

# Ultrasound Guided Access of Intrathecal Drug Delivery System: A Pilot Study



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# Background



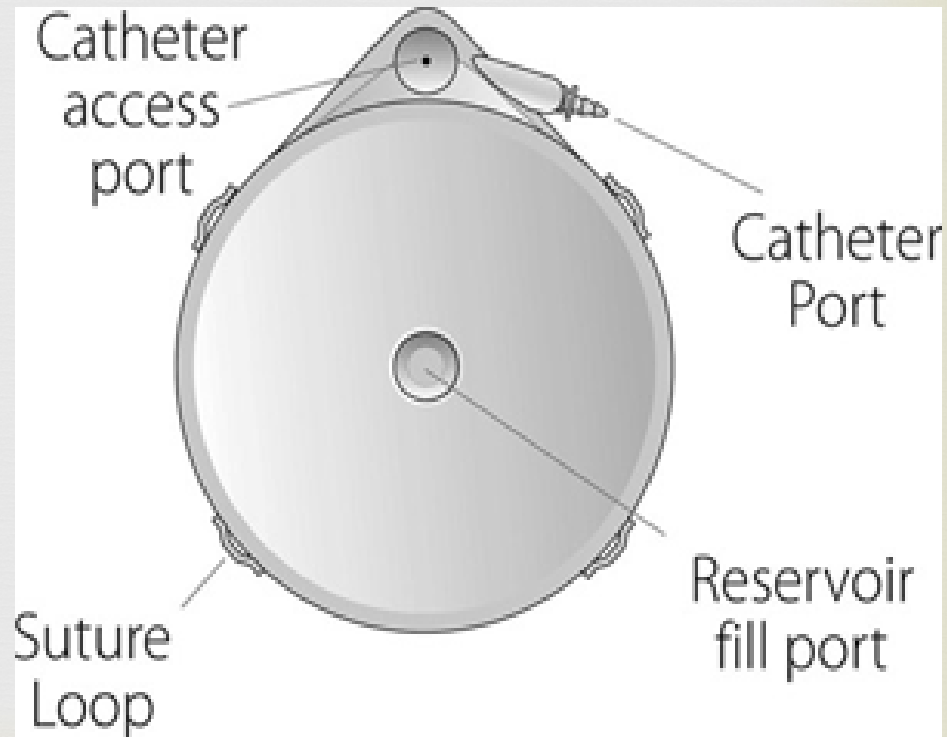
- ❧ Intrathecal Drug Delivery Systems (IDDS)
  - ❧ Severe spasticity of spinal or cerebral origin
  - ❧ Severe chronic, intractable pain of malignant and/or nonmalignant origin
  - ❧ Chemotherapy for cancer

# Background *cont.*



## Design

- ❧ Titanium body
- ❧ Silicone septum
  - ❧ Catheter Access Port (CAP)
  - ❧ Reservoir fill Port (RP)
  - ❧ 500 Punctures
- ❧ Secure placement
  - ❧ Mesh pouch
  - ❧ Suture loops





# Background *cont.*



- ❧ Complication of Refill
  - ❧ Pain
  - ❧ Seromas
  - ❧ Hematomas
  - ❧ Pocket fill
  - ❧ Infections
  - ❧ Meningitis
  - ❧ Drug overdose or withdrawal
  - ❧ Death

# Background *cont.*



- ❧ Difficult refill using standard template
  - ❧ Highly mobile pumps
  - ❧ Inverted pumps (X-ray shows inverted unique 3 letter code)
  - ❧ Deep implantation (recommended no more than 2.5 cm from skin surface)
  - ❧ Fluid collection in the pump pocket
  - ❧ Body habitus from adipose tissue
  - ❧ Level of training

# Background *cont.*



- ❧ Image guided Reservoir fill Port (RP) access
  - ❧ Ultrasound guided
    - ❧ 100% positive & negative predictive value
    - ❧ Portable
    - ❧ No radiation exposure
    - ❧ No Standard Operating Procedure
  - ❧ Fluoroscopy
    - ❧ Less portable
    - ❧ Exposure to radiation
    - ❧ Expensive

# Background *cont.*



- ❧ There were case reports of ultrasound guided localization of difficult to access refill port
- ❧ No existing prospective randomized, case control study to evaluate safety and efficacy of Ultrasound guided IDDS refill

# Objectives



## ☞ Identify

- ☞ The average amount of duration it takes to access RP by health care providers with varying levels experience.
- ☞ The average number of skin penetration it takes to access RP by health care providers with varying levels of experience.
- ☞ Individuals with “difficult to access port (DAP)” intrathecal drug delivery system.



# Objectives *cont.*



## ☞ Design

- ☞ A SOP for ultrasound guided RP access of IDDS.
- ☞ A prospective, randomized case control study to identify safety and efficacy of ultrasound guided IDDS port access vs. template guided IDDS port access based on the outcomes of this pilot study.

# Methods & Materials



- ❧ Participants are individuals with IDDS & any body habitus
  - ❧ Who receive IDDS refill at University of Kentucky
  - ❧ Who are 18 & above at the time of study
  - ❧ Who have had one refill
  - ❧ Who are able to provide informed consent by themselves or by surrogate, by legal guardian
- ❧ Equipment
  - ❧ Ultrasound machine
  - ❧ Sterile Probe Cover
  - ❧ Sterile Ultrasound Gel
  - ❧ IDDS Refill Kit
  - ❧ Drug to be placed in IDDS

# Methods & Materials *cont.*



## Part 1

- Identify, mark CAP & RP using standard template
- Access RP using sterile technique
- Record the number of needle penetrations and time from needle penetration to RP entry
- Successful RP entry – aspiration of residual drug
- Calculate mean time for successful RP entry and mean number of needle penetrations
- 2 SD to define minimum number of needle penetrations and minimum amount of time to access RP

# Methods & Materials *cont.*



## Part 2

- Identify, mark CAP & RP using standard template
- Access RP using sterile technique
- Successful RP access – aspiration of residual drug
- Difficult RP access
  - Unable to identify CAP & RP
  - Unable to access RP after the minimum number of needle penetration and minimum amount of time once RP is localized



# Methods & Materials *cont.*



## ☞ Part 2 *cont.*

- ☞ Difficult to access pump – use ultrasound to identify, mark CAP & RP
- ☞ Access RP using sterile technique after wiping off ultrasound gel
- ☞ Time from needle penetration to RP entry
- ☞ Ultrasound measurements for every participant
  - ☞ Distance between skin surface and pump surface
  - ☞ Angle between long axis of skin and long axis of pump
- ☞ Distance between 2 skin marks placed by Ultrasound and standard template.

# Methods & Materials *cont.*



## ☞ Analysis

☞ *“That the greater the distance between skin surface and pump surface, greater the distance between two skin marks placed using standard template and ultrasound and the greater the angle between the long axis of skin and the long axis of the pump will result in difficult RP access that can be obviated using ultrasound guidance compared to the standard template”*

# Methods & Materials *cont.*



## ☞ Analysis *cont.*

- ☞ Compare the distance between the skin and pump surfaces, as well as the angle between the long axis of pump and the long axis of pump between individuals who received IDDS refill with and without ultrasound
- ☞ Distance between two skin marks placed by using standard template and ultrasound will give us how far away the image guided skin penetration site would have been

# Discussion



- ❧ Average time to access RP
- ❧ Average number of skin penetrations to access RP
- ❧ Skill level based data
- ❧ Identify who are at risk to become difficult to access
- ❧ Develop SOP for ultrasound guided IDDS RP access by identifying road blocks
- ❧ Ultrasound guided RP access is also skill level dependent



# References



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# Questions & Comments



Thank You