The Dark Side of Neuro-Intervention

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By

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To My First Teacher, Tarfa

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Without whom very little would be accomplished

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INTRODUCTION

My first publication as a junior resident was about a complication that occurred following the coiling of an aneurysm at the center I was training in. I still vividly remember my mentor, motivated by his paternal instinct, criticizing me for this publication. He was, of course, looking out for me and his concern is that even if it is not a complication from something I did, readers will associate me with the complication and this paper might give the impression that I am a dangerous interventionalist. This story on a personal scale has parallels with the larger scale of meetings, books, and journals when they are littered with success stories of neurointervention. However, by contrast, complications and procedures gone wrong are not exposed to similar coverage. This is partially because most procedures are, fortunately, successful and end with the desired outcome; however, complications happen and systematically have limited representation in meetings, books, and journals.

The content of this book includes many disturbing complications where the identities of the patient and interventionalist are concealed as it is not the purpose of the book to point fingers but rather to learn. However, in order to be fair to myself, the grossest examples and the overwhelming majority of these cases are not procedures that the author participated in. The cases were compiled over several years and from many centers. Most of the cases fell into my lap when they were submitted to me for review and my opinion on a variety of matters—such as practicing physician safety evaluation (by relevant department, institution, or legal body)—or if it was part of an evaluation to see if some of these patients can be salvaged with further corrective interventional revisions. The bulk of the cases came when I was asked by administrators of an institution to review and audit their neurointerventional cases as an external examiner. This was the starting point of this collection. What I thought was going to be a quick walkthrough of tens of successfully and appropriately managed cases turned out to be a horrific exposure to far too many routinely mismanaged cases that occurred over multiple years. At that point I realized that what is obvious negligence to a well-informed neurointerventionalist may appear as normal and expected to an ill-informed neurointerventionalist. Indeed, this would certainly appear to be the case for the non-specialist who has been exposed to a steady stream of neurointerventional complications that have distorted their expectations, thereby allowing them to be indifferent to outrageously low-quality neurointerventions.

These points have motivated me to write this book, as I believe that unsuccessful procedures have as much, and possibly more, teaching value as successful ones. This focus on neurointerventional complications has been an eye-opening learning experience. I hope the complications and the illustrations of unfortunate cases will translate to an equally beneficial learning opportunity for the readers of this book.

Complications, in general, will be discussed but there will be an emphasis on operator related causes. It also became clear to me while writing that there are many other significant negative aspects of the discipline that are not procedure related, which has also earned them a place in this book.

I have no doubt that this book can be improved with feedback and contributions from others; therefore, if any reader wishes to volunteer an educational case, comment on an existing case or chapter, or has a topic recommendation that I overlooked, please do not hesitate to send your contribution to the following email: OKAILIRN@outlook.com.

> A smart man makes a mistake, learns from it, and never makes that mistake again. But a wise man finds a smart man and learns from him how to avoid the mistake altogether (Roy H. Williams)

INTENDED READERSHIP

Although this book (especially with its illustrative cases and final chapters) is specifically written for neurointerventionalists it, in general, should be beneficial to any medical practitioner who works with an angiographic suite regardless of creed or whether they are a

- Neuroradiologist
- Neurointerventionalist
- Body interventionalist
- Neurologist
- Neurosurgeon
- Vascular surgeon
- Cardiologist
- Radiologist

It also illustrates the wide range of complexities associated with angiographic and interventional procedures, which ought to make this book appealing to beginners and experienced readers. Indeed, the writing is not limited to pure procedural aspects but rather touches on many parts of practice that are not directly linked to direct patient intervention, which could find an audience, beyond that of physicians, that extends to other team members such technologists, nurses, and administrators.

The reader will also be taken outside of the hospital setting to address some relevant issues that force us to leave our typical habitat to interact with non-medical persons such as judges, lawyers, and industry representatives. It addresses some of the challenges and ambiguities that might be useful to medical students and residents who are considering neuro-intervention as a career choice.

THE SCOPE OF THIS BOOK

The dark side of neurointervention can be defined as any undesired outcome related to the discipline of neurointervention in patients, operators, institutions, research, and the scientific recourse or society. This book is an educational effort to highlight these problems with a particular emphasis on technical errors and acute complications.

THE ROOT OF THE PROBLEM

"Uncontrolled variation is the *enemy* of quality" wrote Edward Deming. While an anonymous author wrote that "Complexity is the enemy of safety". Healthcare, in general, is certainly a huge collection of interacting incompletely controlled variables: it is highly complex, and therefore, highly prone to accidents. Similarly, neurointervention is highly prone to accidents as it is a practice that balances many variables in complex ways; for instance, any endovascular interventional suite is a complex environment requiring interactions between a large multidisciplinary team that includes doctors, nurses, radiographers, porters, and clerical staff. The importance of this team interaction cannot be underestimated. Effective and safe practice requires that each member is suitably trained, competent, and familiar with their surroundings. Additionally, the procedures can be complex and in order to reach a successful conclusion the operator must successfully execute a series of actions that start before and continue well after the procedure. Any single step or group of steps that gets mishandled can lead to undesirable consequences; indeed, the sheer number of possibilities of things that can go wrong is large. Therefore, the responsible course toward a more reliable practice should be to encourage acknowledgment of this problem, have serious discussions about it, and to promote an active study that refines our practice instead of leaving it to chance (Wilson et al. 2005).

BACKGROUND AND SCALE OF THE PROBLEM

As we go on with the act of living, errors are inescapable. Rectifying errors is an inseparable part of living and such efforts to diminish errors within any system is a given (Marcus 2006). Much of the work on patient safety was influenced and inspired by safety-critical industries, such as the aviation and nuclear power industries. In medicine, perhaps the first significant alarms were voiced by the Institute of Medicine's (IOM) 2000 report "To Err Is Human". It indicated that "medical care may not be safe" and went on to estimate that, in US hospitals, between 44,000 and 98,000 individuals die annually from medical errors. Furthermore, the cost of medical errors was then estimated to be between 37.6 and 50 billion dollars (Institute of Medicine Committee on Quality of Health Care, 2000). Following this report, worldwide health systems began to collaborate over the concept of "Patient Safety" and began to act; however, studies conducted recently show that the problem remains significant. For instance, more recent estimates put the actual number of deaths related to preventable errors at 400,000 per year in the US; this number is greater than the number of deaths due to traffic accidents, breast cancer, or AIDS. It is likely to take third place among the most common causes of death in the US. It is also presumed that serious but non-lethal harm is10 to 20 times greater than lethal harm (James 2013) (Makary and Daniel 2016). Regarding the particular topic of this book, the scale of the dark side of neurointervention is unknown but given these staggering figures, it is probably underrated in our consciousness.

KEY DEFINITIONS AND CONCEPTS

Adverse events are injuries caused by medical management. They can originate from errors but also some harm can occur in instances where practitioners are blameless.

Error can be defined as failure of a planned action to be completed as intended or the use of an incorrect plan to achieve an aim. They may or may not cause injury to patients.

Preventable adverse events are adverse events due to error.

THE MANY WAYS WE CAN VIEW ERRORS AND MORE

With respect to their outcome, errors can be of three types:

- Near misses: mistakes that did not result in harm.
- Adverse events: all harmful occurrences (note: not all adverse events are errors)
- Sentinel events: Seriously harmful occurrences (note: not all sentinel events are errors)

Although near misses do not cause harm to patients, they are valuable and a great opportunity to learn from and implement preventive measures.

With respect to their source, types of errors can be listed as follows (DeLisa 2004):

- Latent Error (System Errors):
    - Communication and communication skills
    - Heavy workload/fatigue
    - Incomplete or unwritten policy
    - Inadequate training or supervision
    - Inadequate maintenance of equipment/building
    - Understaffing
    - Distractions
    - Patient non-participation
    - Trans-cultural issues
    - Information system
    - Medication errors
    - Tracking and follow-up

- Active Error (Human Mistakes):
    - Action slips or failures (e.g. picking up the wrong syringe)
    - Cognitive failures (e.g. memory lapses, misreading a situation)
    - Violations (e.g. deviation from standard procedures and workarounds)

With respect to the practicing individual, it might be more practical to simply organize errors into:

- Those due to technical skills (which are emphasized in this book)
- Those due to non-technical skills such as cognitive mishaps (which will also be discussed to some extent)

The ingredients for patient safety can be organized into four broad categories: quality, safety, leadership, and culture (Wachter).

- Quality:
  - Evidence-based medicine
  - Guidelines
  - Training
  - Processes
  - Forms
  - Measurements/benchmarking

- Safety:
  - Environment:
    - Room arrangement
    - Distractions/noise
    - Acuity/census
  - Equipment/material
    - Properly maintained inventory
    - Availability and proper storage of disposable items
    - Proper quality assurance of image quality

- Leadership:
  - Response to concerns
  - Culture
  - Policies and procedures
    - Disclosure
    - Hours
    - Reporting
    - Discipline
    - Participation (e.g. on rounds)

- Culture:
  - Communication:
    - Authority gradient

        - Patient input
        - Health literacy
    - Reporting:
        - Sharing or silence
        - Support or firing
        - Change (welcomed or not)

Safety Culture:

Patient safety requires careful organizational responsibility in order to prevent, identify, analyze, and correct possible errors.

All healthcare practitioners are responsible for preventing errors and identifying high-risk situations, as well as reducing the dangers of high-risk situations and adverse events. Entities, where such an attitude exists, promote a culture of prioritizing patient safety. Elements of a patient safety culture include (NHS, 2004):

- An emphasis that errors do happen and that they are frequent
- An effort to stop the culture of blame
- Replace it with the attitude of learning from errors
- Education on contributing human factors (see below)
- A culture that adopts an incident reporting system
- Active in risk management (see below): both when and before incidents happen
- Incorporating team training and simulation as additional methods to disseminate the message of patient safety
- An institution that is inspired and tries to implement principles of high-reliability organizations (see below)

Methods to detect errors include:

- Error reporting
- Audits
- Data-driven defect/error elimination/detection

Error Reporting:

Error reporting is generally accepted as a basic initiative in improving patient safety (Pittet and Donaldson 2006, Andrew 2007), and the main purpose of error reporting systems is to learn from experience. Although error reporting might be effective for large departments and institutions, it seems to me that it might not be as effective for neurointerventional practices (especially for technical errors). These are often manned by one person or a small group of highly specialized individuals with a set of skills and knowledge that is not easily comprehended by the non-specialist, who are often in charge of institution-wide error reporting systems. It seems that self-administered or externally outsourced audits might be the more suitable alternative model for small groups of highly specialized practitioners such as neurointerventionalists.

Data-driven elimination of defects/errors:

This method works best for industries and systems with a large sample size that permits the use of statistical techniques to identify defects in a system. This is the basis of the data-driven techniques of Six-Sigma/ Lean/Lean Six-Sigma, which are not only widely used in industry but have also found their way into healthcare practices, with demonstrable improvement in patient satisfaction and safety. In bare-bones terms, we can describe the Six Sigma's approach as being similar to that of good medical practice used since the time of Hippocrates, where relevant information is assembled leading to a careful diagnosis, which is followed by a proposed treatment and then the implementation of the said treatment. However, strictly speaking, these methods are statistical data dictated techniques that have a place at the larger organization/institution, or even departmental, level but do not seem to translate well on a smaller scale. For instance, most aspects of neurointerventional practices suffer from a small sample size that precludes the wide implementation of Six-Sigma techniques. However, some aspects of neuro-interventional practice are eligible for these techniques—for instance detecting a dip in patient satisfaction, inter-procedure downtime, overutilization of contrast or radiation dosage—which are amenable to Six-Sigma methods. Such metrics, even if they did not detect a gross deficiency, can have a positive influence on practice standard and the work culture if they are shared via scorecards, dashboards, or representative key performance indicators.

What follows after a defect is encountered:

- Risk management and preventing error can follow several strategies and the following is one way to organize it:
    - Designing out the potential for error
    - Rectifying errors
    - Making it more difficult to commit errors
    - Making error discovery easier

- Yet another strategy can be adopted from Six-Sigma, which is dependent on a DMAIC methodology:
  - Define
  - Measure
  - Analyze
  - Improve
  - Control

The evaluation of the pathophysiology of error and the impact of human factors is an essential component in any serious effort to raise patient safety. One way of categorizing these factors is listed here:

- Slips and lapses:
  - Interruptions
  - Fatigue
  - Time pressure
  - Anger
  - Anxiety
  - Fear
  - Boredom etc.

- Mistakes:
  - Incorrect plan of action
  - Misinterpretation of the problem
  - Lack of knowledge
  - A habitual pattern of thought

Human error countermeasures include:

- Studying and knowing the environment
- Anticipation and planning
- Calling for help early
- Exercising leadership and followership with assertiveness
- Distributing the workload
- Regular use and re-evaluate the situation with the 10-second for 10-minute concept
- Mobilize available resources
- Use good teamwork to achieve objectives (coordinate with and support others)
- Speaking up and effective communication
- Use all available information

- Cross and double check and minimize assumptions
- Allocate attention wisely
- Set priorities dynamically and be adaptive

All of these elements can be put to the test and enhanced through the use of simulation (including virtual reality simulators) for both technical skill and nontechnical skills training such as leadership, teamwork, and communication. These are all increasingly recognized as important determinants of patient outcome. Rehearsing crisis scenarios, in particular, may allow the team to deal with real-life crises in a safe and ordered way (Aggarwal et al. 2004).

Elements of High-Reliability Organizations include:

- Safety culture
- Structure and processes
- Team training and simulation
- Organizational learning

Elaboration on Some Selected Topics

Selected topics for further discussion:

1- Privileges, licensing, credentialing, and training
2- Type of practice, volume, and dedication
3- Device or material failure
4- Supporting team failure
5- Issues at the level of medical societies and political turf battles
6- The influence of commercial interest
7- Questionable science and pseudoscience
8- Breaches in ethics

Privileges, Licensing, Credentialing, and Training

Dealing with the central nervous system requires great attention to detail, as well as consistently and obsessively upholding high technical and clinical standards. Neglecting to do so will certainly lead to patients being harmed and potentially cause irreparable damage to an operator's reputation. Less attentive practices and techniques that are often clinically silent for interventions in the liver, heart, or lower extremities are more likely to be clinically overt when applied to the head, neck, and spine. For instance, air escaping into the bloodstream in the spleen, while undesirable, will rarely cause harm but will be potentially devastating in the basilar artery. Mini-fellowships, observerships, and hands-on courses are not sufficient to produce a safe interventionalist. Inadequate radiology and image interpretation skills can lead to devastating miscalculations. The transition from trainee to practitioner might even benefit from a post-training supervised phase before full independence. Furthermore, it might be wise when initially fully independent to be highly selective and outsource cases that are considered to be high risk (Kumar 2014). Following the lead of the aviation industry, some training programs also emphasize training using simulators and have published a favorable article about its value (Dawson et al. 2007). Neurointerventions are complicated and often involve multiple steps, which sometimes occur sequentially and, at other times, simultaneously; therefore, it should come as no surprise that a learning curve exists where the effectiveness of the operator needs time to mature and become seasoned (Yu et al. 2014). Additionally, there are initiatives in the US that push for certain complex cases to be exclusively handled by a selected few centers. The implementation of such initiatives will remove the choice out of the hands of individual interventionalists with respect to certain complex cases (Chaturvedi and Dumont 2009). Published standards of practice are available online and continue to evolve. It is important to be aware of such joint society statements. Although the full statements can be found by directly reading these articles and while these statements are a work in progress and will certainly be modified, some specific basic ideas are worth summarizing (Connors et al. 2004):

- Although technical skills in neurointervention are an obvious requirement, the joint statement emphasized the importance of adequate cognitive training.
- Formal training has no substitute. Mini-fellowships, observerships, and other informal learning pathways are not sufficient.
- Extensive neurodiagnostic and neuroangiographic knowledge and interpretive skills are essential and require formal training.
- The length of the training is important.
- The incremental staging of training is important. As an example, the joint statement cites the cardiology training program where there is a diagnostic clinical learning phase of 24 months, with a minimum of 8 months in the catheterization lab, as a prerequisite for interventional training.
- The volume of case exposure is important. This follows the cardiology training approach which, as a prerequisite for

interventional training, requires 300 supervised diagnostic coronary angiograms.

- Upholding the standards rest on the shoulders of hospital that provides the credentials.
- The definition of the scope of applicable procedures is that any procedure with stroke as a potential complication should only be performed by appropriately trained and experienced operators for both medical and ethical reasons.
- Operator experience improves in a linear fashion up to 100 cases and learning curve analysis suggests that 200 examinations are needed to become competent (Dion et al. 1986).
- Temporary neurological deficits are often 2 to 3 times more common than permanent complications.
- There is a 2 to 3-fold increase complication rate in patients with a history of stroke or TIA.
- The clinically overt complication is an under-representation of the true impact of angiography and intervention. Silent hits, detected by MRI, might be as high as 25% (Bendszus et al. 1999). The term "silent" might be a misnomer as these subclinical hits have been shown to cause cognitive decline on neuropsychologic evaluation (Crawley et al. 2000); in other words, you are only seeing the tip of the iceberg.
- Signs of inexperience that were stated several times include prolonged fluoroscopic time, the performance of arch aortography, and the number of catheters used. These are simple metrics that a non-specialist can monitor (Davies and Humphrey 1993) (McIvor et al. 1987).
- Initial credentialing is not enough, and the maintenance and assurance of continuing quality are important. Metrics cited include: 1-lifelong continuing medical education, 2-continuity of practice, 3-adequate success, and 4-minimal complications.

Type of Practice, Volume, and Dedication

Due to the increase in a number of neurointerventionalist, there is a trend toward more procedures being performed at low volume centers, which is worrisome because high volume centers are known to have better outcomes (Brinjikji et al. 2014) (Grigoryan et al. 2012).

A universal opinion does and may never exist over the question of dedication to the specialty but it is still worth mentioning. In theory, acting as a full-time neurointerventionalist should be the preferred set up in contrast to a practitioner who does many things and so neurointervention is only one of many duties. For instance, a cardiologist who does the bulk of his work on the heart but on occasion intervenes in the head and neck region or, similarly, a body interventionalist who works on the periphery might not be the best at performing a brain intervention. This ought to be a matter of discussion and monitoring. These types of general service are more likely to be associated with lower volumes than dedicated practices. Indeed, the importance of sufficient volumes in order to reach technical maturity for neurointerventions is key, as it has been shown that low enrollment practices are associated with higher complication rates (Nahab, Lynn, Kasner, Alexander, Klucznik, Zaidat, Chaloupka, Lutsep, Barnwell, Mawad, Lane, Chimowitz, and Group 2009, Derdeyn et al. 2013).

Device or Material Failure

The manufacturing of neurointerventional devices is complicated and typically goes through extensive quality assurance evaluation, which is overseen by the commercial party, government agency, institution, and the end user. This process often succeeds in its aim of preventing unsafe devices reaching clinical practices and, when they do reach the marketplace, there is a continued evaluation that allows for the recall of a product at the first sign of problems. For instance, due to these internal product testing mechanisms, a major provider of neurointerventional devices through internal product testing found a risk of embolization in parts of the coating on a stent device, and which was also prone to detachment; this enables the company to take action by recalling the products and informing the FD (Covidien 2014). Despite this, faulty devices can still slip through these processes and then be used on patients; they, therefore, represent an important but rare source of complications that are difficult to anticipate by the end user.

Supporting Team Failure

Different practices have different setups with regard to supporting staff, such as nurses and technologists. Some may have a large core of personnel who cover multiple areas at the same time. For instance, it is not uncommon to have a technologist cover body interventional cases most of the time but get assigned to cover neurointervention following a rotation. I have also come across technologists who are overstretched and are required to cover fluoroscopy, operating room x-ray duty, and body angiography, as well as neurointervention. Additionally, nursing staff can have a similar set up where they practice standard ward nursing, body intervention, and neurointervention at different times. These individuals will obviously function at a lower level than dedicated technologists and nurses who cover neuro-interventions either all or most of the time. This is especially relevant to time-sensitive procedures (e.g. in the case of acute strokes) where the interventionalist will have to focus more on efficiently executing the procedure and may not be able to oversee technologists or nurses, who are the journey team members of the neurointerventional service. A dedicated team are more likely to know where the items are and how to prepare them; they will also know how to position the patient, prepare the flushes, and monitor air in the tubing. This is in addition to optimizing time efficiency (which translates to greater success in time-sensitive procedures), as well as diminishing potential complications and decreasing the chance of miscommunication.

At an Institutional Level

We have previously mentioned the role of the institution in establishing and overseeing an effective credentialing process. The institution is also accountable and should provide the appropriate machinery and devices that are essential for safe practice. Inferior hardware will increase the likelihood of complications.

Medical Societies and Political Turf Battles

This is a charged area that is beyond the scope of this book to tackle. However, it is important to not lose sight of patient safety as an ultimate goal, which should be more important than medical society agenda, specialty ego, political power grab, or economic ambitions. Good luck with that!

The Influence of Commercial Interest

"Even cheap meals influence doctors" was the title of a *Wall Street Journal* piece based on findings published in *JAMA Internal Medicine* (DeJong et al. 2016). Industry and commercial interest is a strong participant in all branches of medicine, in both beneficial and harmful ways. On the positive side, many conferences, workshops, and continuing education programs would not be possible without industry participation. Likewise, industry, along with collaboration with physicians, has pushed