Biocompatibility Evaluation of Bioabsorbable Osteofixation Devices: a Scoping Review = Evaluasi Uji biokompatibilitas terhadap alat osteofiksasi bioabsorbable; scoping review =

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Abstrak

Pencarian dalam melakukan uji biokompabilitas terhadap material bioabsorbable dan osteofixation dilakukan, namun hingga kini banyak penelitian yang dilakukan tidak mengikuti standarisasi yang ada. Tujuan dari penelitian ini adalah melakukan evaluasi terhadap uji biokompabilitas yang telah dilakukan sebelumnya. Pencarian database terhadap scoping review dilakukan di PubMed, Embase and Cochrane Central Register of Controlled Trials (CENTRAL), dengan PRISMA-ScR guidelines digunakan dalam metodologi pemilihan literatur. Terdapat 26 penelitian masuk dalam inklusi penelitian, dengan metodologi animal study. Uji biokompabilitas yang tersedia untuk implant material biabsorbable yaitu uji cytotoxisitas, uji sensitisasasi, uji iritasi, systemic toxicity,uji genotoksisitasy,uji implantasi, dan uji hemokompabilitas, ditemukan hanya satu penelitian yang melakukan seluruh uji biokompabilitas, namun tidak adanya hewan kontrol dalam penelitian tersebut. Uji implantasi dilakukan oleh seluruh studi, yang melakukan evaluasi terhadap reaksi inflasmasi, penyembuhan tulang, dan degradasi implan. Hanya tiga penelitian yang menggunakan International Standard Operation (ISO), sebagai acuan dalam prosedur uji biokompabilitas. .....The quest of performing biocompatibility study for biodegradable material remains to be abstruse. Numerous studies have been conducted to investigate the biocompatibility of a biodegradable material for bone fixation devices. However, they rarely follow any known standard, which might make it difficult to compare, draw a conclusion, or to extrapolate the data. Therefore, this study aims to evaluate the biocompatibility tests performed in those studies in order to take note of their underlying concept and present the key points investigated. Database search of PubMed, Embase and Cochrane Central Register of Controlled Trials (CENTRAL) was conducted, and PRISMA-ScR guideline was used. Twenty-six studies were included in the review, and all of the studies utilize animal preclinical model as their biocompatibility assessment. Among the biocompability test are cytotoxicity, sensitization, irritation, systemic toxicity, genotoxicity, implantation, and hemocompatibility test. It was found that only one study performed all of the biocompatibility tests, however this study did not provide comparative animal control. Most of the studies conducted implantation test, evaluating inflammatory reaction, bone healing, and implant degradation. Only three studies referred to International Standard Operation (ISO) for conduction biocompability test. Although renowned standardization bodies such as ISO has published an international standard on biocompatibility studies, it was found that most researches were not able to thoroughly follow the standard.