Innovations in Endosurgery—Journey into the Past of the Future

To Ride the SILS Bandwagon or Not?

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Abstract Progress in surgical practice has paralleled the civilizational evolution. Surgery has progressed from being the last resort in saving life to being form and function preserver. Post-renaissance Industrial age gave an impetus to this march of surgery. The currently on going digital technological revolution has further catalysed this march. Having achieved the stabilized and acceptable clinical outcomes, the surgeon has embarked on a journey of improving patient reported outcomes (PRO). Improvement in PROs with the advent of laparoscopic surgery with the attendant emphasis on minimising invasion has led to debates about invasion being just parietal or holistic in physiological sense. There is a concern that parietal invasiveness shouldn't be a trade-off for compromised clinical outcomes. Single Incision Laparoscopic Surgery (SILS) in its current avatar with current instrumentation seems to be an enthusiastic bandwagon rolling on with the cosmetic benefits acting as veil to hide the potential clinical concerns. History of surgical innovations is riddled with tales of vindictiveness and

vicissitude. Lest the same fate befalls SILS we would do better to examine the SILS bandwagon in its current form till the emerging technologies address the current concerns.

Keywords Single incision laparoscopic surgery (SILS) · Reduced port surgery · Innovations in surgery · Patient reported outcomes · Informed consent · Metric of innovation · History of innovations

Introduction

And what is good And what is not good, need we ask anyone to tell us these things—Plato [1].

Surgery as a profession has all the three ingredients of good life i.e. learning, earning and yearning [2]. Surgery has progressed from misery alleviation to life saving to limb/function preserving to improving clinical outcomes to respecting patient reported outcomes (PRO) [3, 4]. Change is catalyst for any meaningful evolution but it must confront the stakeholders in the status quo who often become the stumbling block.

History and Innovations in Surgery

History is a great leveler of skeptics, critics and adherents. Heresy today might be reality tomorrow. The pace of technology has advanced the future to today. That “The abdomen, the chest and the brain will forever be shut from the intrusion of the wise and humane surgeon” said Sir John Ericksen, the Surgeon to Queen Victoria in 1937 [5]. Today we enter these sacred spaces and that too with minimal insult. The surgical march has been aided by a rich tradition of innovations but the effort to study the evolution of innovations has been embryonic

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[5]. Thus evaluating any ongoing innovation such as SILS needs an understanding of the innovation pedagogy, lest it be subjected to either undue criticism or uncritical endorsement.

Anatomist, the Innovator Surgeon

That the surgery is an art [6] is supported by the close association enjoyed between the surgeon anatomist and artists. Initial insights were based upon animal dissection; famously by Galen till the founder of modern anatomy i.e. Andreas Vesalius started the concept of cadaver dissection, direct observation and meticulous drawings. Galen was the reigning God of medicine in 16th Century and challenging him was inviting death, as was the fate of Miguel Servetus (Fig. 1), a Spanish surgeon who propounded the theory of a single loop of blood circulation, rather than Galen's twin loop circulation. Servetus was burnt at stakes despite fleeing to Geneva to avoid Spanish Monarch, the Patron of Galen, his whereabouts leaked to Galen by another surgeon i.e. Calvin. Servetus was burnt with all his writings and books but for one that went from a French bookseller to Vesalius, the mentor of Harvey giving him the credit of circulation [7]. Vesalius was called a grave robber and even a "Vesanus" (madman) by a fellow surgeon, Professor Sylvius of Paris for Vesalius's acrimony towards Harvey's plagiarism. Surgeons have unfortunately been known to hurt other surgeons, but in doing so the science suffered [7]. Vesalius had similar fate. Most of his work got credited to Michelangelo, his patient whom Vesalius employed to draw his dissection and illustrations. Vesalius's contribution to surgery is not limited to "De Humani

Fig. 1 Michael Servetus

Fig. 2 Vesalius -"Vivitur ingenio, cactera mortis erunt"

Corporis Fabrica" and is fittingly depicted in one of his sketch (Fig. 2) showing him soliloquizing beside a tomb with the caption "Vivitur ingenio, cactera mortis erunt": ingenuity will live, all the rest will die. Till today it is that spirit of understanding and innovations that drives evolution in surgical techniques. Vesalius died in 1564, same year as Michelangelo and the dissections remained limited to bodies of those condemned to death, leading to a breed of body snatchers turning from grave robbers to murderer (fresh bodies fetched more) as epitomized by famous resurrectionists i.e. Burke and Hare. Social upheaval to stop these led to enactment of Anatomy Act 1932 ensuring supply of cadavers to medical schools.

Innovations Beyond Anatomy

Innovator of laparoscopy i.e. Kurt Semm was ridiculed following presentation of first laparoscopic appendectomy in 1980. In 1985 Erich Muhe was ostracized for laparoscopic cholecystectomy, till his recognition by SAGES in 1999 after a 14 year professional exile [8] (Fig. 3).

The next stepping stone was the evolution of anesthesia. Horace Wells after having self-administered nitrous oxide in 1844 was invited to Massachusetts General Hospital (MGH) in 1845, but he failed to induce complete anesthesia. On 16th Oct 1946 William Morton demonstrated successful anesthesia using ether at MGH and the surgeon John Collins declared "Gentleman, this

Fig. 3 Eric Muhe

is no humbug”. Next day another successful surgery was conducted by Surgeon General George Hayward under Morton’s “Letheon”. The word “anesthesia” was suggested in a letter to William TG Morton by Oliver Wendell Holmes. These were successful applications of much ridiculed observations of Joseph Priestly (1767) and Faraday (1818) documenting easing of toothache by nitrous oxide and ether respectively.

Modern era of anesthesia validated the ancient wisdom of alleviating pain by Indian hemp (*Cannabis indica*), as recorded in *Odyssey* (given by Helen to Ulysses) as “sorrow easing drug”, in Semitic literature as “wine of condemned”, as “wine mingled with myrrh” given to Christ before crucifixion and in *Genesis* as use of mandragora plant (phallus of the field) by the Egyptians [9]. Scientific progress has been subjected to religious bigotry but these advances were acceptable as anesthesia was seen as an act of God, as depicted here [9].

so God empal’d our Grandsire’s (Adam) lively look,
Through all his bones a deadly chillness strook,
Siel’d up his sparkling eyes with iron bands,
Led down his feet (almost) to Lethe’s sands;
In brief so mumm’d his soule’s and bodie’s sense,
That (without pain) opening his side from thence
He took a rib, which rarely He refin’d,
And thereof made the mother of Mankind

Resistance to Innovators

Innovative applications of basic observation by Priestley, Faraday, Vesalius etc had a prolonged neglect. The translational gap of applying basic research into practice continues till today. Another evolution was antiseptis. Lister too faced much ridicule. Ignaz Semmelweis (Fig. 4) in early 1840s demonstrated the use of an antiseptic as preventive of sepsis attributable to some cadaveric particle. Doctors were offended at the suggestion that they should wash their hands. Semmelweis’s practice earned widespread acceptance only years after his death, when

Louis Pasteur confirmed the germ theory. In 1865, Semmelweis was committed to an asylum, where he died of septicemia, at age 47. Lister being aware of Pasteur’s work developed his concept of chemical antiseptis. Despite his documented work (5 publications in *Lancet*) he was denied entry in America by Dr. Samuel D Gross. It took the death President Garfield from rupture of septic splenic artery aneurysm to shake American surgeons from their 15 years long septic slumber.

Thomas Wakley while starting the *Lancet* in 1823 announced “A *Lancet* can be an arched window to let in the light or it can be a sharp surgical instrument to cut out the dross and I intend to use it in both senses”. He found nepotism and corruption in medical profession disgusting and started the *Lancet* to expose it [10].

It was believed that with the onset of industrial age in mid 1880s and simultaneous introduction of anesthesia and antiseptis [11], the surgical evolution will become more objective. But the surgical DNA refused to mutate. Transatlantic ridicule of Justus Ohage for performing cholecystectomy, ordeal of Kurt Semm and the loss to Eliche Muhe bears testimonies to the same DNA [8, 12]. The pace of surgical evolution gathered momentum with the advent of endosurgery in 1980s. The benefits like early return to work with shorter convalescence were so obvious that popular appeal swept away any debate about lack of evidence allowing the endosurgical trot to canter.

Resistance to Exuberant Enthusiasm

The eagerness to translate this canter into a gallop seems to be gathering momentum, challenging the time line for scientific evidence to emerge. The historical guilt of criticism of colleagues and the impatience of innovators seem to be challenging surgical wisdom. While randomized controlled trials (RCT) are welcome but they can’t be seen as substitute of decision making in surgery [13]. Common sense mandates us not to preempt a social good for want of study designed for high level evidence [14, 15].

Fig. 4 Semmelweis overseeing the washing of doctor’s hands

“Evidence based surgery is for those willing to follow behind, new advances can’t wait” seems to be the prevalent sentiment [3]. While privileging with a surgical license to operate, the basic tenet of “Primum non nocere” can’t be sacrificed. It is not as Voltaire said “I may not agree with what you say, but I will defend to the death your right to say it” because while we can defend our colleague’s right to our death but not the same for that of our patient’s. This is so because surgical wisdom transcends the semantics of rhetorical discourse, for surgeons are recognized by more than mere technical excellence and superior knowledge [16]. Surgical wisdom refers to moral, cognitive and collegial aspects of practice such as putting patients first, managing conflicts of interest, honesty and confidentiality, disclosing errors, self regulation and advocacy besides mere technical and knowledge traits [16]. A surgeon has to practice surgery and not merely perform operations. Surgery is what a surgeon practices. An operation is what a surgeon performs. Any innovation has to be surgery with precision and not merely a well performed operation. Isn’t the word precision married to surgery [17]. An innovation has to account for the bench marks of “Surgical wisdom”, “surgical precision” and the notions of patient safety [16–18]. The zeal has to be bereft of any resistance to patient safety [19]. Any criticism from mature stakeholders is not unnatural [20]. Surgical treatments link our actions to the patient response intimately. When outcomes are unexpected, the natural question for a physician is “What happened?” but we are asked “What did you do?” [21]. This is compounded by paradoxical statements that we allude to, “the only surgeon without complications is the surgeon who doesn’t operate” versus “Big surgeon make big incision”. The gears of SILS bandwagon mindset have to shift from “What can I do for this patient?” to “What should be done for this patient” [19].

Surgical Bandwagons and Outcome Metrics

The bandwagon effect is a form of group think-conduct that spreads with the probability of any individual adopting it increasing progressively, leading to others to “hop on the bandwagon” regardless of underlying evidence. The phrase originated with the American political campaigns using the band of Dan Rice, popular circus clown in 1848. Initial march of endosurgery piled on such bandwagons [22]. The endosurgery bandwagon is driven by the industry and patients, armed with media blitzkrieg [22]. Unfortunately academic journals too become the routes down which bandwagons are driven [22]. While some ‘not so good’ developments can ride a bandwagon, others languish in lack of patronage [7]. Anesthesia wouldn’t get public acceptance owing to Vatican dictate that “pain was natural part of suffering” till Queen Victoria asked James Simpson to go ahead with the words “you are right, there is no need to suffer, anesthesia is actually a very good innovation” allowing Dr. John Snow to administer chloroform to her

during the birth of prince Leopold [7]. Evaluation of endosurgical innovation is further handicapped by general perception of our behavior. We justify some adverse outcomes by citing the Institution of Medicine report “To Err is Human” leaving the other half of the sentence credited to pope Alexander VI, which additionally reads “to forgive divine”. But we deal with human bodies and not divinity [23]. We are accused of underreporting adverse outcomes by a factor of >400 times, only the “limelight errors” come to be seen while many go unnoticed as “Cinderella errors” [23]. Healthcare is a far more dangerous profession (1 death per 1,000 encounters) than either the scheduled airlines or nuclear industries (1 death per 100,000 encounters) [23]. More than 50 % healthcare adverse events are surgical, >80 % occurring in routine operations [24, 25].

Even latent/minor errors, being inconsequential, may summate in disaster [26]. Laparoscopic cholecystectomy (LC) is an index endosurgical innovation [27]. Innovative aspects should be part of informed consent and a log of adverse events should be available to patients, but unfortunately we have practiced otherwise [28]. We should remain alert to an adverse event that has not happened because there is a probability of even an improbable event [29].

Metrics of Outcomes in Laparoscopic Surgery

Most of the endosurgical innovation is benchmarked with the bile duct injury (BDI) as an index [30–32]. Misidentification and misinterpretation of the anatomy is the cause of many BDIs. However this doesn’t account for all the injuries and “dangerous anatomy” and “dangerous pathology” and “technical errors” are all involved, as are surgical technique and craft [26]. Technical errors cannot be dismissed because the risk of error (human error) is high in endosurgery [26]. This is attributable to “spatial disorientation” during LC because the operator manipulates reality not directly but indirectly from images leading to psycho-heuristic cognitive ambiguity [27]. Injuries arise due to failure of subjective cognition resulting from trying to see one’s belief rather than believing the seen [33]. This is a wakeup call for innovation enthusiasts who would do well to pay attention to detail and avoid mediocrity [34]. An attitude of don’t ask don’t tell won’t do [35].

Future of Surgery is Here

Technology continues to drive the future. The age of bio-intelligence will simplify man-machine interface with the metamorphosis of industrial revolution to artificial intelligence. Surgical technologies are likely to have intelligent cooperative robotics, microelectromechanical devices relaying haptic, applications of claytronics and nanotechnology driven manipulators [36]. A new concept of “image overlay surgery” consisting of

integration of virtual reality and augmented reality technology will provide 3D reconstruction of operative field [37]. The integrated MR laparoscopic system will further add to this [37]. Integration of these in a robot will allow the surgeon to perform the steps of surgery without them being effected on the patient enabling him to delete/alter his step and saving only the desired ones to finally save the actions of surgery performed on virtually reconstructed patient. The “saved” operation then would be reproduced by the robot in reality. We are converging to an era of IMAGIneering (I-Innovation, M-Molecular biology/Magnetic imaging, A-Artificial intelligence robotics, I-Information technology, N-Nanotechnology) [1].

Technology and SILS

Technology has no moral value; it is neither good nor evil. Rather it is the application of these technologies that raises the moral and ethical issues [36]. SILS is nothing novel as conventional surgery was mostly single incision. The novelty is in camouflaging the incision in a natural scar with the aid of technology that is being applied like placing the cart before the horse. This has compelled some terming it shameful [38]. Einstein forewarned. “It has become appallingly obvious that our technology has exceeded our humanity”. He also cautioned us that “market forces always attract men of low mortality”. He also said “Great spirits have always encountered violent opposition from mediocre minds”.

Concern have been expressed whether SILS is industry driven or it delivers more to surgeon or patient or a shift from “medicine” to ‘medisin’ with the probability increasing even more with inherent man–machine interface [39–42]. There is a need for introspection whether to behave like a cheer leader or a watchdog [43].

Methodological Righteousness Sans Honesty

Evidence based surgery premised on RCTs is another challenge in surgical practice [44]. This leads many surgeons to view RCTs to be difficult and impractical to undertake and irrelevant to their practice [44]. Despite the call, surgical RCTs have been low and that too have focused mostly on aspects relating to pharmacological interventions rather on those that seek to inform clinical decision making [44]. Even when conducted well there have been concern about informed consent process having been violated [44]. Current advances have been subtle hence the increased need for RCTs i.e. the smaller the difference in outcome, the greater the need for RCT [44]. The outcome benchmarks lead to expectations that all surgeons should attain the unrealistic ideal performance. Aim should be to gain proficiency and not exclusive expertise. Evaluation of an innovation versus an established control has a handicap of experience imbalance. Apart from these complexities

in designing adequately powered RCTs in surgery, the key questions to address are :What is the outcome, what are their metrics [45], who are the assessors or and what is the chronology of events, outcomes and their sequel [44].

What Should be the Metrics for Evaluating SILS?

Physician centered clinical outcomes (e.g. mortality/morbidity) are important. Popularity of endosurgery makes patient’s perspective equally relevant. However, the PROs can be subject to patient’s equipoise, their social and emotional function and lead to less than accurate assessment of health related quality of life [46]. Rigorous evaluation of surgical intervention though difficult is achievable and necessary.

This brings us back to innovation in endosurgery, SILS being the latest entrant vying for a cult status, if the proportion of recent publications is an index for it. The mute question remains whether it is an index of “eminence based medicine” or “evidence based medicine”? For it to be latter and hence better, lot needs to be done. Unfortunately, the enthusiasm in riding the bandwagon is not matched by the consideration of lessons learnt from the past mistakes. Critics of any innovations such as SILS have to confront hostile reminder of the generation that fiercely criticized LC in 1980s. But a scientific scrutiny should not succumb to such pressure, for it has been well observed by George Carlin that “anybody driving slower than you is an idiot and anyone going faster than you is a maniac”. Initial LC enthusiasts spoke about better safety in terms of BDI attributable to magnified endo-anatomy. None of them reported or even talked about any BDI. The first report of LC associated BDI was an anonymous publication in NEJM [47], followed up by a report of a managed BDI, patient coming from the locality where it was not reported by [48]. Also mentioned in this report was the BDI being a result of thermal insult. This fact was accepted in subsequent publication in the same journal by the operating surgeon [49]. The early prediction that BDI during LC would decline with experience hasn’t been fulfilled. LC associated BDI is of greater severity and goes unrecognized in majority [50]. It remains a problem because of the inability of surgeon to shed hubris in taking a decision whether to take risk of BDI or not, during challenging surgical situations [51]. Most of the innovation is driven by people driven by high self-belief. It has been found that high self belief does not predict success. In novices it negatively correlates with the skills while in experienced it is independent of laparoscopic performance [52]. Rather it is reported that even when the experienced surgeon has opted for a safer fundus down cholecystectomy, BDIs are extreme ‘vasculobiliary injuries’ [53] having severe consequences needing even a liver transplant [53]. Vascular component of biliary injuries is significantly morbid [53]. Biliary injuries after LC can be quite morbid and lethal with the incidence being underestimated [54]. Underestimation of risk, ambiguity, visual misperception, cognitive fixation, plan continuation and delayed or

unrecognized BDI have been identified as causal psycho-heuristic factors [55]. These psycho-heuristic factors play in performance of SILS where the ergonomics are compromised. This mandates us to achieve “critical view of safety” in SILS [56].

Although BDI has cast its cloud on LC, millions have benefited from this advance. These benefits must be preserved. As per today’s data we expect >3,000 BDI in a year in United States alone [57]. Common BDI is a preventable error and not an adverse outcome [58] hence the need of zero tolerance [59] and chasing zero to make ‘adverse events’ a ‘never event’ [60, 61].

Adverse outcomes are part of surgery. The real problem is not how to stop bad doctors from harming their patients, it is how to prevent good doctors from doing so [62].

The *raison d’être* of the SILS bandwagon is the scar less surgery. But surgery leaves scar on the mind as well, impacting the quality of life much more intensely [63]. In the guise of reducing parietal scar we should not have a visceral play. Three small RCTs have shown similar improvement in cosmetics and/or pain profile [64–66]. But the largest and latest RCT on SILS has raised concerns about patient safety and has blamed publication bias for the spate of SILS publications, creating a false sense of security [67]. It recommends that SILS should be offered only in approved research protocols with mandatory reporting in registries. Pioneers like Connor S have raised doubts about safety, expressing that the increased risk outweighs the potential benefits [68]. He has castigated the suggestion of routine intraoperative cholangiography to detect BDI, thus accepting the higher risk of BDI as routine. He says “The concept is flawed and supports a substandard care. Prevention not detection should be the gold standard of all treatment protocols. We should not allow history to be repeated”. He is supported by another RCT, reporting more complication in SILS without any significant benefits in patient satisfaction, postoperative pain and HrQoL [69]. In fact patients have been reported to perceive cosmetic results of LC as excellent without any betterment in SILS, rather umbilicus port may be a source of problem [70]. A SILS procedure enlarges what is already a painful and undesirable incision [71]. Since patients do not recall the smaller incision, we should ask ourselves whether surgeons and industry care more than do the patients to whom we offer SILS [71]. This observation is supported by a large RCT [72] where both surgeons and patients were preoperatively and postoperatively asked to rank predetermined, outcome variables hierarchically according to their importance. It was found “Cosmetic result” was the only variable being significantly more important from the surgeon’s perspective than from the patient’s perspective. This is ample vindication of the biased and vested interest of SILS surgeon in altering the metrics of evaluation [45]. Patient’s preference on scarless concept may be influenced by age, gender, and surgical/endoscopic history at the cost of increased personal risk. A recent study [73] found that patients with “negative body image” favour scar less concept

accepting increased operative risk [56]. Umbilicus hides the scar of surgical insult in SILS. Its appearance can be altered during SILS thus damaging its aesthetic appeal than mere preservation of cosmetics [12]. It has been reported that even a change in size, shape and color of umbilicus is undesirable [74]. Men are more concerned about the aesthetics of their partner’s belly button and its role in sexual relationship [74].

Need to Drop the Resistance to Patient Safety

Our responsibility needs us to drop the resistance towards patient safety [19]. Ninety percent of published medical information that we rely on its flawed [75]. Ioannidis [75] examined 49 original studies cited more than 1,000 times. It was found that 16 % were subsequently contradicted, 20 % could be replicated and only 24 % remained largely unchallenged [76]. We are being deluged with tsunami of evidence [77] but unfortunately there is a concern that false claims are made in the majority of publications [78]. This is pertinent in light of distorted metrics of reporting SILS outcomes [45]. Evidence based surgery can be guided from the findings of RCTs and meta-analyses but it can never enlighten us about evidence of desired outcomes not included in metrics of evaluation. In surgery there should be at least the assurance of safely derived from parachute level of evidence. We should not try to hide behind distorted vision of handicapped evidence. Rather we should be aware of our role as moral pillar of ethics in surgery. Hiding as if none was watching us won’t help, as reinforced by the fable of “What the pigeon sees”.

A teacher gave a pigeon each to his two disciples, asking them to go into forest to kill the pigeon where none could see them and to bring the dead pigeon as a proof. One of them killed the pigeon finding a secluded spot, bringing the dead body as a proof. The teacher asked the other why he had not followed the instructions. He said, “Wherever I went, the pigeon was looking at me”. Cushing said, “The physician requires a special combination of head and heart, a surgeon of head, heart and hand”. We should add to these the holistic sense of responsibility in this era of bandwagon-driven innovations [1].

Paul Kaugman [79], the Nobel Laureate, expressed his dismay with the whole notion of patients as consumer and healthcare as simply a financial transaction. He reminds us of ethics and that we are something special and are expected to behave according to higher standards than average professionals. Let us not try to reinvent the wheel of patient safety, the wheel that moves the evolution of innovations in surgery. Let us follow the tenets of informed consent truly and educate the society about the SILS its pitfalls and stop misleading them hiding the potential complications as well as selling the reduced port surgery as SILS- single incision surgery [80].

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