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**ULTRASOUND GUIDED VS:
BLIND/TEMPLATED
INTRATHECAL PUMP
REFILLS**

Outline

- Introduction
- Hypothesis
- Objective
- Design
- Study Population
- Procedure
- Outcome Measures
- Expected Outcome

Introduction

- To my knowledge there have been no studies that clinically evaluate the use of ultrasound guidance to access and refill implanted intrathecal pumps.
- Ultrasound is being widely used to help limit procedural complications and allow appropriate localization of anatomic structures.
- There have been a few case reports and descriptions of US guidance for pump refill, but no standardized method.

Hypothesis

- ◎ Ultrasound-guided intrathecal pump refills will:
 - decrease amount of time to access pump
 - decrease number of sticks/maneuvers
 - decrease post-procedure pain
 - increase patient satisfaction.

Objective

- The aim of this study is to compare the efficacy, safety, duration, and patient satisfaction of Ultrasound-guided vs: Blind/Templated intrathecal pump refills.

Design

- Prospective, clinical trial comparing Ultrasound-guided vs: Templated intrathecal pump refills.
- The study will include -patients from our University of Kentucky PM&R Clinic w/ intrathecal pumps.
- Subjects will be randomized to obtain an equal number of pts in each group.
- Patient/Physicians will not be blinded secondary to the use of ultrasound due to limited ability to blind that factor from either the patient or physician.

Study Population

- Inclusion Criteria: patient with implanted intrathecal pumps who are 18 years or older and are willing to participate in the study.
- Exclusion Criteria: <18yrs, Infection/Hospitalization within last month, active fever or current infection, need for pump/battery exchange within next 3 months.

Procedure

- ◎ Template/Blind Group: Risk/Benefits, Informed Consent, Timeout
 - Physician preps injection site and medications ready for refill, with template on sterile field.
 - Physician gloves, templates pump, accesses site w/ number of sticks/needle maneuvers noted, removes current meds, refills pump, patient is then cleaned, bandaged, and reprogrammed.

Procedure Continued

- ◎ US-Guided Group: Risk/Benefits, Informed Consent, Timeout
 - Physician preps injection site, medications ready for refill, US covered, sterile, ready to access pump.
 - Physician gloves, uses ultrasound to access site, removes current pump medications, refills pump, needle removed, patient is cleaned, bandaged, and reprogrammed.

Outcome Measured

- Time:
 - Setup time: After timeout to beginning to access pump.
 - Access time: when template/US touches pump site to access and current pump medication is removed and first seen in the catheter.
- Needle sticks and needle maneuvers per refill
- Number of traumatic taps
- Pain: post-procedure: immediate, at follow-up visit for next refill.
- Complications (infection, pump site bruising, pocket fills): immediate, at follow-up visit for next refill.
- Patient satisfaction: immediate post-procedure.

Expected Outcomes

- Ultrasound will decrease pump access time
- Ultrasound will decrease needle maneuvers/number of sticks
- Pain will be improved by use of ultrasound post-procedure
- Less overall complications with ultrasound.
- Improved Patient satisfaction with the use of ultrasound.

COMMENTS????

● Thank you

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