Reduced versus standard intradetrusor onabotulinumtoxinA injections for treatment of overactive bladder

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OBJECTIVES: To compare the efficacy of a reduced 5-site injection technique of intradetrusor onabotulinumtoxinA to the standard 20-site technique for treatment of overactive bladder.

MATERIALS AND METHODS: In this randomized non-inferiority trial, men and women undergoing treatment of overactive bladder with office intradetrusor onabotulinumtoxinA injections were eligible. Immediately prior to the procedure, subjects were randomized to receive 100 units of onabotulinumtoxinA, administered via a reduced 5-site injection technique with 2mL per site (study) or a standard 20-injection technique with 0.5mL per site (control). Subjects completed standardized questionnaires at baseline and at 4-12 weeks post-procedure to determine symptom severity and treatment efficacy. The primary outcome was treatment efficacy between groups as determined by the Overactive Bladder Questionnaire-Short Form bother and quality of life scales (OABq-SF), International Consultation on Incontinence Questionnaire (ICIQ), and Patient Global Impression of Improvement (PGI-I) scores. Secondary outcomes were incidence of urinary tract infection (UTI) and urinary retention requiring catheterization. A 15-point difference in change of OABq-SF scores was set as the noninferiority margin.

RESULTS: Eighty-one subjects were randomized with complete data for 73 subjects available for analysis (36 control, 37 study). There were no differences in baseline demographics. Both arms demonstrated significant improvement in OABq-SF (Figure 1) and ICIQ scores from baseline to follow-up (p<.001). Treatment success based on PGI-I scores was 58%, with no statistically significant difference between arms (48.7% control vs 67.5% study, p=.12). The change in OABq-SF bother scores was similar between arms (control 45.9 points vs study 34.9 points, p=.07); however, there was a statistically significant difference in the change in OABq-SF quality of life scores (control 32.8 points vs study 21.6 points, p=.03) favoring the control arm. The study arm did not demonstrate non-inferiority to the control arm. Subjects receiving the reduced injection technique expressed more willingness to undergo the procedure again (OR 3.93, 95% CI 1.45-11.22, p=.004, Figure 2). Incidence of UTI and urinary retention were similar between groups (UTI 28.9% control vs 14.2% study, p=.16 and urinary retention 0% control vs 5.4%, p=.49).

CONCLUSION: A reduced injection technique for administration of intradetrusor onabotulinumtoxinA demonstrates similar efficacy to the standard injection technique but did not meet the prespecified criteria for noninferiority. However, the reduced injection technique significantly improved symptoms and quality of life from baseline and conferred similar risks of adverse events. Since patients receiving the reduced injection technique were more willing to repeat treatment, this technique may increase treatment continuation.

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Ergonomic simulation investigating the association between surgeon characteristics and laparoscopic device strain in gynecologic surgery

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OBJECTIVES: Laparoscopic instruments are known to contribute to the ergonomic injury of surgeons. Laparoscopic devices have largely been designed as one-size-fits-all, however women surgeons and surgeons of smaller glove size have reported increased odds of physical strain from use of these devices. Our objective was to perform an ergonomic simulation to assess whether surgeon characteristics, including sex and hand size, were associated with grip strength decline with use of 3 advanced energy laparoscopic devices (LigaSure, HALO PKS, and ENSEAL).

MATERIALS AND METHODS: An ergonomic simulation was performed at an academic tertiary care site. 20 participants were recruited from the Department of Obstetrics and Gynecology between 2/2021-3/2021, matched by surgeon sex. Surgeon demographics and anthropometric measurements were collected in a standard fashion. Each participant was positioned in an idealized ergonomic posture and completed a fatiguing 120-second trial of rapid repetitive use of 3 laparoscopic advanced energy devices (LigaSure, HALO PKS, and ENSEAL) in a randomized order. A 5-minute rest period occurred in between each trial. A handheld dynamometer was used to collect grip strength measurements at baseline and throughout each 120-second trial. Subjects completed the NASA Raw Task Load Index (RTLX) scale after use of each device to assess ergonomic workload.

RESULTS: 10 women (50%) and 10 men (50%) were recruited to complete the simulation. Women compared to men were found to have a significantly smaller hand span (20 vs 22 cm, p<0.01) and lower baseline grip strength (304 vs 428 N, p<0.01). Subjects with glove size <7 compared to size ≥7 also had a significantly lower baseline grip strength (286 vs 409 N, p<0.01). Grip strength decline was not found to be significantly associated with either surgeon sex or hand size. While female and male participants reported similar levels of RTLX workload for each device, surgeons of glove size <7 compared to ≥7 reported significantly more ergonomic workload for all cumulative devices (5.4 vs 4.3, p=0.04).

CONCLUSION: Although surgeon sex and hand size were not found to be significantly associated with the amount of grip strength decline experienced throughout an ergonomic simulation using laparoscopic advanced energy devices, surgeons of smaller hand sizes still reported experiencing greater ergonomic workload. It is critical to further evaluate surgeon experiences using laparoscopic devices both in the operating room and through simulation models in order to fully understand the factors related to surgeon ergonomic strain.

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06 Watching surgical tapes: video playback as an educational tool for improving resident laparoscopic performance
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OBJECTIVES: In this single masked, randomized controlled study, we evaluate if watching video recordings of oneself performing Fundamentals of Laparoscopic Skills (FLS) exercises results in an improvement on the 30-point Global Operative Assessment of Laparoscopic Skills (GOALS) assessment among Obstetrics & Gynecology (Ob/Gyn) residents.

MATERIALS AND METHODS: Participants were randomized to verbal feedback only (control) or verbal feedback and watching their video recording (intervention). Each participant completed the five FLS exercises using a laparoscopic box trainer while being timed, video recorded and receiving real-time feedback from an Ob/Gyn faculty member. Baseline GOALS assessment was completed by participants and faculty evaluator. Participants randomized to the intervention were allowed to watch their video recording and the faculty evaluator was masked to this randomization. All participants then repeated the FLS exercises while being timed and this was again scored using the GOALS assessment. In addition, all participants completed a pre- and post-test survey to gauge their laparoscopic comfort level. Two-sample t-test was used to assess within-group differences in overall GOALS scores and exercise times while Wilcoxon Rank Sum test was used for within-group comparisons of survey responses. Between-group analysis for change in GOALS scores, exercise times and survey responses was performed using the Mann-Whitney test. Differences in variables across Post Graduate Year (PGY) levels were evaluated using ANOVA and Kruskal-Wallis tests.

RESULTS: Twenty-three Ob/Gyn residents in the 2020-2021 academic year completed the study; 12 were randomized to the intervention and 11 received verbal feedback only. Relative to baseline, there were significant within-group improvements in the faculty (p<0.01) and self-reported GOALS scores (p<0.01). Between the groups, the intervention group improved by 3.2 points more than the control group based on masked faculty evaluation (95% CI 1.4 to 5.0 points, p<0.01). This between-group difference was not significant in resident self-scores. Overall time improved for all participants (15:54 ± 0.21 minutes pre and 13:13 ± 0.14 minutes post) but this difference was not significant between groups. Higher PGY residents reported significantly more comfort performing laparoscopic tasks, earned higher GOALS score (faculty and self-scores), and completed the first set of exercises in less time. A significant interaction between PGY and intervention was detected using 2-way ANOVA with between-group improvement in GOALS score most strongly associated with PGY4 residents (p<0.01).

CONCLUSION: This suggests that while all learners objectively benefit from watching recordings of themselves performing surgical tasks, advanced learners may benefit the most when video recordings are used as an educational tool.

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07 Development and validation of a simulation model for laparoscopic myomectomy
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OBJECTIVES: To design a low-cost, low-fidelity laparoscopic myomectomy simulation model and to evaluate the model’s construct and face validity.

MATERIALS AND METHODS: The model was constructed using a foam cylinder, felt, a 5cm stress ball, self-adhesive bandage wrap, and multipurpose sealing wrap for a total cost under $5. Participants were recruited at a quaternary care academic center and at the Society of Gynecologic Surgeons scientific meeting. The simulation task involved