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The study design was inappropriate in the article by Shahi et al.: “Serum D-Dimer Test Is Promising for the Diagnosis of Periprosthetic Joint Infection and Timing of Reimplantation”

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The original clinical research by Alisina Shahi and colleagues studied the diagnostic accuracy of serum D-dimer for periprosthetic joint infection (PJI) and concluded that serum D-dimer was a promising marker for PJI diagnosis (1). We, however, consider that the study design of this research is inappropriate and the results of this research is questionable.

The authors of current research prospectively enrolled patients who were undergoing primary total joint arthroplasty (TJA) or revision arthroplasty. After screened, patients enrolled in this study were grouped into five groups: those undergoing primary TJA (group A), those undergoing revision arthroplasty due to aseptic failure (group B), those undergoing resection arthroplasty and spacer insertion for the treatment of PJI (group C), those with treated PJI undergoing reimplantation surgery (group D), and finally, patients with known infection in a site other than a joint (group E). In order to evaluate the diagnostic values of D-dimer, ESR, and CRP, the authors conducted a 2×2 table in Table IV. According to the data in the 2×2 table, No. of “True negative” plus No. of “False positive” was equal to 139 or 138, and No. of “True positive” plus No. of “False negative” was equal to 57 or 56. Hence, we deduce that the authors investigated 57 PJI (group C) and 138 non-PJI (group A, group B, and group D) to evaluate the diagnostic values of D-dimer, CRP, and ESR. After abundantly and carefully reviewing, we consider that the design of non-PJI cohort is inappropriate.

Patients undergoing primary TJA (group A) and patients with treated PJI undergoing reimplantation surgery (group D) could not be enrolled in the non-PJI cohort. In essence, a study evaluating the efficacy of a novel diagnostic test should define a population at risk for having the diagnosis. Authors described “A venous blood sample was obtained preoperatively on the day of surgery and analyzed for serum D-dimer, ESR, and CRP” in the Materials and Methods part. Patients undergoing primary TJA (group A) before surgery do not have the risk for having PJI. So, enrolling patients undergoing primary TJA (group A) in the non-PJI cohort is inappropriate. Patients with treated PJI undergoing reimplantation surgery (group D) were a group of people who had been performed the prosthesis removal and spacer insertion surgery, and after infection well controlled, were undergoing reimplantation surgery. A spacer should not be regarded as a general component of joint prosthesis, and spacer infection should not be confused with PJI. Therefore, enrolling group A and group D together into the non-PJI cohort is inappropriate in the current study. In fact, the correct option of non-PJI is the population undergoing revision arthroplasty due to aseptic failure (group B). We reviewed other studies about the diagnostic tests on PJI (2,3,4), and agree that aseptic loosening population is the correct option for the non-PJI cohort. Patients with aseptic loosening are populations who have a painful joint after TJA and have the risk of PJI before definitive diagnosis according to a set of criteria. PJI is also named septic loosening (5), and the major difference between PJI and aseptic loosening is infected by sepsis or not. So, regarding aseptic loosening patient as non-PJI group is acceptable in the diagnostic test of PJI.

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