Randomized controlled trial of Traxi panniculus retractor use for improving surgical time and patient and provider reported outcomes

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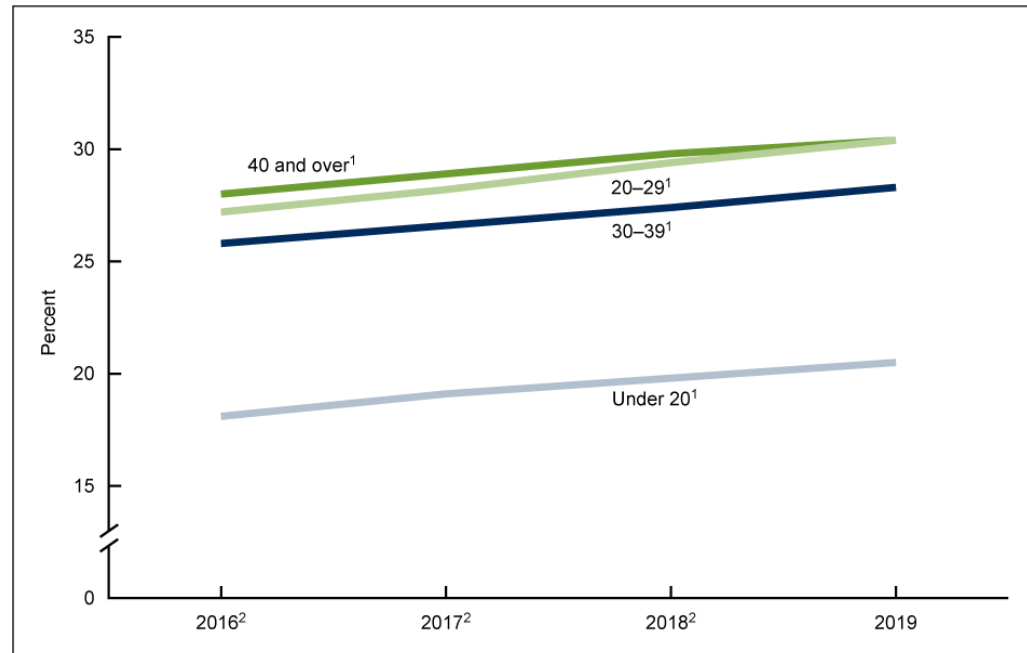Beth Israel Lahey Health

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Prevalence of Obesity in Pregnancy

- 29% of pregnant individuals have pre-pregnancy obesity (BMI ≥ 30 kg/m^2)[1]
  - Rate increased steadily among women of all ages 2016-2019

Figure 2. Prepregnancy obesity, by maternal age: United States, 2016–2019

[1]Significant increasing trend from 2016 through 2019 ($p < 0.05$).
[2]Significant difference between all age groups ($p < 0.05$).
NOTES: Obesity is a body mass index of 30.0 or higher. Total includes all race and Hispanic-origin groups. Access data table for Figure 2 at:
https://www.cdc.gov/nchs/data/databriefs/db392-tables-508.pdf#2.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Natality file.

Risk of Obesity in Pregnancy and Delivery

- Maternal obesity is a risk factor for development of adverse pregnancy outcomes

- Increasing BMI correlated linearly with cesarean delivery rates (Chu et al., 2007)

- Odds ratio of Cesarean Delivery:
  - Overweight (1.46)
  - Obese (2.05)
  - Severely Obese (2.89)

- Surgical time is increased in association with BMI (43 normal BMI to 55 min BMI >40)

- Risk of PPH and increased rate of wound complications

Girsen et al. 2014. Obset & Gynecol)

Retraction Methods

- Some patients with class 3 or greater obesity (BMI ≥ 40 kg/m^2) have overhanging abdominal panniculus that can obstruct the surgical field

  o Methods of retraction include taping, extra personnel

  o Other studies looked at use of panniculus retractor on neonatal outcomes and surgical time (Stewart 2023) See next slide for examples

- Studies have looked at the efficacy of retraction devices

Need for more evidence for improving surgical outcomes for cesarean in patients with obesity

Background– Traxi Panniculus Retractor

Limited published data but available for clinical use

Retracted clinical trial (terminated due to low enrollment–only 4)

- https://clinicaltrials.gov/ct2/show/NCT02865083?term=pannus+retraction&rank=1

Product review from our neighbors at BWH (not primary literature)

- http://contemporaryobgyn.modernmedicine.com/contemporary-obgyn/news/product-reviews-c-sats-and-traxi?page=full

A single case report ePoster

- http://www.epostersonline.com/rcog2016/node/6734?view=true

General retraction during cesarean and neonatal outcome (not specific to Traxi)

- https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0036-1581054

Add the noenatl outcome 2023 abstract from AJOG Rimza et al.

traxi® intraoperative panniculus retractor

Commercially available Class 1 FDA-exempt device designed to provide reliable retraction of panniculus during surgical procedures

▲ Without traxi

▲ With traxi

▲ Less involved than tape or straps

Objective

1. Evaluate use of traxi in patients with obesity undergoing non-emergent cesarean birth in improving surgical time

2. Evaluate whether use of traxi improves patient and provider-reported experiences
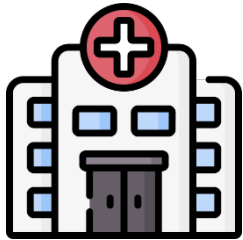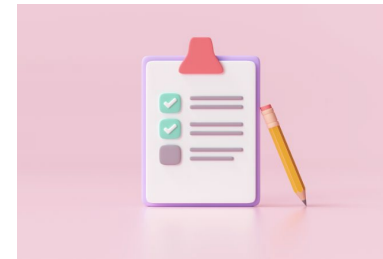
Methods

Enrollment

Randomization

Surveys and Medical Record Review

Two Boston hospitals (BIDMC & BWH)

Traxi vs. standard care

Methods – Enrollment

Eligibility Criteria:

- o Pregnant (single live gestation)

- o Body mass index (BMI) $\geq$ 40 kg/m^2 with retractable panniculus

- o Undergoing non-emergent cesarean delivery

- o At least 18 years of age and willing to provide informed, written consent

Exclusion criteria:

- o Known adhesive allergy

- o Disruption of abdominal skin (rash, abrasion, laceration)

Methods – Randomization

Standard of Care (control)

Traxi Device

- Computer-generated block 1:1 randomization

- Randomization was stratified by whether or not the patient had a history of cesarean delivery/open abdominal surgery

- Target enrollment= 240 to detect a difference of 10 minutes in operative time

Primary outcome

- **Primary: <mark>Surgical time from skin incision to closure</mark>**

- **Secondary: Patient and provider surveys**

  o Provider survey was distributed to personnel involved in the delivery via REDCap

  o Assessed participant satisfaction via survey made available on paper or via REDCap after delivery

- **Other outcomes: Medical record review**

  o Wound complications, surgical blood loss

  o Neonatal outcomes

  o Scrubbed personnel and level of training

  o Pulmonary function tests

Statistical Methods

- Intention to treat analysis

- Comparisons made using Wilcoxon rank-sum test for continuous variables (surgical time)

- Chi-squared test for dichotomous variables (survey response)
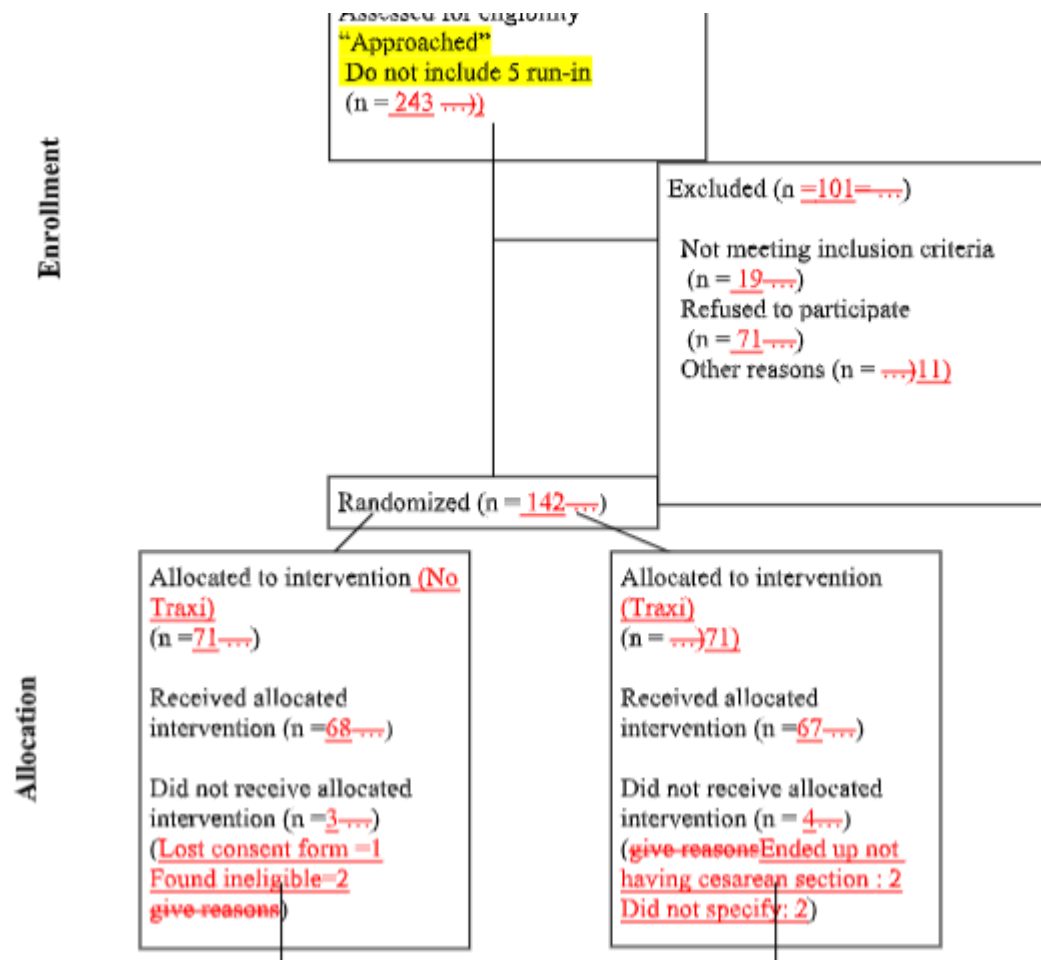
CONSORT diagram

Table 1. Baseline Demographics

Variables	TRAXI (n=67)	No TRAXI (n=68)
Maternal age	34 (31, 37)	35 (31,38)
BMI at enrollment	48 (45-52)	50 (45-53)
Gestational Age (weeks)	39 (37-39)	39 (38-39)
Race/Ethnicity		
Asian	0 (0%)	1 (1.5%)
Black or African-American	15 (22%)	14 (21%)
Hispanic	14 (21%)	9 (13%)
White	33 (49%)	34 (50%)
Other/multiple/unknown	19 (28%)	19 (28%)

Data reported as median (interquartile range) or number (percent)

Table 1.

Variables	TRAXI (n=67)	No TRAXI (n=68)	P-Value
History of prior abdominal surgery or c-section			
Yes	69%	68%	
Number of prior c-sections			
0	32%	37%	
1	44%	46%	
2	17%	11%	
3+	8%	6%	
Missing	1.5%	4%	

Primary Outcome

Variables	TRAXI (n=68)	No TRAXI (n=67)	P-Value
Duration of cesarean delivery (mins)	65 (55, 81)	70 (57, 86)	0.31

Data reported as median (interquartile range) or number (percent)

Secondary outcomes: Provider assessment

Variables	TRAXI (n=67)	No TRAXI (n=68)	P-value
Total number of respondents	219	169	
Number of respondents/patient	3	3	
How effective was this method for panniculus retraction?			<0.001
Very	74%	38%	
Somewhat/Undecided/Not really/Not at all	26%	62%	

Secondary outcomes: Patient Response

Variables	TRAXI (n=67)	No TRAXI (n=68)	P-value
I felt physically uncomfortable	N=40	N=23	0.04
Not at all/A little bit	93%	74%	
Very/somewhat	8%	26%	
I would choose this method of taping if I needed another cesarean delivery			0.06
Definitely would	70%	46%	
Probably would/Definitely would not/Probably would not	30%	55%	

Conclusions

- traxi panniculus retraction reduced surgical time by median of 5 minutes compared to the control arm but not statistically significant

- traxi was associated with improved provider and patient-reported satisfaction

  o Efficacy, comfort, likelihood to choose again

Limitations

- small sample size (study cut short due to clinical equipoise)

- Varied number of respondents to provider/patient surveys

Future Steps

Other outcomes:

- Measured pulmonary function tests
- Maternal and neonatal outcomes

Acknowledgement

- **Participants and their families**

- BIDMC OBGYN: Ai-ris Collier, Anna Modest, Michele Hacker, Tyler Lueck

- Brigham OBGYN department: Tooba Anwer

- Labor and Delivery providers, medical staff in OB clinic

- OB RAs: Ricardo Aguayo, Melissa Dzinoreva, Tina Yi Jin Hsieh, Audrey Mutoni

2018 (study start)

2024 (study end)

Thank you for your attention :)

Any Questions?

References

Appendix: Application of traxi

1. Manual Retraction

Manually retract panniculus to expose surgical site.

2. Remove 'A' Tab

Remove Tab 'A'.

3. Position & Apply

Position retractor 5cm above incision line. Align to midline, apply to patient.

4. Remove 'B' Panels

NOTE: Backing removes by pulling down & away.

Remove the 'B' panels while holding film in tension above patient.

5. Tension & Apply

Hold in tension while smoothing down onto patient's skin, midline outward.

6. Remove 'C' Panel

Retrograde device to relax panniculus to natural position. Remove 'C' panel by simultaneously pulling 'C' tabs.

7. Tension, Lift, Pull

Together, in tension, lift and pull retractor cephalad, anchoring at the xiphoid.

See Instructions for Use for full instructions, warnings, precautions and contraindications.

Extra tables

Variables	TRAXI (n=68)	No TRAXI (n=67)	P-Value
Duration of cesarean delivery (mins)	65 (IQR25, IQR75)	70 (IQR25, IQR75)	0.31
Estimated Blood Loss (ml)	800	800	0.7571
Scrubbed personnel No.			0.5573
3	60%	59%	
4	36%	40%	
5	5%	2%	

Appendix Patient survey
Appendix Provider survey