Validation of a Point of Service, Disposable Rectal Expulsion Device (RED) to Identify Constipated Individuals with an Evacuation Disorder

William D. Chey MD[1,2], Eric Shah MD[3], Jason R. Baker PhD[1,2,4], Lydia Watts BS[1,2], Moira Armstrong BS[1,2], Gabrielle Ezell MS[1,2], Adrienne Harris MSE[5]

1. Division of Gastroenterology, Department of Internal Medicine, University of Michigan, Ann Arbor, MI
2. Michigan Bowel Control Program, University of Michigan, Ann Arbor, MI
3. Gastroenterology & Hepatology, Dartmouth-Hitchcock, Lebanon, NH
4. Atrium Health, University of North Carolina – Charlotte, Charlotte, NC,
5. In2being, Saline, MI

BACKGROUND

- More than a third of chronically constipated patients who fail to improve with laxatives have an evacuation disorder.
- Balloon Expulsion Testing (BET) effectively identifies patients with an evacuation disorder.
- Currently available BET devices are not designed for point of service use and require a separate visit to a GI physiology laboratory.
- To bring testing for an evacuation disorder to any community gastroenterologist, we created a disposable, self-inflating Rectal Expulsion Device (RED) which is intended for in-office use.

OBJECTIVES

- Determine test agreement between RED vs. the gold standard BET device.
- Assess subject's perceptions of RED and the BET device..

METHODS

- Six healthy volunteers (HVs) & 14 CC patients underwent BET & RED from 9/19 – 11/19.
  - HVs had no GI symptoms or health issues.
  - CC patients had ongoing chronic constipation symptoms despite laxative therapy.
- Each subject underwent traditional BET (Mui Scientific, Mississauga, Ontario) and RED.
  - After rectal insertion, BET was inflated with 50 cc of normal saline.
  - After opening a stopcock, RED *self inflates* to a preset volume identical to BET.
- The order or performing BET or RED was randomized.
  - An abnormal BET or RED was defined as the inability to pass the device in <60 seconds.
  - Each subject was provided 120 seconds to expel the devices.
  - If a subject was unable to pass BET or RED at 120 seconds, it was removed using gentle traction by the investigator.
- Following BET & RED, each subject self-reported characteristics for each device including smoothness (SM), shape (SH), size (SZ), overall comfort (OC), and procedure duration (PD) (1 = Unbearable and 10 = Highly Acceptable).
- Kappa (*k*) and independent t-tests were performed.
  - P-values <0.05 were considered statistically significant.

Disclosures: WDC, ES, JRB, AH – jointly hold the patent for RED

DEMOGRAPHICS

Demographic Variable	Healthy Controls (HC) (n = 6)	Chronic Constipation (CC) Subjects (n = 14)	P-Value
Age: Mean (SD; Range)	47.5 (SD = 13.7; Range: 28 - 69)	50.0 (SD = 13.5; Range: 22 - 76)	0.70
Body Mass Index: (SD/Range)	28.6 (SD = 7.0; Range: 18.2 - 38.2)	28.0 (SD = 5.3 Range: 21.3 - 39.7)	0.83
Sex			0.37
Male	16.7%	5.3%	
Female	83.3%	94.7%	
Race (Caucasian %)	83.3%	84.2%	0.53

RECTAL EXPULSION DEVICE (RED)

Fully Open Rectal Expulsion Device (RED)

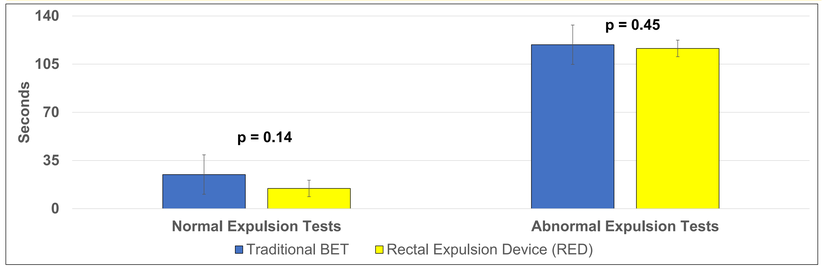
Compressed Rectal Expulsion Device (RED)

AGREEMENT BETWEEN TRADITIONAL BALLOON EXPULION DEVICE (T-BET) AND THE RECTAL EXPUSLION DEVICE (RED)

Test Result	BET	RED
Normal (< 60 seconds)	45.0% (n = 9)	45.0% (n = 9)
Abnormal (≥ 60 seconds)	55.0% (n = 11)	55.0% (n = 11)

Device Agreement = 100%, Sensitivity=100%, Specificity=100%, Accuracy=100%; All HVs had a normal BET and RED

MEAN EXPULSION TIME FOR NORMAL AND ABNORMAL TESTS: TRADITIONAL BALLOON EXPULSION DEVICE (T-BET) VS. RECTAL EXPULSION DEVICE (RED)



SUBJECT-REPORTED CATHETER CHARACTERISTICS: TRADITIONAL BALLOON EXPULSION DEVICE (T-BET) VS. RECTAL EXPULSION DEVICE (RED)

Metric	BET	RED	P-Value
Smoothness (SN)	8.40 (SD = 1.81)	8.20 (SD = 1.80)	0.73
Shape (SH)	8.20 (SD = 2.17)	8.35 (SD = 1.81)	0.81
Size (SZ)	8.00 (SD = 2.22)	8.05 (SD = 2.32)	0.95
Overall Comfort (OC)	8.15 (SD = 2.03)	8.20 (SD = 1.88)	0.94
Procedural Duration (PD)	8.20 (SD = 2.40)	8.40 (SD = 1.96)	0.77

SUMMARY

- Device agreement between BET & RED was 100%.
  - All Healthy Volunteers had normal BET & RED.
  - For the entire study cohort, 9/20 (55.0%) subjects had an abnormal BET and RED.
  - The mean time to device passage in those with an abnormal test was 119.1 (SD=3.1) seconds for BET and 116.4 (SD=12.1) seconds for RED (p=0.45).
  - For those with a normal test (45.0%), the mean time to expel BET or RED were similar: BET (24.8 seconds; SD=14.3) and RED (14.7 seconds; SD = 6.0), p = 0.14.
- There were no statistically significant differences in patient-perceptions of BET or RED
  - SN (p = 0.73), SH (p = 0.81), SZ (p = 0.95), OC (p = 0.94), and PD (0.77).

CONCLUSION

- A novel, disposable, self-inflating RED yielded nearly identical results to a commercially available BET device.
- RED allows community gastroenterologists to identify constipated patients with an evacuation disorder at the point of service.
- The information yielded by RED will allow providers to identify constipated patients most likely to respond to biofeedback training rather than further laxative therapy.