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CORR Insights®: Do Glycemic Markers Predict Occurrence of Complications After Total Knee Arthroplasty in Patients with Diabetes?

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Where Are We Now?

The prevalence of diabetes among patients undergoing TKA has been steadily on the rise. Patients with diabetes have an increased risk of infections and wound complications following TKA. For

patients with diabetes undergoing TKA, maintaining proper glycemic control is a necessity, potentially reducing the risk of perioperative complications. Clearly, within this context, the study by Hwang and colleagues is clinically relevant. Still, the study touches upon a number of areas that remain unsettled.

Hwang and colleagues concentrated on identifying the glycemic markers most associated with the occurrence of surgical site infections and postoperative wound complications in patients with diabetes after undergoing TKA. The number of affected patients in the current study are low—462 patients with diabetes who underwent a total of 714 TKAs. Consequently, Hwang and colleagues were unable to perform an evaluation of patients with deep infection because there were no cases of this serious complication within the study group. A previously published study [2]

in a similar setting evaluating nominal data proved that 13,474 procedures would be necessary to detect a difference of one revision rate percentage point between two groups and 3008 cases to statistically support a relatively large difference of two percentage points. The number of cases required is unrealistic for clinical studies, and such studies are unfeasible in practice.

Where Do We Need To Go?

Careful scientific research, as demonstrated by Hwang and colleagues, will continue to be the basis of any good study. Hwang and colleagues have given us a good start by highlighting the effects of the most common elevated glycemic markers. Still, it is not surprising that given the size and importance of the topic, a number of unanswered questions remain. What are the potential confounders associated with controlling glycemic blood levels? What are the modifiable patient- and/or surgeon-related factors associated with glycemic control? What are the medical approaches to improve the care of patients with

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CORR Insights

diabetes? Can we prevent infection using implants with antibiotic coatings or other antibiotic regimens?

The complexities of diabetes will naturally raise some methodological issues. The revision rates between individual departments and countries vary by several hundred percent [1, 3, 5]. Additionally, the reproducibility of individual studies is sometimes subject to considerable limitations [4]. A more detailed layout of how the authors conducted the study would be useful in order for the reader to estimate whether the results are transferable to their own patient care environment.

A study with narrow inclusion criteria will likely have a more exact, but smaller study cohort, potentially resulting in a higher probability of error. Obtaining access to the largest possible number of patients and developing a sufficiently sized and well-defined patient cohort is one possible solution.

Electronic health records, as used in the current study, can be useful in data acquisition. Electronic health records are often considered significantly better structured data collection tools than paper files. Unfortunately, in my experience implementing arthroplasty registries, data collection is quite subjective—and actual documentation does not reflect reality as homogeneously as it often seems.

One possibility to improve this situation is using hard endpoints that

follow a structured decision process. While not the perfect fit for all cases, Patient Related Outcome Measures (PROMs) have become increasingly popular instruments for measuring clinical outcomes. Direct feedback by the patient certainly is of great value and can eliminate the physician's subjective perspective as a potential confounder. An inherent limitation of PROMs are its ability, or inability, to adjust for factors not associated with the treatment—such as a patient who also suffers from depression.

Clearly, measurable surrogate endpoints like laboratory parameters are another way of objectification, but even in this case, issues such as the actual effect of the indicator on the final clinical outcome are frequently challenged. Clear and accurate definitions would be most helpful in solving this problem. However, at present, standardized definitions are primarily available for serious complications such as deep infection. For less grave situations like superficial infections, no classification has been established, resulting in the documentation of greatly varying, subjective impressions.

How Do We Get There?

The use of registries can add significant value to future studies investigating patients with diabetes.

However, the efficient use of such data sources depends on standardized documentation through clear definitions and comprehensive implementation in routine patient care. Apart from a legal framework allowing for both data protection requirements and efficient data linkage, evaluation and interpretation procedures should be defined and scientifically approved on a worldwide scale.

When running scientific projects, it would be sensible for researchers to give greater consideration to the planned endpoints and the prevalence of the primary outcome parameter in study design. For statistical reasons, nominal (yes/no decisions) and ordinal (ranking scales like many clinical scores) data require relatively large patient groups and are appropriate for studies based on routine data. Metric data are more easily handled in conventional clinical studies. PROMs can provide a comprehensive overview on the subject and link the individual data sources.

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