SELECTED ABSTRACT

Never Events in Surgery': Mere Error or an Avoidable Disaster

Jitendra Kumar and Rajni Raina, Indian J Surg. 2017 Jun; 79(3): 238–244.

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Abstract

Method

Authors carried out a systematic review of literature to find out analyse the commonest never events recorded and to identify the risk areas and look for broad based areas where solutions can be reached. Search of literature in English language was performed using online search engines: PubMed NCBI database, Google search, and other digital sources available online. Out of 374 related studies from all sources, finally, at the end, 35 studies were selected for review and ultimate analysis.

Results

Authors concluded that no studies were reported from developing countries, most research and reporting came from developed countries. However authors identified key areas of failure leading to never events as; Human error, Communication error, System failure and Equipment failure.

Conclusions

Authors recommended that key solutions in order to prevent a never events lies in multiple areas within the health care organisation. These include:

1. Creating awareness
2. Mandatory and voluntary reporting of events via incidence forms etc,
3. Sound communication and team culture: "A good communication in clear and straightforward way is required among all surgical team members, anaesthetists, nurses, and paramedics at every stage of surgical care." Say the authors. These include briefing debriefing, which are sharing of all patient-related information preoperatively, sign in when the patient is handed over to the theatre staff. Another useful example is a concept of 'time out' or 'surgical pause' just prior to the incision. Finally once the surgery is completed final the process called a sign out hands over checks and post-operative management verbally.
4. Professional fitness and competency
5. Oversight organisation
6. Documentation

Commentary

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Above article emphasises the importance of "Never events" in surgical practice. While developing countries due to many reasons such as quality assurance and litigation have identified the importance of this the developing countries seem to ignore the problem.

However countries such as Sri Lanka with high health indices should lead in identifying and developing mechanisms to minimise surgical never events from happening. Incidence reporting is the key to start the process. With high case load never events are bound to happen in any country. However by careful identification, incidence reporting and naming the "never events list" to that particular set up and applying in place check lists and protocols these can be minimised. Surgical community in conjunction with other specialties such as anaesthesia initially develop a list of events and together with clinical teams should develop suitable protocols in a Sri Lankan set up. Then implement them with help of administrative staff. Further it appears to be the correct time to formulate a national policy and implement it via the ministry of health.

References

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Why a P-Value is Not Enough

Solla, Federico, Antoine Tran, Domenico Bertoncelli, Charles Musoff, and Carlo M. Bertoncelli.

Why a P-Value is Not Enough. Clinical Spine Surgery: November 2018: 31(9);385–388

Background

All doctors know that P-value<0.05 is "the Graal,"but publications require further parameters [odds ratios, confidence interval (CI), etc.] to better analyze scientific data.

Aim

The aim of this study was to present P-values, CI, and common effect-sizes (Cohen d, odds ratio, and various coefficients) in a simple way.

Description

The P-value is the probability, when the null hypothesis is true (eg, no difference or no association), of obtaining a result equal to or more extreme than what we actually observed. Simplistically, P-value quantifies the probability that the result is due to chance. It does not measure how big the association or the difference is. The CI on a value describes the probability that the true value is within a given range. A 95% CI means that the CI covers the true value in 95 of 100 performed studies. The test is significant if the CI does not include the null hypothesized difference or association (eg, 0 for difference). The effect-sizes are quantitative measures of the strength of a difference or association. If the P-value is < 0.05 but the effect size is very low, the test is statistically significant but probably, clinically not so.

Conclusions

Scientific publications require more parameters than a P-value. Statistical results should also include effect sizes and CIs to allow for a more complete, honest, and useful interpretation of scientific findings.

Commentary

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This article highlights the importance of reporting effect sizes and confidence intervals to provide more meaningful and interpretable scientific findings. The P value indicates the incompatibility of observed data with a null hypothesis. The P value only quantifies the probability that the results is due to chance when the null hypothesis is true. However, it does not quantify the compatibility with the alternative hypothesis and does not quantify the effect size or clinical importance of the scientific finding. A P value can become very small when the sample sizes, measurement precision and data uniformity are high. Further, labelling results as "statistically significant" and "not significant" based on a predefined limit (i.e. 0.05) has mislead scholars to think P value as a binary variable rather than a continuous variable (eg. can we consider a P = 0.049 better than P=0.051 to arrive at a decision?). This approach could halt publishing "insignificant" results. In medicine, clinical significance is could be more important than a P value under 0.05. Effect sizes provide quantitative measures for the strength of statistical relationship between variables. This will allow understanding whether the difference is both statistically and clinically significant. Commonly used statistics to measure effect sizes include Odds Ratio, Correlation Coefficient, Coefficient of Determination and Regression Coefficients. Therefore, scientific results should also include effect sizes along with their confidence intervals to provide more meaningful and interpretable scientific findings.

Mechanical and oral antibiotic bowel preparation versus no bowel preparation for elective colectomy (MOBILE): a multicentre, randomised, parallel, single-blinded trial

Laura Koskenvuo, Taru Lehtonen, Selja Koskensalo, Suvi Rasilainen, Kai Klintrup, Anu Ehrlich et al.

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Background

Decreased surgical site infections (SSIs) and morbidity have been reported with mechanical and oral antibiotic bowel preparation (MOABP) compared with no bowel preparation (NBP) in colonic surgery. Several societies have recommended routine use of MOABP in patients undergoing colon resection on the basis of these data. Our aim was to investigate this recommendation in a prospective randomised context.

Methods

In this multicentre, parallel, single-blinded trial, patients undergoing colon resection were randomly assigned (1:1) to either MOABP or NBP in four hospitals in Finland, using a web-based randomisation technique. Randomly varying block sizes (four, six, and eight) were used for randomisation, and stratification was done according to centre. The recruiters, treating physicians, operating surgeons, data collectors, and analysts were masked to the allocated treatment. Key exclusion criteria were need for emergency surgery; bowel obstruction; colonoscopy planned during surgery; allergy to polyethylene glycol, neomycin, or metronidazole; and age younger than 18 years or older than 95 years. Study nurses opened numbered opaque envelopes containing the patient allocated group, and instructed the patients according to the allocation group to either prepare the bowel, or not prepare the bowel. Patients allocated to MOABP prepared their bowel by drinking 2 L of polyethylene glycol and 1 L of clear fluid before 6 pm on the day before surgery and took 2 g of neomycin orally at 7 pm and 2 g of metronidazole orally at 11 pm the day before surgery. The primary outcome was SSI within 30 days after surgery, analysed in the modified intention-to-treat population (all patients who were randomly allocated to and underwent elective colon resection with an anastomosis) along with safety analyses. The trial is registered with ClinicalTrials.gov, NCT02652637, and EudraCT, 2015–004559–38, and is closed to new participants.

Findings

Between March 17, 2016, and Aug 20, 2018, 738 patients were assessed for eligibility. Of the 417 patients who were randomised (209 to MOABP and 208 to NBP), 13 in the MOABP group and eight in the NBP were excluded before undergoing colonic resection; therefore, the modified intention-to-treat analysis included 396 patients (196 for

MOABP and 200 for NBP). SSI was detected in 13 (7%) of 196 patients randomised to MOABP, and in 21 (11%) of 200 patients randomised to NBP (odds ratio 1·65, 95% CI 0·80–3·40; p=0·17). Anastomotic dehiscence was reported in 7 (4%) of 196 patients in the MOABP group and in 8 (4%) of 200 in the NBP group, and reoperations were necessary in 16 (8%) of 196 compared with 13 (7%) of 200 patients. Two patients died in the NBP group and none in the MOABP group within 30 days.

Interpretation

MOABP does not reduce SSIs or the overall morbidity of colon surgery compared with NBP. We therefore propose that the current recommendations of using MOABP for colectomies to reduce SSIs or morbidity should be reconsidered.

Commentary

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Although mechanical and oral antibiotic bowel preparation (MOABP) has been historically favoured before elective colorectal surgery, there has been a reluctance to use this routinely. This is due to the unpleasantness of the preparation, the physiological derangements it causes, the recommendations of Enhanced Recovery After Surgery (ERAS) programs to minimize bowel preparation and the lack of convincing evidence regarding its benefit.

There have been conflicting conclusions in several meta-analyses. A meta-analysis by Rollins et al. failed to identify a benefit of mechanical bowel preparation on anastomotic leak rates, surgical site infection (SSI), intra-abdominal collection, reoperation, hospital length of stay or mortality . The same authors in 2019, however, have identified a benefit of reducing SSI, anastomotic leak, and 30-day mortality when mechanical bowel preparation was combined with oral antibiotics . When compared to MOABP, oral antibiotics alone provided similar benefits in SSI and anastomotic leaks . However, the findings of Toh et al contradict the advantage of antibiotic-alone bowel preparation .

The present study is a large, multi-center trial and the first prospective randomized trial focussing on the effect of MOABP on SSI and other complications. Similar to some of the previous meta-analysis , this study failed to demonstrate any benefit regarding the primary and secondary endpoints. One of the main limitations was that the study was underpowered to identify the difference in SSI, where they estimated an eight percent difference but found only a four percent difference. The overall complication rate, however, is a more relevant endpoint and was similar in the two groups.

Some surgeons favour mechanic bowel preparation for laparoscopic colonic resections claiming a loaded colon is more challenging to manipulate laparoscopically. Others prefer mechanical bowel preparation for anterior resections to minimize contamination during the anastomosis. Several large surgical societies continue to recommend MOABP because of the benefit shown regarding SSI and overall complications. These decisions and recommendations may need revisiting with the availability of new evidence.

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The evolution of acute burn care – retiring the split skin graft.

JE Greenwood

Abstract

The skin graft was born in 1869 and since then, surgeons have been using split skin grafts for wound repair. Nevertheless, this asset fails the big burn patient, who deserves an elastic, mobile and robust outcome but who receives the poorest possible outcome based on donor site paucity. Negating the need for the skin graft requires an autologous composite cultured skin and a material capable of temporising the burn wound for four weeks until the composite is produced.

A novel, biodegradable polyurethane chemistry has been used to create two such products. This paper describes the design, production, optimisation and evaluation of several iterations of these products. The evaluation has occurred in a variety of models, both in vitro and in vivo, employing Hunterian scientific principles, and embracing Hunter's love and appreciation of comparative anatomy. The process has

culminated in significant human experience in complex wounds and extensive burn injury. Used serially, the products offer robust and elastic healing in deep burns of any size within 6 weeks of injury.

Commentary

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The article describes reasons for split skin grafts not being replaced by a substitute. Epidermis being derived from ectoderm epidermis has the potential to regenerate. However, the dermis is like all the mesodermal structures cannot regenerate but replaces with a scar. The microstructure of the dermis dictates the outcome of the quality of the dermis. The suppleness and the amount of scar tissues are inversely related.

The new discovery is the biodegradable polyurethane that can provide the scaffolding for the dermal superstructure. The second product is something extraordinary that very well be the precursor for great things to come before humans. Growing skin that actually can function normally or at least near normally has been a dream. The technology has evolved with the pressure falling on the burn surgeons to find cultured skin to use as grafts in burns with minimal donor site to harvest grafts from.

The author will take the reader to a new dimension that unlocks the potential of creativity of a surgeon that shows he is not a mere technical person.