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RESEARCH ARTICLE

GENERAL GUIDELINES IN USE OF BIOLOGICS –MONOGRAPH

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ABSTRACT

The Institute of Medicine defines clinical practice guidelines as "Statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options Guidelines for their use in licensed indications (e.g. rheumatoid arthritis, psoriasis, inflammatory bowel disease) include recommendations and guidance for patient selection and subsequent monitoring with discussion of potential adverse effects. An under- standing of these is important when managing patients receiving biologic therapy for systemic disease and use in oral medicine. Studies on knowledge and awareness among dental health professionals about Biologics and general guidelines is rarely reported hence the present study is carried out.

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INTRODUCTION

Biologic agents are a new category of drugs designedto block specificpathways involved in pathophysiology of immune mediated and neoplastic diseases. These agents are promising and have targeted anti-inflammatory or immunosuppressive action in comparison to corticosteroids and corticosteroid-sparing immunosuppressants .They presumably represent a pathogenesis based treatment and not just organbased palliative therapy (Jackson, 2007). Biological agents can either be a cytokine, an anti- body, or a fusion protein .The biological agents are used in various dermal diseases (Gonzalez-Moles *et al.,* 2008). Inflammatory ulcerative diseases of the oral mucosa are wide ranging but include especially aphthous and apthous like ulceration, vesiculobullous disorders and erosive lichen planus.While most patients with these conditions respond to conventional topical and / or systemic immunosuppressive agents, treatment-resistant cases remain challenging . The use of biologics such as tumour necrosis factor alpha (TNF-a) inhibitors or rituximab may be of benefit (Lodi *et al.,* 2005; Scully *et al.,* 2008).

Licensed indications

In general biological products are regulated (licensed for marketing) under the Public Health Service Act originally by the National Institutes of Health (NIH) and its precursors and later, starting in 1972, by the FDA and chemical drugs are regulated (approved for marketing) under the Federal Food Drug and Cosmetic Act by the FDA (Thongprasom *et al.,* 2011).

Biologic control act 1902

The regulation of biologics by the federal government began with the Biologics Control Act of 1902, "the first enduring scheme of national regulation for any pharmaceutical product.

- Pure Food and Drugs Act and the Federal Food Drug and Cosmetic Act
- The Public Health Service Act (Informed Consent: American Medical Association)

Guidelines and recommended guidance on use of biologics for TNF-alpha and Rituximab

Eligibility

- Severe disease or resistance to standard systemic therapy.
- Patient should be fully informed of risk and benefits of therapy and that treatment is off – label

Contraindications

- Hypersensitive to agents
- Active infections

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- Severe heart failure (NYHA Class III /IV)
- Pregnancy and lactation (rituximab)
- Demyelination disease

Pre-treatment screening

- History and physical examination consider possible contraindications
- Full risk : benefit assessment
- Full blood picture : liver function test, consider testing, screening for HCV, HBV and HIV, immunoglobulin level, consider radiograph of chest
- Asses necessity of vaccination, do not administer liver vaccination.

Adverse events possible

- Hypersensitivity reaction
- Exacerbation of cardiac failure
- Potential increase risk for malignancy
- Opportunistic infections

Monitoring

- Early signs and symptoms of infection throughout treatment
- New onset or exacerbation of cardiac dysfunctions
- Evidence of malignancy

Assessment of patient before treatment

Patient should be given the opportunities to select their preferred route of drug administration. They should always be informed about the drug therapy, have signed the relevant consent forms for BSR Biological registers and local trust policy (Jane *et al.,* 2004; David and Dudzinski).

Patient monitoring

It is logical to take steps necessary to prevent infection in patient who are immunosuppressive by medication such as biological therapies.

Protocol prior to biologic therapy initiation

- Review previous and current medication (including vaccination review)
- Fully informed consent Screen:
- Cardiac function:Cardiac failure is aggravated during TNF-a blockade
- TB (skin testing; chest radiography) Virus infections (HBV/HCV/HIV)
- Full blood counts (FBC):To rule out potential risk of hepatic dysfunction, especially with infliximab
- Liver function tests (LFTS)
- Plan for dealing with acute reactions to biologic agents (Avery, 2001)

Assessment of patient during treatment

Laboratory tests in monitoring patient on biological therapies

- Annual TB skin test ;alternative include the QuantiFERON-TB gold blood test and chest x-ray if indicated
- CD4+ T-lymphocyte count every two weeks for alefacept
- Complete matabolic panel with liver function test for each infliximab infusion and with signs of hepatic injury
- +/- complete metabolic panel every 3 to 6 months on all biologic therapies
- +/- complete blood count every 3 to 6 months on all biological therapies
- +/- Hepatitis screen and HIV testing when risk factors present on all biological therapies (Avery, 1999; Duchini *et al.,* 2003).

Vaccination

- +/- Influenza and pneumococcal vaccination
- Vaccination may not be beneficial in patient taking efalizumab (O'Neill and Scully, 2012; Gniadecki, 2006).

Informed consent in biologics

An informed consent according to the American Medical Association (AMA) is the communication process between a patient and his or her physician that results in the patient's agreement to undergo a particular medical procedure or treatment. The concept of informed consent is rooted in medical ethics and codified as legal principle it is based on the assertion that a "competent person has the right to determine what is done to him or her. FDA approved prescription medications such as parenteral biologics? We all know that patients are entitled to informed decisions about their healthcare, but there is little to no guidance on the topic of informed consent for biologic infusions. It is important to remember that the primary goal of the informed consent process is to convey significant safety information so the patient can decide whether or not to undergo medical treatment. Sources of information include the product manufacturer, product or package labelling, medication guides, continuing medical education (Camacho-Alonso *et al.,* 2005; Martin *et al.,* 2009).

Conclusion

In recent years Biological agents have been used to treat immunologically mediated disease such as phemphigus, phemphigoid and other other oral ulcerative diseases. This monogram proves the need for future case studies exploring the significance of use of biologics exclusively in various oral diseases. Further studies in use of biologics in oral disease will be helpful in framing specific guidelines in use of biologics in oral disease.

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