From Vision to Practice:
The Development of a High Dose IL - 2 Program

Kaley F. Benson, RN, OCN
Cindy Waddington, RN, MSN, AOCN

Program Outline

- General overview of HD - IL - 2
- Development of HD - IL - 2 program
- Safe administration and management of HD - IL - 2

Our Lady of the Lake Regional Medical Center

- 600 bed not for profit non teaching hospital
- IL-2 program within 4 bed stem cell transplant unit
- Providing HD IL-2 for 4.5 years
- Total 48 patients, 126 weeks of admissions
- Program Coordinator has worked with HD IL-2 for 4.5 years
- Several physicians order and administer HD IL-2

Christiana Care Health System

- 1,000 bed not for profit regional tertiary care teaching health system
- IL-2 Program within 6 bed Bone Marrow Transplant Unit
- Providing HD IL-2 for 1.5 years
- Total 5 patients, approx. 7 weeks
- Program Coord. has worked with IL-2 for 1.5 years
- One physician orders and administers HD IL-2

Interleukin-2 Overview

- What is it?
- How does it work?
- Who is it for?
- Side Effects/Toxicities
- Why give IL - 2?

What is IL-2? How does it Work?

- A cytokine, produced by activated killer T-cells.
- An immunomodulator, promotes activation of cytotoxic T-cells, Natural Killer cells & monocytes.
- Plays a central role in immune regulation
- Recombinant DNA technology

Who is IL-2 For?
- Approved for treatment of metastatic melanoma and metastatic renal cell carcinoma.
- The approved method of administration is high dose intermittent bolus for both cancers.

Side Effects/ Toxicities
- Flu like syndrome
- Capillary leak syndrome

Why give IL-2???
- Potential for complete response
- Responses are lasting

Program Development
Cindy Waddington, RN, MSN, AOCN
- Program Feasibility Assessment
- Program Development Committee
- Process and tools to be developed
- Staff education
- Marketing
- Preparing for first patient

Program Feasibility Assessment
- Interest in program?
- Data supportive?
- Familiar with drug?
- Key administrative support?
- Reviewed reimbursement info?
- Identified appropriate unit to administer?
- Physician champion?
Program Development Committee
- Identify content experts and stakeholders
- Physician champion
- Nurse partner
- CNS
- Nurse Manager
  - Staff nurse
  - Nurse educator
  - Pharmacist
  - Care Coordinator

Tools/ Process to be Developed
- Administration Policy
- Nursing Resource binder
- Patient Flow
- Patient education process
- Discharge planning

Maintain a Time Line
- Identify completion goal/subgoals
- Establish routine meeting dates/times
- Reserve meeting rooms
- Identify subtopics
- Assign subtopics to team members
- Establish time line for completion
- Critique & revise projects and time line

Standardized Progress Note - OLOLRMC
- Date: Patient admitted for high dose interleukin – 2 administration for the treatment of metastatic__________. Since admission, patient has received______ out of______ doses of interleukin – 2 each infused over 15 minutes.
1. Admin to bone marrow transplant patient.
2. Chemotherapy admission for high dose (Proleukin) infusion.
3. Diagnosis: (check one and complete metastatic sites)
   - Renal cancer with metastasis to
     - Kidney with metastasis to
4. Intensive care unit (ICU)
5. Regular diet as tolerated
6. Activity of
7. No urinary catheterization (urinary or topical)
8. No IV medications
9. No procedures requiring IV contrast
10. Vital signs pre-treatment and q 4 hours around the clock
11. Pulse oximetry reading, bedside and arm
12. Continuous cardiac monitoring for systolic blood pressure > 90 and/or heart rate > 120
13. NPO status
14. Oxygen 2 liters as needed for shortness of breath
15. Daily weight q am

16. Prolactin (Interleukin-2) 800,000 units per kg per dose in
   units in NPB to be infused over 15 minutes 0.8 hours times 14 doses.
   Do not piggyback through running IV solution.
   Flush IV tubing with 50 mL of DSW after each dose.
   ** Assess patient prior to each dose of Proleukin using the Dose
   Modification Algorithm.**
   ** If necessary, Albumin may be added at final concentration of 1 mg per mL
   to maintain stability.
   *CALL PHARMACY PRIOR TO EACH DOSE TO HAVE THEM
PREPARE THE PROLEUKIN INPB.*
26. Prophylaxis for line infection:
Caphalixin (eg Keflex) 250 mg PO BID once line is placed
if patient allergic to penicillin, substitute with
Cilindamycin (eg Ciflox 300 mg PO BID instead of Septra)

27. Side-effect Management:
- Diarrhea: Florfenicol (eg Fortum) 25 mg PO every 6 hours PRN for 5 days
- Nausea: Florfenicol (eg Fortum) 25 mg PO every 6 hours PRN for 5 days
- Vomiting: Florfenicol (eg Fortum) 25 mg PO every 6 hours PRN for 5 days
- Hypersensitivity: Florfenicol (eg Fortum) 25 mg PO every 6 hours PRN for 5 days

28. Regimen/Protocol Summary:

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Educating Staff

- Unit nurses
- Pharmacy
- Physician office staff
- IV nursing
- Billing/coding

- Education just prior to first patient
- Social work/health psychology follow up


Nursing Education

- Credentials
- Resource speakers
- Continuing ed programs
- Virtual Preceptorship CD
- Self learning packets
- Internet resources
Educational and Professional Resources

- IL - 2 brochures available from Chiron Therapeutics (1-800-CHIRON-8)
  - Proleukin (Aldesleukin): Patient Management Guidelines
  - Management of Patients receiving Interleukin - 2 Therapy

Educational and Professional Resources (cont.)

- National Cancer Institute
  - 1-800-4CANCER (telephone cancer information service)
  - Biological Therapies: Using the Immune System to Treat Cancer (fact sheet)
  - National Kidney Cancer Association (1-800-850-9132)
  - Interleukin-2 and Biologic Therapy: A Booklet for Patients and Their Families
  - IL-2 Therapy: What You Should Know

Educational and Professional Resources (cont.)

- Oncology Nursing Society
- Proleukin Therapy: Information for patients and Their Families (video) (Write to: American Medical Communications, Houston, TX)
- Interleukin-2 Therapy: Information for Patients and Their Families (booklet) (Write to Medicailliance Inc., Columbia, MD)
  - 1-412-921-7373 (customer service)
  - http://www.ons.org
Educational and Professional Resources

- Publications
  - Biotherapy: Considerations for Oncology Nurses (newsletter) (Write to: Scientific Frontiers, Inc., Washington Crossing, PA)

First Patient

- Pre:
  - Identify core nursing team
  - Educate around the clock
- During:
  - CNS/manager/Care Coord. support
  - Recognition
  - Medical director visit
- Post:
  - Social work follow up
  - Opportunities for improvement

Marketing

- Within system
- As a referral center
- As your program grows

As a referral center

As your program grows
Safe Administration and Patient Management
Kaley F. Benson, RN, OCN

- Patient Selection
- Schedule
- Pharmacy Issues
- Patient Management and Nursing Considerations
- Patient Scenarios
Safe Administration and Patient Management

- Patient Selection
- Schedule
- Pharmacy Considerations
- Patient Management/Nursing Considerations
  - Side Effects/Toxicities
  - Patient Monitoring Guidelines
  - Dose Administration Criteria

Patient Selection

- Severe toxicities mandate rigorous patient screening!
- Patient Selection Criteria:
  - Performance status of ECOG of 0-1
  - Normal organ system function
  - No immunosuppressive or corticosteroid therapy

 Certain co-morbidities and risk factors indicate candidate is high risk
  - Symptomatic brain metastases
  - Poor performance status (ECOG of >1)
  - Active infection
  - Recent use of corticosteroids
  - Limited pulmonary function
  - Active cardiac disease

High Dose Interleukin-2 Schedule

1 Course

- Cycle 1: IL-2 IV Q 8 hours x 14 doses maximum
- Rest Period: 7 – 10 Days
- Cycle 2: IL-2 IV Q 8 hours x 14 doses maximum

Pharmacy Considerations

- Sterility
- Stability
- Compatibility
- Dose Administration Guidelines

Pharmacy Considerations

- Communication is Key!
- Pharmacy notification prior to admission
- 08 hour authorization
- Standard administration times

References:
Capillary Leak Syndrome (continued...)

- Leads to hypovolemic state & excessive fluid in the extravascular space

- May manifest as:
  - generalized edema
  - pleural effusions
  - weight gain
  - ascites
  - pulmonary congestion

- Hypovolemia → decreased blood flow to kidneys, gut, heart, & brain → oliguria, ischemia, & confusion


Adapted with permission from Chiron from Proleukin (aldesleukin) for Injection: High-Dose Guidelines 2003.
Flu-like Symptoms
- Chills, fever, and malaise are most common and most predictable side effects.
- Usually develop 1-2 hours after first or second dose.
- Fatigue may persist between cycles

Gastrointestinal Effects
- Transient nausea, vomiting, diarrhea, and anorexia are common.
- Abdominal pain, gastritis, mucositis, and xerostomia may develop, are less common.

Neurological Effects
- Can be caused from IL-2, “ICU Psychosis” or other meds
- Confusion, somnolence, disorientation, anxiety, & dizziness
- Altered sleep patterns
- Agitation & combativeness; vivid dreams, paranoia, emotional lability, hallucinations

Cardiopulmonary Effects
- Hypotension, tachycardia, & dyspnea most common.
- Hypotension & tachycardia - within 2 hours after first dose & progress in severity as therapy continues.
Dermatologic Effects

- Manifests as erythema
- Pruritus on face, neck & trunk
- May persist up to 6 weeks
- May cause hair loss or thinning, usually mild

Infection

- Usually occur in the urinary tract or at site of venous catheter placement
- Usually Staphylococcus aureus & S. epidermidis.

Symptoms Chart: Corrective Measures

- See handout #14
- Handout Description: List of Potential symptoms with corresponding nursing actions & medications

Relative and Absolute Criteria

- Criteria Overview
- Guidelines for decision making: Administer, Delay, or Discontinue IL-2
- Guidelines involved in the decision making process.
**Patient Monitoring Guidelines**

- See Handout #16
- Pre High Dose IL-2 Worksheet: Worksheet with criteria and guidelines to aid decision making in reference to dose administration.


**Patient Scenarios**

- Metastatic Melanoma Patients
- Metastatic Renal Cell Carcinoma Patients

**Summary, Questions**

**Contact Us**

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KBenson@ololrmc.com