Beaumont Health

Beaumont Health Scholarly Works and Archives

Conference Presentation Abstracts | Urology

2-2021

Incomplete Bladder Emptying and Urinary Tract Infections After OnabotulinumtoxinA Injection for Overactive Bladder in Men and Women: Multi-Institutional Collaboration From the SUFU Research Network

William Stuart Reynolds

Anne M. Suskind

Jennifer T. Anger

Benjamin M. Brucker

Anne Pelletier Cameron

See next page for additional authors

Follow this and additional works at: https://scholarlyworks.beaumont.org/urology_confabstract

 Part of the Urology Commons

Recommended Citation

Reynolds WS, Suskind AM, Anger JT, Brucker BM, Pelletier Cameron A, et al. Incomplete bladder emptying and urinary tract infections after onabotulinumtoxinA injection for overactive bladder in men and women: multi-instutional collaboration from the SUFU research network. Paper presented at: The Annual Winter Meeting of the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction; 2021 Feb 25-27; Virtual. Available at: https://sufuorg.com/docs/meetings/sufu2102/program-book-abstracts.aspx

This Conference Proceeding is brought to you for free and open access by the Urology at Beaumont Health Scholarly Works and Archives. It has been accepted for inclusion in Conference Presentation Abstracts by an authorized administrator of Beaumont Health Scholarly Works and Archives. For more information, please contact janet.zimmerman@beaumont.org.

Authors

William Stuart Reynolds, Anne M. Suskind, Jennifer T. Anger, Benjamin M. Brucker, Anne Pelletier Cameron, and Priya Padmanabhan

This conference proceeding is available at Beaumont Health Scholarly Works and Archives: https://scholarlyworks.beaumont.org/urology_confabstract/38

The number of minor adverse events is similar between women treated with vaginal laser vs. not (RR 1.76 [95% CI 0.44-7.06]; Low CoE). Findings were consistent in subgroup comparisons of laser vs. sham or laser vs. topical estrogen.
Conclusion: Vaginal lasers appear to have little to no effect on continence based on clinician or patient measures. However, we have very little to limited confidence in the effect estimates for the outcomes. Addition of data from the 16 trials that ongoing will improve the quality of evidence in the future.

Vaginal Laser compared to No Laser (all other interventions) for treating stress urinary incontinence in women

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects: Risk with No Laser (all other interventions)	Anticipated absolute effects: Risk difference with Laser
Number of Continent Women by clinician assessment, short term (< 1 year)	45 (1 RCT)	⊕◯◯◯ VERY LOW [a,b]	RR 0.97 (0.60 to 1.57)	609 per 1,000	18 fewer per 1,000 (243 fewer to 347 more)
Change in patient reported incontinence, short term (< 1 year)	246 (3 RCTs)	⊕⊕◯◯ LOW [a,c]		The mean change in patient reported incontinence, short term (< 1 year) was 0 SD	MD 2.66 SD lower (3.94 lower to 1.39 lower)
Number of Continent Women by patient reported measures, short term (< 1 year)	113 (1 RCT)	⊕⊕◯◯ LOW [a,e]	RR 6.60 (1.54 to 27.49)	36 per 1,000	196 more per 1,000 (19 more to 946 more)
Incontinence Specific Quality of Life Measures, short term (< 1 year)	62 (1 RCT)	⊕⊕◯◯ LOW [a,e]		The mean Incontinence Specific Quality of Life Measures, short term (< 1 year) was 0	MD 15.6 lower (22.59 lower to 8.61 lower)
Clinical measures of urinary incontinence, (mean number of voids on 3 day voiding diary); short term (< 1 year)	51 (1 RCT)	⊕⊕◯◯ LOW [a,c]		The mean clinical measures of urinary incontinence, (mean number of voids on 3 day voiding diary); short term (< 1 year) was 0	MD 0.11 lower (1.48 lower to 1.26 higher)
Patient Reported Sexual Function, short term (< 1 year)	234 (4 RCTs)	⊕⊕◯◯ LOW [a,b]		The mean patient Reported Sexual Function, short term (< 1 year) was 0	MD 0.86 lower (3.35 lower to 1.63 higher)
Minor Adverse Events (Clavien-Dindo I, II, III)	416 (5 RCTs)	⊕⊕◯◯ LOW [a,c]	RR 1.76 (0.44 to 7.06)	290 per 1,000	296 more per 1,000 (218 fewer to 2,364 more)

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence Interval; RR: Risk ratio; MD: Mean difference

GRADE Working Group grades of evidence: High certainty: We are very confident that the true effect lies close to that of the estimate of the effect; Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect; Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations: a. High risk of bias for blinding and unclear risk for attrition and reporting. b. Confidence intervals of the absolute effect cross from a lower risk of effect to higher risk of effect. c. Allocation concealment is unclear in all studies. Blinding is high risk in 2 of 3 studies. d. When the effect size is converted to units change on the IOQ and UDI-6, it spans above and below the minimally important clinical difference for the survey instruments. e. Only one trial for this outcome and risk of bias is unclear for A-D and F, and high for E (attrition bias). f. One study with high risk of bias for blinding of personell. g. Confidence interval crosses the threshold for a clinically meaningful effect. h. Allocation concealment is unclear in all but one study. Blinding is high risk in all

T32 Grant # T32DK007782. This project was supported by the National Institute for Health Research, via Cochrane Infrastructure funding to Cochrane Incontinence. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Evidence Synthesis Programme, the NIHR, NHS or the Department of Health and Social Care.

#37 | INCOMPLETE BLADDER EMPTYING AND URINARY TRACT INFECTIONS AFTER ONABOTULINUMTOXINA INJECTION FOR OVERACTIVE BLADDER IN MEN AND WOMEN: MULTI-INSTITUTIONAL COLLABORATION FROM THE SUFU RESEARCH NETWORK

William Stuart Reynolds[1], Anne M. Suskind[2], Jennifer T. Anger[3], Benjamin M. Brucker[4], Anne Pelletier Cameron[5], Doreen E. Chung[6], Stephanie Daignault-Newton[5], Giulia Lane[5], Alvaro Lucioni[7], Arthur P. Mourtzinos[8], Priya Padmanabhan[9], Polina X. Reyblat[10], Ariana L. Smith[11], Una J. Lee[7]
[1]Vanderbilt Medical Center, [2]University of California San Francisco, [3]Cedars-Sinai Health System, [4]New York University, Langone Health, [5]University of Michigan, [6]Columbia University, [7]Virginia Mason Medical Center, [8]Lahey Clinic, [9]Beaumont Health, [10]Kaiser Permanente, Los Angeles, [11]University of Pennsylvania

Presented By: W. Stuart Reynolds, MD, MPH, FACS

Introduction: OnabotulinumtoxinA (BTX) is an effective third-line therapy for overactive bladder (OAB), however the potential for adverse events may prevent patients from initiating therapy. The objective of this study is to report rates of incomplete emptying and urinary tract infection (UTI) in men and women undergoing BTX for OAB and to identify potential risk factors for these adverse events.
Methods: Eleven clinical sites performed an IRB-approved retrospective study of adult women and men undergoing first-time BTX injection (100 units) for non-neurogenic OAB in 2016. Exclusions included: post void residual (PVR) >150ml, prior BTX, pelvic radiation, or catheterization. Clinical data was collected 6 months before the index procedure. Incomplete emptying was defined as the need for clean intermittent catheterization (CIC) or a post-procedure PVR≥300 ml without the need for CIC within 6 months of the BTX. UTI was defined as symptoms combined with either positive culture or urinalysis or empiric treatment up to 6 months after BTX. We compared rates of incomplete emptying and UTI between sex and individually by sex, using univariate and multivariable models.
Results: 278 patients (48 men and 230 women) met inclusion criteria. Mean age was 65.5 (range 24-95), 13% had history of prior UTI. Within the 6 months after treatment, 35% of men and 17% of women had incomplete emptying and 17% of men and 24% of women had UTI. Outcomes of CIC, PVR≥300mL, incomplete emptying, and UTI by sex are summarized in Table 1. In multivariable analysis, men were associated with 2.4 (95% CI 1.04-5.49) higher odds of incomplete emptying than women. For UTI, 8 (17%) men and 54 (23.5%) women had ≥1 UTI (p=0.30), the majority of which occurred within the first month following injection. The strongest predictor of UTI was history of prior UTI compared to those without (OR 4.2 [95% CI 1.7-10.3]).
Conclusion: In this multicenter retrospective study rates of incomplete emptying and UTI were higher than many previously published studies. Men were at particular risk for incomplete emptying. Prior UTI was the primary risk factor for

post-procedure UTI. Other clinically significant predictive factors were not identified in this multicenter cohort.

Table 1: Summary of adverse events within 6 months of onabotulinumtoxinA injection, by sex

Outcome	Total (N=278)	Male (N=48)	Female (N=230)	p-value (male vs female)
CIC	45 (16%)	13 (27%)	32 (14%)	**0.024**
PVR ≥ 300mL	36 (13%)	11 (25%)	25 (12%)	**0.024**
Incomplete emptying*	56 (20%)	17 (35%)	39 (17%)	**0.004**
UTI	62 (22%)	8 (17%)	54 (23.5%)	0.3

CIC= clean intermittent catheterization; PVR=post void residual; UTI=urinary tract infection.
*Incomplete emptying is a composite definition: need for CIC or post-procedure PVR ≥ 300 ml without need for CIC within 6 months of the BTX.

Funding: SUFU/SUFU Foundation

#38 | MODELS FOR PREDICTING EFFICACY OF TREATMENT AND COMPLICATIONS IN WOMEN AFTER INTRADETRUSOR ONABOTULINUMTOXINA FOR NON-NEUROGENIC URGENCY INCONTINENCE

Whitney K. Hendrickson, MD[1], Gongbo Xie, MS[2], David D. Rahn, MD[3], Megan Bradley, MD[4], Vivian Sung, MD[5], Jim A. Hokanson, PhD[6], Ariana L. Smith, MD[7], Anthony Visco, MD[1], Cindy L. Amundsen, MD[1], Shen Luo, PhD[2], J. Eric Jelovsek, MD, MMEd, MSDS[1]

[1]Duke University Medical Center, Division of Urogynecology, Department of OBGYN, Durham, NC, [2]Duke University, Department of Biostatistics Bioinformatics, Durham, NC, [3]UT Southwestern Medical Center, Division of Female Pelvic Medicine and Reconstructive Surgery, Department of OBGYN, Dallas, TX, [4]University of Pittsburgh School of Medicine, Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics, Gynecology and Reproductive Services, Pittsburgh, PA, [5]Women and Infants Hospital, Brown University, Division of Urogynecology and Pelvic Reconstructive Surgery, Department of OBGYN, Providence, RI, [6]Duke University, Department of Biomedical Engineering, Durham, NC, [7]Perelman School of Medicine at the University of Pennsylvania, Division of Urology, Department of Surgery, Philadelphia, PA

Presented By: Whitney K. Hendrickson, MD

Introduction: Objectives were to develop statistical models to predict treatment efficacy and probability of self-catherization for urinary retention after 100 or 200units of onabotulinumtoxinA in women with non-neurogenic urgency incontinence.

Methods: Statistical models were developed with 307 women from two multi-center randomized trials assessing efficacy of onabotulinumtoxinA for non-neurogenic UUI by the NIH/NICHD Pelvic Floor Disorders Network. Cox, linear and logistic regression models were fit using three respective outcomes: 1)time to recurrence defined as “Strongly disagree,” “Disagree” or “Neutral” on the Patient Global Symptom Control over 12 months, 2)change from baseline in daily urgency incontinence episodes (UUIE) at 6 months and 3)need for self-catheterization over 6 months. Model discrimination of cox and logistic regression models was calculated using a c-statistic, and calibration was demonstrated using calibration curves. Accuracy of the linear model was determined using mean absolute error and error plots. All models were internally validated using cross-validation.

Results: Median time to recurrence was 4.0(IQR: 2.1-6.2) months. Baseline factors associated with decreased time to recurrence included: increasing age, higher BMI, premenopausal status, higher Incontinence Impact Questionnaire-7 (IIQ-7), higher UUIE, and 200units of onabotulinumtoxinA. The bias-corrected c-statistic was 0.61(95%CI:0.61-6.2) and model predictions were accurate when an individual’s probability ranged between 0.4 to 1.0 (Figure 1A). Median change in daily UUIE from baseline at 6 months was -3.7(IQR:-2.3,-5.0) episodes. Increasing age, higher BMI, non-Hispanic, non-white, non-Black, premenopausal status, diabetes history, no recurrent UTIs, lower baseline PVR, higher baseline IIQ-7, higher baseline Overactive Bladder Questionnaire-Short Form (OABq-SF), lower baseline UUIE, and 200units of onabotulinumtoxinA were associated with greater improvement in UUIE. The mean absolute error predicting change in UUIE was accurate to 1.66(95%CI:1.59-1.67) episodes (Figure 1B). The overall rate of self-catheterization was 28.3%(95%CI 23.5-33.8%). Lower BMI, increased baseline PVR, increased maximum capacity, lower baseline Urogenital Distress Index-6, lower baseline OABq-SF and 200units of onabotulinumtoxinA were associated with higher risk of self-catheterization. The bias-corrected c-statistic was 0.62(95%CI:0.61-0.63) and model predictions were accurate when an individual’s probability ranged between 0 to 0.8 (Figure 1C).

Conclusion: These predictive models for treatment response after onabotulinumtoxinA for non-neurogenic UUI showed acceptable discrimination and calibration. These models will assist clinicians in providing more accurate