Avaliando a qualidade dos estudos relatando aplicações clínicas da fração vascular estromal: Uma revisão sistemática e proposta de novas guidelines (CLINIC-STRA_SVF)

Autores: Kalluf, G; Araújo, R, S; Ferreira, L, M; Ferreira, M, Y; Junior, J, C, C.

Introdução:

A Fração vascular estromal (FVE) é uma fonte rica de células tronco adiposas (CTAs), que apresenta uma combinação eficiente de rendimento e facilidade de aplicação — fato que facilita significativamente a pesquisa acerca das CTAs. Em vista do fato que as CTAs apresentam qualidades regenerativas, ao se diferenciarem em múltiplas células especializadas do corpo (ex: condrócitos e miócitos) [1], além de propriedades imunomoduladoras, anti-inflamatórias, entre outras, a FVE tem sido vastamente explorada, uma vez que as qualidades únicas das CTA à conferem um potencial de aplicação terapêutica em diversas especialidades, em especial para patologias sem tratamentos efetivos estabelecidos [2]. Deste modo, a comunidade médica tem muito a ganhar com pesquisas de alto rigor científico, com as quais protocolos clínicos possam ser elaborados, a fim de habilitar aplicação abrangente destes benefícios.

Objetivo: Avaliar a qualidade dos estudos relatando aplicações clínicas da FVE e, a partir dos dados gerados, propor guidelines para padronização de pesquisas futuras.

Metodologia:

O presente estudo consiste em uma revisão sistemática da literatura norteada pelas guidelines PRISMA [3]. As bases de dados utilizadas foram MEDLINE, LILACS e EMBASE, enquanto o recorte temporal avaliado abrangeu de 01/12/2012 até 01/12/2022. Os descritores gerais utilizados foram: “stromal vascular fraction” AND “clinical application”; porém sinônimos catalogados na plataforma MeSH também foram incluídos com booleanos OR durante a captação de artigos. O nível de evidência dos estudos foi avaliado utilizando o sistema GRADE [4] e o rigor metodológico usado na publicação dos resultados foi mensurado de acordo com as guidelines indicadas na plataforma EQUATOR [5]. A guideline CLINIC e STRA-SVF foi desenvolvida após compleição da revisão sistemática.

Resultados:

Um total de 538 artigos foram encontrados, destes, 77 foram selecionados após leitura de título, abstract e remoção de duplicatas. Então, 15 estudos foram eliminados por não se encaixarem nos critérios de inclusão, deixando um total de 62 [6-67] estudos (Fig.1). A guideline CLINIC e STRA-SVF foi desenvolvida e consiste de 33 itens individuais e duas tabelas. A maioria dos artigos presentes na literatura são de baixo nível de evidência, sendo somente 6 (9,7%) ensaios clínicos randomizados e 26 (41,4%) ensaios clínicos. Ademais, grande parte dos estudos carecem de métodos validados para a documentação dos efeitos adversos (n=59; 95,16%), o que torna impossível uma análise dos dados agregados e, em múltiplos estudos, se traduziu em dados faltantes ou obtusos.

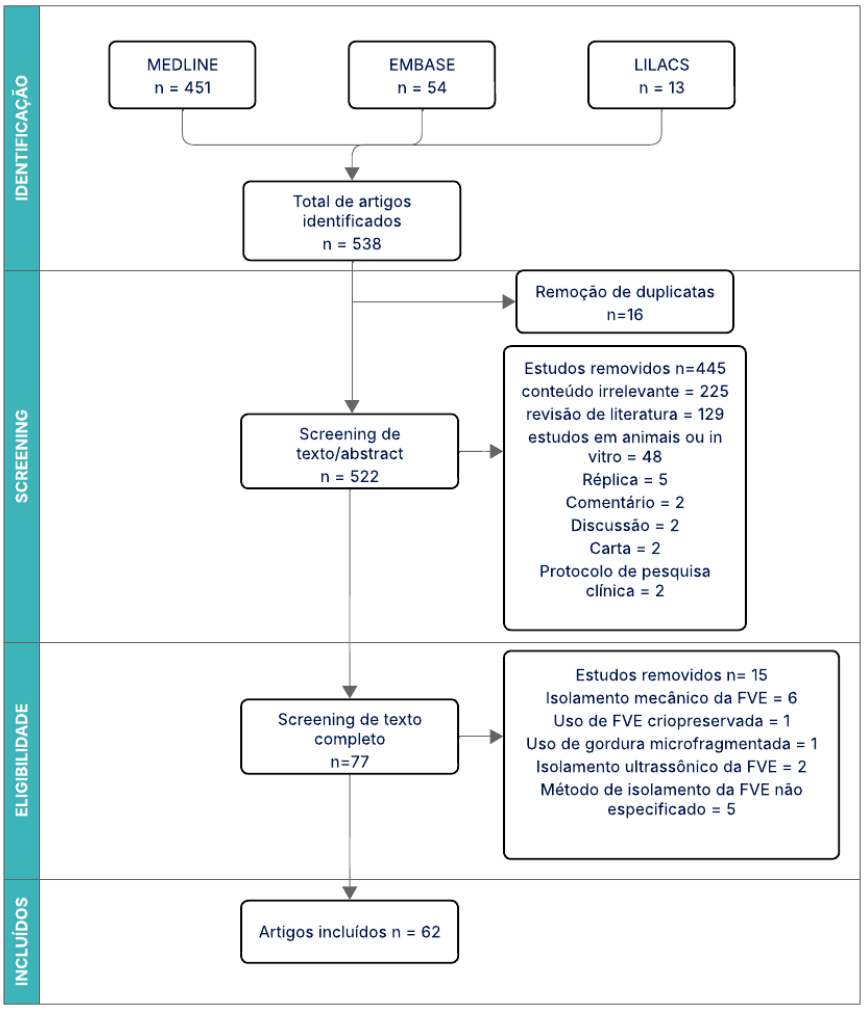

Figura 1: Fluxograma PRISMA

Conclusão: Existe uma quantidade significativa de evidência científica para a viabilidade das aplicações clínicas da FVE. Entretanto, uma parcela esmagadora da evidência disponível é oriunda de estudos de baixa qualidade e/ou rigor científico — que carecem, primariamente, de padronização. As guidelines CLINIC e STRA-SVF propostas neste estudo visam, justamente, padronizar desenhos de estudo, conduta de acompanhamento, apresentação e coleta de dados para ensaios clínicos, coortes e outros desenhos de estudo que tenham como objeto de pesquisa a FVE;

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