Blenderized Tube Feeding ENFit® Connector Testing

1/17/2016

Product Testing

- Goal – Establish impact of ENFit™ Connector on feeding tube performance and characterize current user practices with regard to blenderized tube feeding BTF
- Mayo Clinic (Rochester, MN)
  - Ryan Hurt, MD; Manpreet Mundi, MD; Lisa Epp, RD
- FDA (Silver Springs, MD)
  - Suvajyoti Guha; Josh Silverstein
- GEDSA and Oley supporting by supplying products and review of testing protocols only

Third Party Product Testing

- Testing Protocol
  - FDA and Mayo program based on previous Mayo and industry work
  - Tubes and Syringes blinded in all testing and reporting
- Products being tested
  - Feeding tubes – Legacy and ENFit
    - 14, 18, 20, and 24 FR Balloon G Tubes
    - Bolus extension sets for low profile
    - Head to head legacy vs. ENFit®
  - Syringes – Legacy and ENFit
  - Commercial Formulas
    - Standard 1, 1.5, 2.0 calorie from Nestle and Abbott
    - Peptamen 1.0, Boost VHC and Orange Juice
    - Nourish from Functional Formularies; Salmon from Real Food Blends
  - BTF recipes from Mayo and Oley members

Third Party Product Testing

- Measure viscosity and particulate size for each formula and BTF recipe

- Flow testing using gravity
  - Flow rates (in time) using standard set up and relying on gravity
  - 3x for each tube and formula
  - New tube for each test

- Pressure testing using syringe
  - Measure pressure to deliver formula using a rate of 60 mL per minute
  - 3x for each tube and formula
  - Limit syringe to 5 uses
  - Using a range of blenders and blending at 3 minutes and 6 minutes

Flow Testing Results – Commercial Formula

- 14 FR
  - One ENFit® tube had slower than corresponding legacy tube
    - Unrelated to ENFit connector, but related to changes in overall tube design smaller diameter inner lumen and longer tube
  - All other products showed no difference between legacy and ENFit
- 18 and 20 FR no difference between legacy and ENFIt products in flow rates
- 24 FR – slower flow rates for the ENFit design when compared to legacy
  - Typical rates – Legacy 275 mL to 300 mL/hr vs. ENFit® 150 mL to 165 mL

Pressure Testing Results – BTF

- Blending does matter
  - Particulate size and viscosity are importatn
  - “Higher” end blends do a better job of blending
  - Technique is critical
    - Minimum of 3 minutes
    - Sufficient water to allow ingredients to turn over and be chopped
- Results vary based on recipe, tube design and syringe
  - Impact of the connector change is hard to isolate
- Observed trends
  - 14 to 20 FR similar to gravity flow – no major difference
  - 24 FR may be less impacted by ENFit® connector

Next Steps

- FDA to compete syringe testing
- Data must be analyzed using best practice statistical methods
- Target for review by researchers is March

Home User Questionnaire - Background

- Create a validated, objective data base of home tube feeding practices from a broad patient that can be used for publication, input into standards and decision making
- Build on Mayo/Oley survey to identify home tube feeding practices
  - Demographics
  - Commercial vs. BTF use
  - Reimbursement
  - BTF practices such as – equipment used, foods used, motivation for BTF, challenges with current equipment
- Includes key stakeholders – Patients, Manufacturers, Clinicians and Suppliers

GEDSA	Mayo	ASPEN	Oley
Coram	PHS	OptionCare	FTAF

Home User Questionnaire - Status

- Survey live September 1 to October 15
  - Online link through Feeding Tube Awareness Foundation, Oley, Coram, Pediatric Home Services and ASPEN
  - Phone option through Oley

- Results:
  - 1703 respondents
  - 66.7% pediatric (under 18)/33.3% adult
  - BTF use not as prevalent as first Mayo/Oley survey – less than one quarter of respondents
  - BTF more common in pediatrics

- Journal Submission planned during Q2 2017