contrary to this, the vacuum mattress supports the natural curves of the spine (those the emergency physician may never have heard about). Even the worst vacuum mattress – there are important differences [7] – is thus better than the best spine board. I shall not go further into the matter; if you need to be convinced and accept an unscientific approach, set the kitchen watch for 30 minutes and 'stabilize' your back on the bathroom floor, with no carpet in-between.

A beautiful example of the stupid construct of clinical studies of new principles was given with the introduction and sadly rapid disappearance of a new resuscitation principle, the 'Active Compression-Decompression' (ACD). As all ingenious new inventions, it was the product of a coincidence, one that was not immediately understood and is now waiting for a second renaissance. A man in San Francisco got cardiac arrest while on the toilet. His wife, having given alarm, found little place to perform a classical CPR, apart from being alone with the husband. Beside the toilet, however, the Plummer's cup was standing, and this was now used, intermittently producing compression and suction. Ventilation was *not* performed. In short, the man survived this event and another similar later, and some physicians realized that they might be standing for an improved method of CPR.

With our own use of a device, made for ACD (Cardiopump <sup>TM</sup>), we realized that the negative pressure phases not only reduced the intracranial pressure but it really improved the artificial circulation; however, it was necessary to reduce the frequency (40-60 instead of traditionally 80-100/min) and ventilation should be added cautiously. We produced spectacular successes with this tool, until it was removed [8]. That occurred following the demands that it be tested using the same principles used for standard-CPR, by which the device could not profit from its unusual advantages, of which arose the *third claim*: **If you use a new tool the wrong way, possibly even evaluated by irrelevant parameters, it will probably not demonstrate improved therapy**. Now, 15 years later, emergency physicians discuss if ventilation is actually always advantageous in CPR, and without an understanding of the particular problems related to CPR and ventilation, there is reason to fear their conclusions.

The problem of appropriate timing anyhow comes to a new technique, or *fourth claim:* **Nobody misses anything they never heard about**, and the first reaction is therefore possibly blunt rejection. By no means can you expect appropriate rules waiting for introduction along with a new device (or drugs with new features). Recognitions and inventions may be excellent but without being presented at the appropriate time and for the rarely found open-minded audience, they will have no chance

The list of wasted possibilities is still long but I have now, for health reasons, left the scene. Let me just mention the question set up for our (emergency physicians') options [9]: Which important therapy can only be performed after the admission of the patient to the hospital? The answer is: hardly any, but search in vain may delay the on-scene time crucially. It was, however, possible to improve prehospital care crucially, to threaten setting in-hospital emergency care in a dubious light. Maybe that was the mistake?

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<sup>7.</sup> Schou J, Kiermayer H, Ummenhofer W, Herion H-P. In Search of the Most Suitable Technique for Truncal Spinal Immobilization with Associated Radiography. Eur J Emerg Med 2001;8:89-92.

<sup>8.</sup> Schou J, Kübler J, Scherb M, Deklerk J. Active compression-decompression in CPR. Acta Anaesthesiol Scand 1993;37(Suppl. 100):S228.

<sup>9.</sup> Schou J. Maximum vs. optimum in prehospital emergency care — a call for compromise (editorial). JEUR 1995;8:125-6.