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Letter to the Editor

How has the nationwide use of off-label experimental endovascular devices been allowed for two decades as first choice and sometimes the only alternative to conventional standard and advanced surgical techniques?

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Dear Sir,

I attended the one-day symposium on "Cutting-Edge and Future technology in Ischemic and Hemorrhagic Stroke" at the Congress of Neurological Surgeons 2014, Boston, MA, USA. I expected to learn about the advances in treatment of cerebro-vascular accidents and "cures" for ischemic and hemorrhagic strokes. Instead, presenters focused on "the ways to place and navigate 'off-label' devices such as wires, coils, balloon catheters, pipelines, and stents in the complex vasculatures of the brain in patients worldwide." The subject was presented as the modern achievements of nano-technology, necessitating the wide acceptance of the new era of cutting-edge of endovascular technology. In some of the presented cases, young patients with brain aneurysms received multiple stents, pipelines, and coils. The use of these devices was advocated by many endovascular interventionalists as "first choice approach" that might replace the conventionally utilized surgical clipping and vascular reconstruction. The presenting interventionalists admitted to the poor obliteration rates of brain aneurysms and the years of "steep learning curve" in the use of these devices.[3-6] In fact, with the use of "pipelines and coils" for giant aneurysms, the authors reported complications in more than 50% of cases. Following the European example, many US hospitals nationwide have been using "off-label" devices for two decades. Such devices have been presented to patients as the "first choice" and sometimes the "only choice" that replaced the standard of care surgical aneurysm clipping and vascular reconstruction.

In recent medical and surgical history, the large-scale nationwide use of off-label devices is unique to endovascular surgery. Modern medicine and regulatory authorities had allowed such a practice to flourish, despite awareness of the inferior results to the standard of care obtained by surgical techniques. The situation makes it difficult for patients to make informed decisions, since many patients see us as sacred medical and surgical care givers. Adopting cutting-edge technology should not lead to acceptance of inferior results. It is truly surprising in 2014, to witness the industry-led medical management for, based on the assumption that "open surgery" is "old and bad" and needs to be replaced with high tech procedures. Of note, surgical clipping is currently performed through "mini open" technique with short length of stay.

The literature demonstrates ample evidence of substandard obliteration rate and significant complication rate following endovascular techniques.[3-6] Fifty percent obliteration rate is widely reported in studies of endovascular techniques.[3,4] How could we accept

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such results in our patients? How could hospitals in the industrialized world continue to practice "endovascular first choice" and "endovascular only choice." I am fully aware of hospitals that adopted "endovascular as the only choice" protocol for all brain aneurysms. Initial posttreatment obliteration rate was reported as 48%.[3,4] The goal of intervention for brain aneurysm is a simple one. The gold standard technique with the best obliteration rate is surgical clipping. Recently, in a "first choice" surgical clipping for various MCA aneurysms (ruptured and un-ruptured, simple and giant or complex), results were reported as a 98.3% success rate for permanent cure.[7] The industry keeps "pushing" their techniques despite recent reports of significant complications and substandard rates of obliteration.[8] In fact, incorporation of newer devices such as pipelines was reported with high complication rate including mortality.[5] Recent literature of using various intravascular devices does not suggest better outcomes.[6]

Who is paying the ultimate price other than patients for gaining the "experience"? I thought that in modern medicine, the "learning curve should be restricted to animal and simulation laboratories and patients' lives should not be endangered. I do understand that there is no profit, but expenses during development of medical devices. Outside medicine, we have never heard of technology enforced in patients prior to formal adequate testing and meeting the regulatory agencies' criteria for safety. For example, in the automobile industry, cars approved for the market must meet high standards of safety and will be immediately removed from the market should any safety concerns arise. Another example; in the aviation industry, we have never heard of a new design of airplanes allowed to fly and carry passengers on board to examine their safety. The "Air Buses" were developed and allowed to fly but then grounded when untoward events occurred that jeopardized passenger safety.

Why are we allowing the opposite to occur in neuroscience? I personally see medicine as an almost sacred profession based on the Hippocratic Oath of "doing no harm." What happened to the modern healthcare? Perhaps, this observation is based on modern corporate medicine being incorporated tightly with industrial medicine. I thought the regulatory agencies are forcing "measures to cut cost" and implement so much of protocols, procedures, check lists and performance improvement measures, etc., In fact, in the field of neuroanesthesiolgy, there is a growing "push" to not to have highly specialized neuroanesthesiologists to care for neurosurgery patients and not to use so many well-known interventional procedures and pharmacological agents because of "no data to support the positive impact on patients' outcome."[2] The uses of these "off-label" devices are costly and in the long run are resource-consuming. The implementation of these devices is just the beginning of a lifetime journey of further treatments such as repeated and serial angiograms, pharmacological costs, laboratory testing, and further interventions till the aneurysms are completely obliterated. With multiple diagnostic and therapeutic procedures come financial gains.

In 2009,[1] I wrote a letter-to-editor describing my personal experience in Illinois entitled "Hospital protocol for universal use of coiling to all brain aneurysms in non-university setting: Is it too late to be corrected?"[1] What is the data to support aggressive placements of multiple devices intravascularly within the brain? What are the long-term effects of such devices in growing brain for years to come? I got to understand the disclaimers that majority of these devices are not Food and Drug Administration (FDA) approved. In fact, many of the endovascular interventionalist speakers are consultants of the device manufacturers. Yet in the most civilized countries such USA and Europe, they are the first choice in so many institutions. The devices are marketed as "cutting edge" technology that "protects" patients from surgery. They are introduced under the umbrella of "stroke treatment". Patients do not know any better.

How can the investigational devices, non-FDA approved, take over the conventional standard neurosurgical clipping? I asked the question to the presenters and the attendees. A considerable number of patients worldwide suffered and died while the technology was being refined. The obliteration rate of endovascular coiling when started in 1996 was 8% and 18 years later ranges between 60% and 80%. Who paid the ultimate price of technological progress other than the patients? Surgical clipping has an established success rate of more than 90%. The approaches were refined but the aneurysmal clip itself remains practically unchanged. At the same time, the endovascular devices vary and evolve continuously. In fact, there are known cases of placing multiple stents and coils in the same patient.

When our colleagues introduced cardiac stenting, robotic surgery, and laparoscopic surgery, these approaches were justified because they were superior to the conventional open surgical techniques. Furthermore, the complication rate was not higher than that of the open techniques. Certainly, the failure rate to accomplish the surgical goal was not high. The discipline of Neuro-interventional medicine stands alone in adopting premature off-label devices with inferior results into routine practice.

In this current age, technology and newer treatment modalities should only replace the conventional techniques if shown to be superior to and achieving the standard surgical goals. Like any other experimental devices, endovascular devices should not be an exception. There is no rush, we currently have a standard alternative

with remarkable results. The use of these devices should be restricted for "passionate use" in humans and limited to the laboratory. Only when fully developed and approved in experimental studies performed in humans and proven superior to surgical clipping should such techniques be adopted.

Patients have become victims of the endovascular technology and we as medical and scientific community should not allow hospitals to practice endovascular treatment as a first choice. In highly developed nations in 2014, it is not appropriate to subject so many patients to experimental off-label devices for the sake of "cutting-edge technology" and the "learning curve." Neuroscientists and hospitals should not adopt or encourage such management strategies. The use of endovascular devices in aneurysm treatment should not be indiscriminate within the framework of "stroke management" The off-label devices should not be described as "superior" to the old conventional "surgical clipping." Such approach leaves patients with no options. I expect that the regulatory committees will look into this matter and ensure patients' safety through strict guidelines on the use of endovascular devices.

By the end of the one-day symposium and the "practical dinner," I felt obligated to write this letter to the editor. I was disappointed to learn about the "innovative techniques" that were not safe in management of ischemic and hemorrhagic strokes.

REFERENCES

1. Ghaly RF. Hospital protocol for universal use of coiling to all brain aneurysms in non-university setting: Is it too late to be corrected? Surg Neurol Int 2010;1:18-9.
2. Ghaly RF. Does neurosurgeons need neuroanesthesiologist: Does every neurosurgical procedure need neuroanesthesiologist?" Surg Neurol Int 2014;5:76.
3. Johnson AK[1], Heiferman DM, Lopes DK. Stent-assisted embolization of 100 middle cerebral artery aneurysms. J Neurosurg 2013;118:950-5.
4. Johnson AK, Munich SA, Heiferman DM, Lopes DK. Stent assisted embolization of 64 anterior communicating artery aneurysms. J Neurointerv Surg 2013;5 Suppl 3:iii62-5.
5. Lin N, Brouillard AM, Keigher KM, Lopes DK, Binning MJ, Liebman KM, *et al*. Utilization of Pipeline embolization device for treatment of ruptured intracranial aneurysms: US multicenter experience. J Neurointerv Surg 2014 Sep 17. [In Press].
6. Lopes DK, Johnson AK, Kellogg RG, Heiferman DM, Keigher KM. Long-term radiographic results of stent-assisted embolization of cerebral aneurysms. Neurosurgery 2014;74:286-91.
7. Rodríguez-Hernández A, Sughrue ME, Akhavan S, Habdank-Kolaczkowski J, Lawton MT. Current management of middle cerebral artery aneurysms: Surgical results with a "clip first" policy. Neurosurgery 2013;72:415-27.
8. Waldron JS, Halbach VV, Lawton MT. Microsurgical management of incompletely coiled and recurrent aneurysms: Trends, techniques, and observations on coil extrusion. Neurosurgery 2009;64 (5 Suppl 2):301-15.