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S/D Plasma

A CLINICAL PRACTICE CHANGE

Overview

- Why the change?
- What is Octaplasma?
- Dosage
- Clinical considerations
- Administration
- Indications and contraindications
- Special considerations
- Patient monitoring
- Additional resources

Why The Change?

THE CANADIAN BLOOD SUPPLY SYSTEM: BASIC PRINCIPLES

It is recommended that the Canadian blood supply system be governed by five basic principles:

a) Blood is a public resource.

b) Donors of blood and plasma should not be paid for their donations, except in rare circumstances.

c) Whole blood, plasma, and platelets must be collected in sufficient quantities in Canada to meet domestic needs for blood components and blood products.

d) Canadians should have free and universal access to blood components and blood products.

e) **Safety of the blood supply system is paramount**

(Krevar Inquiry pg 1047)

What is Octaplasma?

- Octaplasma is a pathogen-reduced form of frozen plasma that reduces the risk of transfusion-transmitted viral infections and other adverse reactions.
- Until March 2023, Octaplasma, the S/D plasma manufactured by Octapharma, was only available for special patient populations.
- The most timely and cost-effective path to a pathogen-reduced plasma supply is through the expanded purchasing of Octaplasma.

Summary of benefits: S/D plasma

- Pathogen inactivation enhances safety profile
- May potentially decrease incidence of adverse reactions: allergic, TRALI, other immunologic reactions
- Consistent levels of coagulation factors
- Consistent unit volume

<u>System benefits</u>

- Increased Canadian plasma available for fractionation

Solvent/Detergent treatment of plasma

S/D treatment reduces the risk of transfusion-transmitted pathogen infections and provides an additional layer of safety against:

- Enveloped viruses (including hepatitis B and C and HIV)
- Bacteria (gram-positive, gram-negative, spirochete)
- Protozoa parasites
- Prions
- White blood cells (leukocytes)

Benefits of Pathogen Inactivation

- Reduces the residual risk of transfusion-transmitted infections, providing an additional layer of safety and complementing donor selection criteria and donation testing.
- Reduces the risk of emerging or unknown pathogens that can be transmitted during transfusion to a patient.
- Removal of white blood cells reduces the risk of transfusion-associated graft versus host disease, a rare and usually fatal adverse reaction.

What's the difference?

S/D PLASMA

- Volume: 200ml
- Can be stored for 4 years from date of manufacture.
- Made from 1000's of donors.
- Takes 30 minutes to thaw.
- Once thawed, can be used up to 5 days later.

FFP

- Volume 500-1000ml
- Can be stored for 1 year from date of collection.
- Made from 1 donor.
- Takes 20 minutes to thaw.
- Once thawed, must be used within 24 hours.

Clotting factor activity

- Octaplasma has similar pharmacokinetic properties as FP
- The coagulation activity values are close to the corresponding values for normal human single-donor FP and a minimum of 0.5 IU/mL is obtained for all clotting factors.
- More consistent and standardized clotting factor content compared with single donor plasma (levels in single donor plasma may have a wide reference range [50–200%]).
- Levels of protein S, alpha-2 antiplasmin are reduced.

S/D Plasma has decreased the incidence of:

- Allergic reactions, both mild and anaphylactic
- Non-hemolytic transfusion reactions
- Febrile non-hemolytic transfusion reactions
- TRALI
- TACO

Dosage

From the Octaplasma product monograph:

- The dosage depends upon the clinical situation and underlying disorder
- 12–15 mL/kg body weight is a generally accepted starting dose.
- This dose should increase the patient's plasma coagulation factor levels by approximately 25%.

Sample Octaplasma dose calculation

- Dose for a patient weighing 70 kg, where one unit of S/D plasma has a volume of 200 mL.

70 kg x (12–15 mL/kg) = 840 – 1,050 mL = 4–5 units

Clinical considerations (from Product Monograph)

Clinical efficacy

- Similar to FP

Dose

- Dosing volume is similar to that for FP (12–15 mL/kg)
- Dosing by number of units may be different

Selection of patients

- Acceptable for almost all patient groups
- Severe protein S deficiency is very rare (may present with thrombosis)

★ If a patient has a contraindication to the use of Octaplasma, FP remains available

Administration (from Product Monograph)

- Must be ABO-blood group compatible
- High dosages or infusion rates may induce hypervolemia, pulmonary edema and/or cardiac failure.
- High infusion rates may cause adverse effects as a result of citrate toxicity (fall in ionized calcium), especially in patients with liver function disorders.

Testing of donors and plasma pools

- Controls are applied to the selection and screening of donors for hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) infection.

The plasma pools are also tested for:

- Hepatitis B surface antigen (HBsAg)
- Anti-HIV (type 1 and 2 antibodies)
- Nucleic acid testing (NAT) for: HIV, HAV, HBV, HCV, HEV and parvovirus B19

Enveloped Virus Inactivation

- Solvent/Detergent solutions are able to disrupt an enveloped virus's lipid membrane, thus it can't bind to and infect other cells.

- These solutions do not affect the plasma proteins nor do they affect the final octaplasma product.

- Examples of enveloped viruses:
  - HIV
  - Hepatitis B and C
  - West Nile Virus

Non-Enveloped Virus Inactivation

- Octaplasma is treated with immune antibodies to neutralize non-enveloped viruses.

- Examples of non-enveloped virus:
  - Hepatitis A
  - Parvovirus B19

Indications for S/D Plasma

- Complex deficiencies of coagulation factors
  - Coagulopathy due to sever hepatic failure, massive transfusion, or repeated large plasma exchange.
  - Consumption coagulopathy i.e. DIC
- Emergency substitution therapy in coagulation factor deficiencies
  - For example, can be used with specific coagulation factor concentrate is not available.
- Rapid reversal of effects of oral anticoagulants when vitamin K is insufficient in emergency situations, or in patients with impaired liver function.

Contraindications

- IgA deficiency with documented antibodies against IgA as it may cause severe anaphylaxis.
- Protein S deficiency as it may result in an increased risk of developing blood clots.
- Patients with hypersensitivity to this drug or to any ingredient in the formulation, including any non-medicinal ingredient or component of the container.

Special Considerations

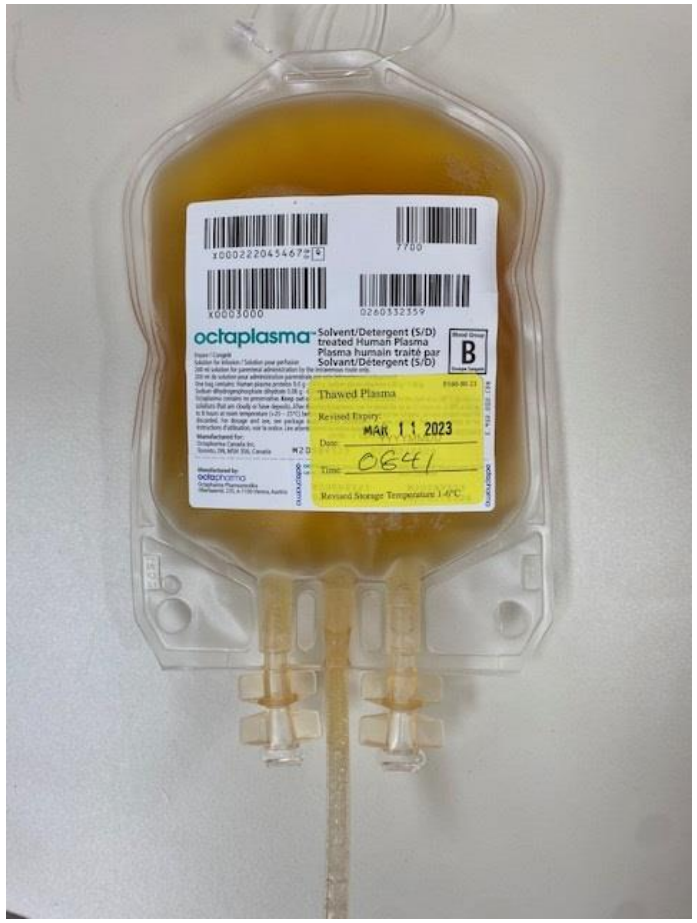
Risk/Benefit analysis shall be taken for populations such as:

- Pregnancy/Lactation
- Pediatrics
- Neonatal/Intrauterine

For a full list of other special patient populations and for more information, please refer to the Octaplasma Product Monograph.

This document may be found on: Canadian Blood Services' professional education website, profedu.ca
Information is current to January 12, 2023. Always refer to the Product Monograph for up-to-date information. Our product portfolio (octapharma.ca)

What will my Plasma Look Like?



Patient Monitoring

- Refer to Manitoba Transfusion Best Practice Resource Guideline
- Transfusionist must remain with patient for first 15 minutes
- VS are to be monitored:
  1. within 30 minutes prior to transfusion
  2. 15 minutes after initiation
  3. Every hour during infusion
  4. Upon completion of infusion

Will anyone still get FFP?

- Documented adverse reactions to Octaplasma.
- Patients with Protein S deficiency.
- Patients with IgA deficiency with documented antibodies against IgA.
- Intrauterine transfusions

Rollout

- We will start seeing Octaplasma issued effective 27 March 2023
- FFP will be gradually used up/phased out
- Transition completed Fall 2023

Resources

- Octapharma Canada website (https://octapharma.ca)
- Octaplasma product monograph (https://octapharma.ca/en/therapies/product-overview)
- FAQ: Solvent detergent (S/D) treated plasma (Octaplasma) (under publications on profedu.ca)
- Including additional resources:
- Octaplasma: Clinical overview slide deck – short version (also available as narrated video)
- Octaplasma: Information for laboratory technologists slide deck (also available as narrated video)
- Octaplasma (S/D plasma): One-page clinical summary