

An Innovative Approach to Symptom Management when the Oral and Sublingual Routes Fail

*Use of a New Rectal Administration Catheter
(Macy Catheter, Hospi Corporation)*

Contents

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Symptom Management Challenges at Home

How are we doing?

- **Kehl et al. (2013)** – Large lit review -dyspnea (56.7%), pain (52.4%), respiratory secretions/death rattle (51.4%), and confusion (50.1%) [1]
 - Doing better than this but we still have room for improvement
- **SUPPORT Study (1998)** - >80% patients reported the desire to die at home – only 50% died in the home[2]

Managing Symptoms at The End of Life

80% EFFECTIVE SYMPTOM CONTROL USING ORAL & SUBLINGUAL

20% ORAL & SUBLINGUAL NO LONGER EFFECTIVE

- Terminal Agitation
- Seizures
- Severe pain
- Respiratory distress

Symptom Management

Symptoms well controlled ~80% → Oral and SL → \$ Symptoms Controlled

Oral/SL route no longer effective ~20% → -SQ/IV
-Suppositories
-Transdermal
-Continue SL → \$\$\$ Delay in Sx. Control (hours to days)

↳ Macy Catheter → \$\$ Immediate Symptom Control

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The Macy Catheter Concept

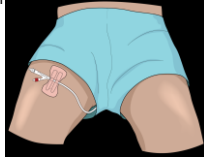
- Easily placed by the nurse when oral and sublingual fail
- Use meds already at bedside
- No delay for delivery of alternatives
- Discreet, comfortable, easy to use
- Stays in place for ongoing delivery
- No turning / bothering patient for medications
- EOL meds quickly / effectively absorbed

Macy Catheter General Information

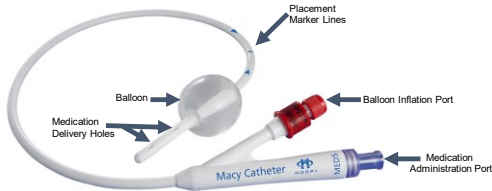
FDA Indication: Macy Catheter provides rectal access to administer liquids and medications.

Guidelines

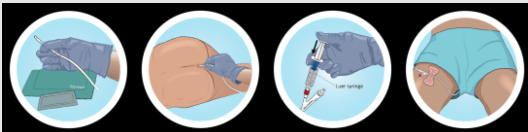
- MD/NP order for use
- Can remain in place up to 28 days
- Non-sterile placement
- Latex free



The Macy Catheter Up Close



Catheter Placement



Step 1: Lubricate Step 2: Insert Step 3: Inflate Step 4: Secure

Most Common Macy Catheter Uses

- Terminal agitation
- Severe Pain (high dose opioids)
- Nausea and Vomiting
- Seizures
- Shortness of Breath
- Fever



The Macy Catheter in the Home Setting

- Enables continuation of medication at the bedside when oral/SL fails
- Facilitates same-visit symptom relief
- Eliminates the delay in symptom control efforts
- Empowers caregivers to easily and safely medicate patient
- Eliminates the costs associated with other alternatives and delivery



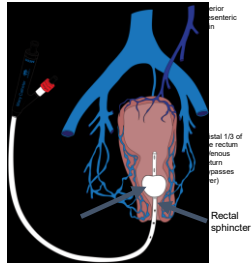
The Macy Catheter in the Inpatient Setting

- More cost-effective than parenteral options
- Hospices reporting equivalent or more rapid symptom relief vs SubQ in most instances
- More comfortable and safer symptom management
- Easier set up, maintenance and drug disposal
- A more home-like atmosphere
- An easy way to discharge patients back into the home



Why does it work so well?

- Mucosa is highly vascularized
- High % absorptive cells
- Liquid medications absorbed more quickly than suppositories
- Rapidly enters the circulation



Versatile Route of Delivery

Medication Absorption*	Rectal	SQ	IV	SL	Transdermal	Intranasal
Opiates - (Morphine, fentanyl, Hydromorphone, methadone, more)	X	X	X	X	Fentanyl	Fentanyl
NSAIDs - (Ibuprofen, Indomethacin, ASA, ketoprofen)	X			Toradol	Lidoc	
Benzodiazepines (Lorazepam, Diazepam, Midazolam, Clonazepam)	X	X	X		Alpram	Midazolam
Antinauseants - (Metoclopramide, Prochlorperazine, Ondansetron, promethazine)	X	X	X			
Anti Seizure - (Valproic Acid, Carbamazepine)	X		X			
Sedatives - (Phenobarbital, Pentobarbital)	X	X	X			
Anti-depressants - (Tricyclics, Doxepin, Imipramine, Clomipramine)	X					
Neuroleptics - (Haldol, Thorazine)	X	X	X			
Anti-cholinergics - (Atropine, Dimethylrate, Glycopyrrone)	X		X	X		
Steroids - (Bekasmethasone)	X	X	X			
Antibiotics - (Amoxicillin, Erythromycin, Metronidazole, Fluoroquinolones)	X		X			
Acetaminophen	X			W/Alc		
Furosemide	X					

*Pharmacokinetic studies have been done on the above drugs. Absorption has been found to be effective in the routes marked in green. For specific absorption via rectal route, see Davis et al. (2002)

American Journal of Pain and Symptom Management (2016): "Pharmacokinetics of Phenobarbital in Microenema via Macy Catheter vs. Suppository"

Results

- Phenobarb blood levels 12x higher for MC-20 and 8x higher for MC-6 compared to suppository.
- Concentrations achieved in 30 minutes via MC-20 took 4 hours to achieve by supp.
- Variability between subjects much less with ME vs Supp
- Two suppositories failed to produce ANY blood level of Phenobarb

Conclusion

- Results suggest that phenobarbital oral tablets crushed and suspended in water and administered via the Macy Catheter is superior to suppository in delivering medication reliably and rapidly.

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Journal of Hospice and Palliative Nursing (2016): Case Study: A New Intervention for Rapid End-of-Life Symptom Control in the Home Setting
Reviews benefits and burdens of the usual alternative routes

- Presents overview of SL, Parenteral Route, Transdermal, Rectal Route, Suppositories and Macy Catheter
- Presents Case Study with Macy Catheter Intervention

PATIENT

- 62 y/o male end stage prostate cancer metastatic to liver/bone with goal to die at home
- Oral medications not working to control nausea/vomiting, increased pain
- Oral route eventually compromised

INTERVENTION

- Macy Catheter initiated and same oral medication regimen was given via the Macy.

OUTCOME

- 20 min following med administration via the MC the RN noted relief of agitation and pain

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NHPCO 2016 Poster Presentation
 Utilizing the Macy Catheter to Facilitate Rapid Symptom Control in the Home Setting: A Case Series
 Pia Christensen RN, Hope Hospice Dublin CA

- **Case Series (Three Patients)**

- A 68 y/o male with Glioblastoma Multiform Stage IV
- A 56 y/o female with End Stage Liver disease,
- A 62 y/o male with Lung Cancer mets to liver and bones

Patient	SYMPTOMS PRESENT	SEVERITY PRIOR TO INTERVENTION	SEVERITY AFTER INTERVENTION	TIME TO ACHIEVE COMFORT
1	RESTLESSNESS CONGESTION	SEVERE SEVERE	SLEEPING MODERATE	10 MINUTES
2	AGITATION PAIN	SEVERE 10	CALM 3	15 MINUTES
3	PAIN	10	2	10 MINUTES

Davis (et al.) Literature Review on Rectal Absorption

Support Cancer Center (2002): "Symptom control in cancer patients: the clinical pharmacology and therapeutic role of suppositories and rectal suspensions"

Pharmacology Review of rectally administered palliative medications

Results:

- **Most classes of drugs used at the end of life have at least one and usually several drugs within that class that have evidence for absorption rectally in either ME or suppository form.**

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Morphine - Oral vs. Rectal Micro-enema

• **DeConno et al. ("Journ. of Clin. Onc." 1995)**

- 34 patients - Met. CA.
- Randomized, double blind, double dummy crossover study

Results

- Significant pain relief in 10 min (p=.03) via rectal ME vs 60 min oral
- Pain intensity continued significantly lower only by rectal route at 180 min

(1) Hosp Corp MAC-14-001798

Methadone Oral vs Rectal Micro-enema

Dale et al. (Brit. J Clinical Pharmacology (2004))

Compared Oral vs Rectal ME absorption Kinetics and Pain efficacy

Results

- Bioavailability 88% to oral
- T-max 1.4 hr rectal vs. 2.8 oral
- Took 60 minutes (oral) achieve same blood concentration reached in 10 minutes (rectal)

(1) Hosp Corp MAC-14-001798

Diazepam Rectal ME vs IM, oral, suppository

Moolinaar et al. (Int. Journal of Pharmaceutics (1980))

Compared t-max, variability, and bioavailability for (IV, IM, Oral, Rectal Supp. and Rectal ME)

Results

- T-max 17 min (rectal ME) vs. 52 min (oral) vs. 95 min (IM) vs. 82 min (supp.)
- Rectal ME Bioavailability vs IV 100%
- Intra-subject variability lowest via rectal ME
- Intra-subject variability was highest for oral dosing

(1) Hosp Corp MAC-14-001798

Ohio's Hospice of Dayton Story



- Agency had opioid shortage crisis at end of 2017
 - PBM gave them 4 days before out of morphine, methadone and hydromorphone
- Switched in mid-November
 - Have used in > 1000 patients since
- Using Macy instead of SQ in almost all patients
 - Except patients that have contraindications for rectal delivery
- Finding Macy Catheter faster, easier and more cost efficient



"Based on my experience on our hospice inpatient unit, the Macy Catheter is faster than subcutaneous in controlling pain with opioids and I am able to control pain with less opioid dose adjustments. It is also very effective in most instances in quickly controlling terminal agitation and other symptoms. It saves nursing time and decreases medication cost and waste. I will never go back to my prior practice and will continue using the Macy Catheter."

Dr. Wendy Schmitz, M.D. Vice President of Medical Services,
Ohio's Hospice of Dayton

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Hospice Buffalo

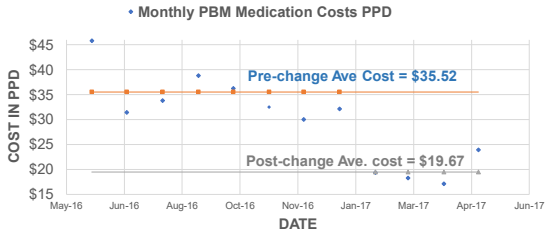


- White paper done by CMO, Director of Pharm, Nursing Leadership
 - Looked at the Challenges facing hospice
 - Clinical, quality and cost benefits their agency has experienced using the Macy Catheter.
- (Paper available at www.macycatheter.com)

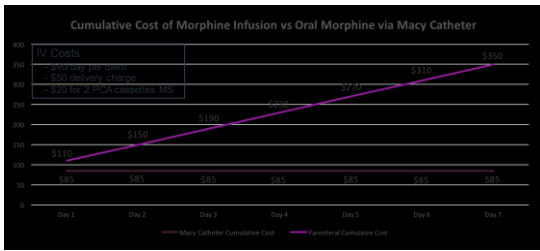
Cost Savings Experienced

- Total 2017 Savings \$92,000
- Total Patients in IPU = 640
- MC Patients = 230 (36%)
- \$401 savings per MC placed

Hospice Buffalo - Decreased PBM Costs in the IPU

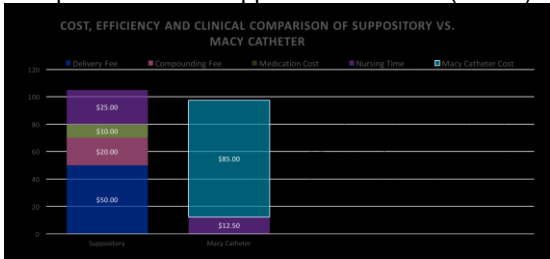


Hospice Buffalo - Infusion vs. MC (Home Care)



(© Hosp Corp MAC-14-0017B)

Hospice Buffalo – Suppositories vs. MC (Home)



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Case Stories



Heart and Home Hospice



PATIENT

- 70 y/o female with a primary diagnosis of COPD and comorbidities of CHF, CAD, and DM
- As patient transitioned, she started having seizures, quickly escalating to status epilepticus and left her unresponsive.

INTERVENTION

- Discussed Macy Catheter with family who were open to try it
- Placed easily
- 10mg valium given

OUTCOME

- Status epilepticus was controlled in 10 minutes
- Family was very relieved to see patient resting so quickly after 8 hours of seizure activity
- Family able to easily and comfortably administer medication
- Patient passed comfortably and seizure-free

Hospice of Fairbanks Memorial Hospital, AK

PATIENT

- Male with metastatic lung cancer, mid-50s experiencing symptoms of pain and agitation escalating over several days
- Haloperidol doses titrated upward, but symptoms continued to get worse
- Became severely agitated, climbing out of bed, and now refusing to take medications

INTERVENTION

- Wife initially reluctant to try rectal medication at first
- Nurse explained he would not feel it and said if it did not work he would take it out
- She agreed and same dose of haloperidol and morphine were given that were being given PO

OUTCOME

- Within 20 minutes patient was calm and relaxed with no overt sign of pain or distress
- Wife stated, "Why didn't we do this sooner?"
- Wife was able to continue giving medications through the catheter easily until he died peacefully and comfortably at home

Hope Hospice, Dublin CA



PATIENT

- A middle-aged male, brain tumor, unresponsive with terminal restlessness and severe pulmonary congestion.
- Patient was an MD and several family members were in medical profession
- Patient's doctor had told family that due to the location of the tumor in the brainstem, nothing but IV morphine and Ativan would work to control symptoms
- Family insisting on IV set up

INTERVENTION

- Nurse explained IV would take hours to arrive and recommended trying Macy Catheter while waiting
- Family agreed and MC was placed. MS 20mg and Ativan 1mg were given

OUTCOME

- The patient's symptoms were managed within 10 minutes.
- The family was absolutely amazed, very much relieved and grateful.
- The hospice never needed to start an IV and the patient died comfortably within 24 hours

Rainbow Hospice

PATIENT

INTERVENTION

OUTCOME

Rainbow Hospice

PATIENT

INTERVENTION

OUTCOME