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Are randomized controlled trials of surgical procedures a waste of time, money and effort?

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Objective: Despite the lack of supportive evidence, the claim that randomized trials (RCT's) is the Gold Standard is unfortunately too popular to be questioned. This is a presentation of original research exposing the fallacies of RCT's in surgery.

Material & Method: A prospective study of enrolment patterns in the largest completed Australian RCT for laparoscopic surgery for colon cancer (ALCCaS) was conducted for a six-month period and the results compared with those from other published studies. This was followed by a systematic review of the reasons for non-entry of eligible patients in surgical RCT's. The results of an RCT and of a case control study performed under the same conditions were statistically compared. Two contemporaneous meta-analyses of RCT's and of non-randomized comparative studies (NRCS's) of the same procedure were then conducted and their results statistically compared.

Result: At best, 45% of eligible patients are enrolled in RCT's of surgical procedures. The most commonly recorded reason for failure to enroll is a preference for one form of surgery. In the ALCCaS, about 1 in 5 accredited surgeons never recruited any patients and a further 29% ceased to be involved very early in the trial. There is a strong suggestion that systematic differences between enrolled and eligible but not enrolled patients do exist. There is a suggestion that a NRCS of surgical procedure may exaggerate the effect estimate compared with and a RCT but the evidence for this is weak. The results of the meta-analysis of 12 RCT's (2512 resections) and those of the meta-analysis of 49 NRCS's (6438 resections) for 13 variables common between the two meta-analyses, were more than 95% similar.

Conclusion: There may be no need for us to bother with RCT's for surgical procedures as the results of their meta-analyses are probably just as accurate or just as inaccurate as those of NRCS's.

Biography

Ned Abraham is a Professor of Colorectal Surgery at UNSW Australia, Coffs Harbour Campus, NSW. He has graduated with Honors in 1986 and obtained the degrees of Master of Medicine and a PhD in Surgery from the University of Sydney. He is a Practicing Colorectal and General Surgeon, an Endoscopist with close to 20 years of experience. His main areas of interest include evidence-based surgery, enhanced recovery after surgery programs, capsule endoscopy and biofeedback. He is a Fellow of Royal Australasian College of Surgeons and Royal College of Surgeons of England. He got trained at Royal Prince Alfred Hospital in Sydney and is a Member of Colorectal Surgical Society of Australia and New Zealand. His research has been widely published and cited in international peer reviewed journals and he has been an invited guest speaker at multiple national and international meetings in Asia, Europe, USA, Australia and New Zealand.

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