

Prospective Randomized Controlled Trial to Study the Safety of a Parachute! Quo Vadis ? Caveamus Medicus. Vest Deus Tecum?

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Almost a million clinical trials float around the globe for attention of the decision makers in healthcare¹. Surgeons continue to strive for evolution of 'best practice' consensus from plethora of conflicting guidelines. Revolution in communication, media, information technology and techniques of surgery continues to threaten the evolutionary pace of consensus generation. According to Institute of Medicine report, the deluge of evidence notwithstanding, its authenticity is plagued by "conflict of interest issues" and surgeon's tendency to suppress negative clinical data². Randomised controlled trials (RCTs), touchstone for any meaningful evidence are difficult to design in surgical practice³. Improving the 'patient reported outcome' (PRO) is always close to the heart of every surgeon. They deserve a licence to innovate sans RCTs if the aim of improving PROs is sincere^{4,5}. Validation of all such innovations by RCTs is not mandatory due to difficulty in designing RCTs and also due to structural, cultural and psychological resistance emanating from both surgeon's as well as patient's equipoise⁶. While being a support system, RCTs cannot be a substitute for holistic decision making process in surgical profession^{7,8}. Thus there exists ample evidence to grant surgeon a licence to innovate sans RCTs^{9,10}. But surgical dishonesty, under-reporting of adverse events and surgeon's ego send shock waves amongst those who swear by RCTs⁹. Surgeon's tendency to benefit from the treatment of the residual disease by labeling the residual disease as recurrence, adds fuel to the fire of suspicion. Recurrent fistula is a blatant example of same. With the advent of laparoscopic surgery we have started to invent new pathologies e.g. stump appendicitis & 'post-cholecystectomy cholecystodocholithiasis' to cover up for an incomplete job done (or the surgical necessity of incompleteness not informed to the patient) in the first place.

Fingers pointed at our integrity and sense of ethics is supported by some despicable acts committed by scientific geniuses. Jean Denis laid the foundation of blood transfusion in 1667. But his colleagues jealous of his possible fame murdered his patient to stall his recognition¹¹. Kepler, credited with overturning the geocentric model of universe, based his work on stolen data. Data that belonged to his benefactor colleague Tycho Brahe, whom Kepler poisoned, after laying his hands on data¹². Insults heaped on Justus Ohage in advocating cholecystectomy rather cholecystostomy, on George Crile Jr. for advocating a less radical mastectomy and on Joseph Lister for advocating pre-surgical hand wash are studies in abhorrent behaviour of scientific community towards the innovation driven colleagues¹³. Need for RCTs should not become weaponry for such vindictive scientists. So a golden mean has to be found between the extremes of pre-evidence innovation and innovation stifling RCTs, the fulcrum being improved PRO. The parachute is a good example of such an innovation enhancing human experience/safety and well accepted sans any RCT. This can be achieved if our intentions are honest and awareness of our ignorance intact. We should not disregard anything of which we know nothing about. Interventions in surgery can be made more acceptable and less invasive to our patients with our knowledge of disciplines outside modern science i.e. arts like literature, culture, music and poetry etc. They have a potential to provide a complementary approach to many clinical dilemmas. We have a disturbing vulnerability to swing from rational to irrational, from being detached to being passionate, from being deliberate to being spontaneous and from being deluged with certainty to uncertainty¹⁴. Such dangerous uncertainties in our actions as surgeons, can be minimized

by our optimal understanding of prevalent cultural wisdom. Not only the respect of now established but once neglected discipline like Yoga but of seemingly unrelated discipline like poetry and music etc can improve our pursuit of improving PROs^{15,16}. We in India are fortunate in having a treasure of traditional wisdom neglected by us so far but respected by the west long back. Fibonacci sequence made popular by the famous "Da Vinci Code" book credited to Italian Liber Abaci was credited to 6th century India by Liber himself. We need to revisit our traditional knowledge, howsoever non-conformist it may seem to be. We should not stifle the non-conformist with a noose of RCT just to inflate our ego and satiate our envy. Modern science has seen paradoxical theories validated. Matter and antimatter is an obvious existential paradox. Professor Wilczek FA of MIT won a Nobel in 2004 for describing a force stronger than gravitational forces, a force which grows with the distance between two particles. Scientists are respecting nature and are trying to reproduce the mechanics of nature for the good of mankind. We are yet not half as close to the efficiency of locomotion and communication in fellow planet dwellers like insects, birds, fish, dolphin and penguins etc., with the best of technological revolution in, aerodynamics and energy guided systems¹⁷. Another scientist Daniel Nocera has reproduced nature in laboratory by making an artificial leaf for delivering energy from water and sunlight for development of an individual power plant¹⁸. Recent Tsunami in Japan is a wakeup call for us to integrate our thinking, practice and pursuit in harmony with nature. In this era of technologically driven limelight seeking behaviour we should shun the attitude of relying upon technology alone to intervene innovatively on our patients. Technology should not be "Deus ex machina" We have to innovate with holistic knowledge so that God is with us (Deus vobiscum) lest the society chastises us "where do you go, doctor beware, Is God with you? (Quo Vadis? Caveamus Medicus. Vest Deus Tecum ?)

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