INTRATHECAL OPIOID TRIALING PROTOCOL COMBINING PCA BOLUS AND CONTINUOUS INFUSION WITH AN EFFICACY/SAFETY SELF -EVALUATION CHART

PAIN-PRE. Protocolo de Analgesia INtratecal PRE-Implante
(Intrathecal Analgesia Pre-Implant Protocol)

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INTRODUCTION

Prior to Intrathecal opioid pump implantation a trial is recommended. Controversy exists regarding the long term predictive response[1,5,7] . Even the controversy, trialing is performed before implantation[1-6].
Currently, no consensus exists about the most appropriate techniques for trialing[1, 2,3,8,9]. Single epidural or subarachnoid injections or the placement of percutaneous catheters for "long-term"(days to weeks) trials (both either IT or epidural), have all been used.

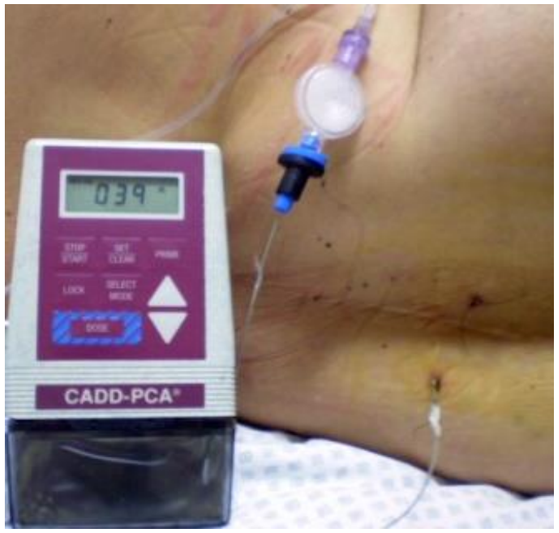
In our practice, due to the cost of an implantable pump, it's mandatory to perform a trial to get payer's authorization of the implantable pump. Main objectives of the trial are[2,3,5]:

- Patient objective response to IT opioids
- Safety of IT opioids and tolerability
- To address the optimal "starting dose" for the implantable pump programming
- To test under "almost real life"conditions the IT opioid efficacy
- To document patient satisfaction with IT opioids.
- To get patient consent for implantable pump procedure.

We describe a trialing technique using an external PCA pump that allows PCA bolus and continuous infusion during a 3 – 4 day inpatient trial with a pain, adverse reaction, patient satisfaction and pump implant acceptance evaluation chart.

OBJECTIVE

To describe an IT opioid trialing protocol using PCA IT bolus and a continuous infusion. A patient self-evaluation chart is used to evaluate analgesia, side effects and patient satisfaction with the procedure.



Tunnelled catheter and PCA pump (bandages were taken off for visual purposes).

MATERIALS AND METHODS

After patient evaluation, opioid analgesics dose is gradually tappered up to a 30% of the regular daily dose received.

DAY 1

Patient is admitted to the hospital. A self evaluation chart is explained to the patient to be completed before each PCA bolus. Pre implant pain and adverse reactions scores are documented using Numeric Rating Scales .

An intrathecal tunnelled catheter is placed under aseptic technique at the L4/5 or L3/4 level and passed under fluoroscopic guidance to the T11 vertebral level. According to patient prior opioid dose requirement, a 0,15 - 0,30 mg of preservative free morphine bolus is administered and documented in the chart. A portable PCA external pump (CADD®-PCA 5800, Smiths Medical ASD, Inc) with 50 - 100 ml of preservative free morphine 0,05 – 0,1 mg/ml is connected to the tunnelled catheter using a 0.22-micron filter.

4 – 6 hr after first IT bolus patient is evaluated by a trained physician. According to pain relief and tolerability external pump is programmed to administer PCA boluses of 0,15 – 0,3 mg with a 12 hr. lockout period.

DAY 2

Total 24 hr morphine requirement is calculated and written in the chart. Numeric rating scales for pain and adverse reactions are checked. If pain relief was acceptable but adverse reactions were important, PCA bolus are adjusted downward and PCA bolus modality is kept for the next 24 hr.
If no adverse reactions were present, pump is programmed to deliver the closest allowed daily dose in a continuous infusion. PCA rescue boluses are calculated as 10% – 15% of the daily morphine requirement and programmed with an 8 hr. lockout period.

DAY 3

Total 24 hr requirement is calculated and written in the chart. Numeric rating scales for pain and adverse reactions are checked. If pain relief was acceptable with no adverse reactions pump is programmed to deliver the closest daily dose (daily continuous infusion dose + rescue dose requirements) by continuous infusion. Morphine rescue doses are maintained according to the 10% of the required daily dose with a lockout 8hr. period.

DAY 4

Total 24 hr requirement is calculated and written in the chart. Numeric rating scales for pain and adverse reactions are checked. If pain relief was acceptable with no adverse reactions and NO rescue doses were needed. Patient rates trial satisfaction as: Very Satisfied, Moderately Satisfied, Poorly Satisfied, Unsatisfied or Not able to evaluate. Catheter is removed and patient discharged.
If morphine rescue doses were required continuous infusion is increased according to 24 hr. total requirement. Patient is discharged next day after trial satisfaction is rated.

Patients are discharged with their prior opioid full dose and a visit is scheduled 7-10 days later to allow time for the trial evaluation. This allows patients unable to rate trial satisfaction to have more time to evaluate trial results.

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INTRATHECAL OPIOID TRIALING PROTOCOL

Date and Time	Pre - Trial	/ / hr.	/ / hr.	/ / hr.	/ / hr.	/ / hr.	/ / hr.	/ / hr.	/ / hr.
		Name:							
DOSE		mg	mg	mg	mg	mg	mg	mg	mg
PCA Bolus		mg	mg	mg	mg	mg	mg	mg	mg
Cont. Inf + Bolus		/ mg	/ mg	/ mg	/ mg	/ mg	/ mg	/ mg	/ mg
Cont. Inf		mg	mg	mg	mg	mg	mg	mg	mg
PAIN RATING (NRS)	/10	/10	/10	/10	/10	/10	/10	/10	/10
ITCHING (NRS)	/10	/10	/10	/10	/10	/10	/10	/10	/10
NAUSEA (NRS)	/10	/10	/10	/10	/10	/10	/10	/10	/10
VOMITING (NRS)	/10	/10	/10	/10	/10	/10	/10	/10	/10
SHORTNESS OF BREATH (NRS)	/10	/10	/10	/10	/10	/10	/10	/10	/10
HEADACHE (NRS)	/10	/10	/10	/10	/10	/10	/10	/10	/10
URINARY RETENTION (NRS)	/10	/10	/10	/10	/10	/10	/10	/10	/10
PATIENT SATISFACTION	Very Satisfied ☐	Moderately Satisfied ☐	Poorly Satisfied ☐	Unsatisfied ☐	Not able to evaluate ☐				

Please fill teh boxes qualifying each symptom according to the score: 0 = NO symptom (i.e.: NO PAIN), 10 = worst symptom (i.e.: worst pain I can imagine)

Patient's Signature: Doctor's Signature:

Print Name: Stamp:

Chart to document pain & AE ratings pre-trial, during trial and patient satisfaction.
Pump parameters and daily morphine requirements are documented.

RESULTS

With this protocol we can optimize IT opioid trials minimizing side effects by the use of PCA boluses during the first 24 hours. Continuous infusion + PCA bolus allows dose titration to check tolerability and analgesia. Finally we can mimic "real life conditions" with continuous infusion. There is no catheter manipulation after the PCA pump is connected with a lower risk of infection. Self-evaluation chart is a way to increase safety and get patient involvement in the trial. Results can be more objective and implant agreement can be addressed at the end of the trial.

CONCLUSION

Prior to implantation of an internal IT pump, a successful trial needs to be performed with at least 50% pain reduction without side effects. Consensus recommends that each practitioner should develop a trialing protocol for his or her practice that is based on safety, adherence to safe algorithmic principles, and proper patient monitoring. Described trial methodologies are IT single bolus, IT multiple bolus or IT continuous infusion. No combined methods using PCA boluses and continuous infusion were found in the literature.
This 3-4 day trialing technique can provide an opportunity to assess IT opioid response with a safer and reliable methodology. Patient self-involvement and final agreement allows a more objective evaluation and helps decision making for internal pump. Implantagreement can be addressed at the end of the trial.

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