Exclusion Criteria: Relegation Belies Wisdom

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We have read the article “Study of two techniques for midline laparotomy fascial wound closure” by Gurgar et al. with interest [1]. This randomized trial has evaluated the continuous and interrupted sheath closure techniques in the light of postoperative wound complications. Formulation of stringent inclusion and exclusion criteria for recruitment of patients is an essential component in the planning of a clinical trial. The excluded patients are those who may otherwise satisfy the inclusion criteria but are rendered unsuitable for enrollment due to coexistent confounding factors.

The study population in this article comprised of adult patients undergoing elective as well as emergency laparotomies through vertical midline incision. The authors had excluded patients having pre- or postoperative diagnosis of malignancy with peritoneal involvement. So, a patient requiring laparotomy for an advanced malignancy will not be enrolled for the study; however, a patient can be detected with a malignant process in the postoperative period following inclusion and randomization into one of the treatment arms. The outcome in such a patient is likely to be adversely affected by the malignancy and will not be truly reflective of the closure technique. The appropriate method of outcome analysis should be selected in these patients for better interpretation of the results. For example, the patients with postoperative diagnosis of malignancy can be included in the primary data analysis when an intention to treat protocol is followed, the outcome in these selected patients can also be evaluated by a subgroup analysis, and alternatively, these patients can be

considered for postrandomization exclusion during the final outcome analysis.

The other exclusion criterion of preexisting cause of raised intra-abdominal pressure (IAP) is equally perplexing. Intra-abdominal hypertension (IAH) is a common but under recognized entity in patients undergoing emergency intervention. The association of IAH with new organ dysfunction is known as abdominal compartment syndrome (ACS). Both IAH and ACS adversely affect the postoperative wound healing. According to the World Society of the Abdominal Compartment Syndrome, the predominant risk factors for IAH and ACS are as follows: decreased abdominal wall compliance following major trauma and prior abdominal surgery; increased intraluminal contents encountered in ileus, volvulus, and colonic pseudo obstruction; and increased intra-abdominal contents resulting from hemo or pneumo-peritoneum, intra-abdominal abscess, fluid collection, and tumors [2]. So, going by this definition, majority of the patients requiring emergency laparotomy will be at risk for IAH and fear exclusion from the study. We feel that subjecting the patients to routine preoperative measurement of IAP and excluding those found to have an elevated IAP would have been a more logical approach.

The postoperative wound outcome particularly following emergency surgery depends on a multitude of factors such as presence of preoperative shock, malnutrition, compromised renal function, gross intra-abdominal contamination, and prolonged duration of surgery apart from the type of suture material used and the technique of fascia closure. The incidence of wound infection in this study cannot be attributed to the technique of fascia closure alone in absence of data concerning proper identification and management of other known risk factors.

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