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Improving clinical research study design: An analysis of recent evidence for surgical site infection prevention

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Statement of the Problem: A clinically meaningful question can lead us to a research project to answer. Subject populations, interventions, comparison, outcomes, and duration of data collection are well described components of research. Although the question might be meaningful, underprepared studies lack an organized research team, biostatistical or methodologic input[1,2].

Mapping the problem with findings: Closed incision negative pressure therapy (ciNPT) for reducing surgical site infection (SSI) is an established technique. This benefit is more remarkable in high-risk patients4. Patient selection for SSI prevention studies may be deceptive. Some of the prospective studies are conducted exclusively in high-risk patients, whereas some studies include all-comers. Retrospective studies are also diverse. In a 2023 article ciNPT was compared with standard of care in all-comers for oncoplastic breast surgery5. The decision to use ciNPT was at the individual surgeon's discretion. The ciNPT group had significantly higher BMIs ($p<0.004$) and ASA levels ($p<0.002$) which are both well-known risk factors for SSI. Despite the selection bias against it, the ciNPT group had significantly lower complication rates.

Conclusion & Significance: In SSI prevention studies, the risk factors for SSI should carefully be considered when recruiting participants to observational studies or analyzing retrospective studies. The outcome is closely related to risk factors of the patient population and is subject to readers' bias especially if the findings are not favorable for the intervention group.

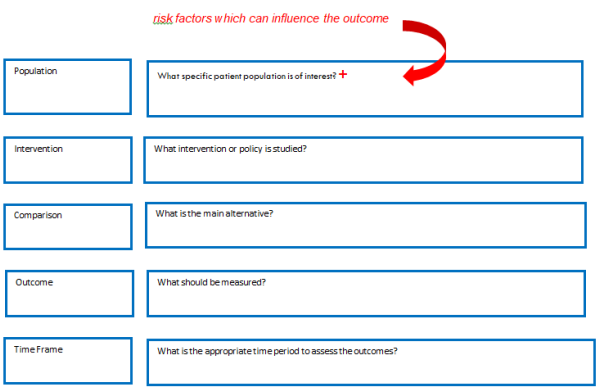

Figure 1: PICOT Format for Clinical Research[3]

Biography

Levent Afsar graduated from Istanbul University, Istanbul School of Medicine in 1993. After his university training he completed his residency in ear, nose, throat, head, and neck surgery at Taksim Research and Training Hospital in Istanbul. He served in the military as a surgeon for one year. In 1999 he joined the pharmaceutical industry. He worked at Pfizer and Merck in the CNS, Neurology, CVS and pain fields. Dr Afsar received an Executive MBA degree from the Bilgi University-Manchester Business School joint program. During 2013-2016 he worked in Medipol University as an an ear, nose, throat, head, and neck surgeon. In 2016 Levent joined Acelity Turkey as a senior regional medical manager. In 2020, following the 3M-Acelity merger he became a scientific affairs and education manager/medical science liaison responsible for Europe, Middle East, and Africa (EMEA) in the 3M Medical Solutions Division. Dr. Afsar has several publications in pain and arthritis. He is a member of the Fascial Plastic Surgery Association and the Turkish Medical Association.

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