

Administration of Subcutaneous Monoclonal Antibodies in Patients With Cancer

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PROBLEM IDENTIFICATION: Subcutaneous (SC) formulations for monoclonal antibodies (mAbs) must be evaluated for efficacy and safety in comparison with preexisting IV formulations to identify potential benefits and risks.

LITERATURE SEARCH: This is a systematic review of clinical trials. MEDLINE®/PubMed, EMBASE, Cochrane Library, LILACS (Latin American and Caribbean Health Sciences Literature), and reference lists were searched for relevant studies.

DATA EVALUATION: Data regarding efficacy and safety were registered in a form designed for this review. Risk of bias was assessed using the Jadad scale.

SYNTHESIS: SC administration of alemtuzumab, trastuzumab, and rituximab presented therapeutic efficacy with similar safety profiles compared to their respective IV formulations, except for the higher prevalence of local adverse events following SC administration.

IMPLICATIONS FOR PRACTICE: SC mAbs require slow administration (no less than five minutes), and the injection site should be changed at each cycle. Patient guidelines should include information about expected adverse effects, signs or symptoms of side effects requiring emergency care, and how to reduce potential discomfort caused by the injection.

KEYWORDS monoclonal antibodies; subcutaneous injection; neoplasms

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Monoclonal antibodies (mAbs) represent major advances in the treatment of several types of cancer, and they have significantly improved patient survival with fewer side effects. Traditionally administered by the IV route, mAbs used in cancer treatment until 2013 were administered by infusion for 30 minutes to four hours at doses based on body surface area. However, the treatment of other chronic diseases has demonstrated the possibility of subcutaneous (SC) administration of mAbs (Jackisch, Müller, Maintz, Hell, & Ataseven, 2014; Leveque, 2014).

This route of administration has become attractive for use in cancer treatment because of its potential to eliminate the risks of venipuncture and reduce treatment time and costs (Jackisch et al., 2014). However, when changing the route of administration, the limitations of the SC tissue, particularly those related to volume, need to be considered. The SC tissue is composed of an extracellular matrix that maintains the structure of the skin and regulates the flow of fluids. Volumes exceeding 3 ml increase local pressure, distort the matrix, and cause pain (Arthur, 2015). To overcome the volume limits for bolus injection, SC formulations should contain hyaluronidase as an excipient.

Hyaluronidase is an enzyme that naturally occurs in the body; its function is to hydrolyze hyaluronic acid, one of the components responsible for the structure of the SC tissue. This process reduces extracellular matrix resistance and facilitates the infusion of fluids (Arthur, 2015). Hyaluronidase has been successfully used to facilitate SC delivery of drug volumes exceeding 3 ml (Arthur, 2015; Dychter et al., 2014).

The SC route represents a reduced risk of infection, allows self-administration by patients trained by healthcare providers, is more convenient for patients and nurses, shortens administration time, and can reduce treatment costs (Jackisch et al., 2014).