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The Design of a Prospective Trial to Evaluate the Role of Preoperative Frailty Assessment in Older Women Undergoing Surgery for the Treatment of Pelvic Organ Prolapse: The FAST Supplemental Trial

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Abstract

Objective—We present the rationale for and the design of a prospective trial to evaluate the role of preoperative frailty and mobility assessments in older women undergoing surgery for the treatment of pelvic organ prolapse as a planned prospective supplemental trial to the Apical Suspension Repair for Vault Prolapse In a Three-Arm Randomized Trial Design (ASPIRe) trial. The Frailty ASPIRe Study (FAST) examines the impact of preoperative frailty and mobility on surgical outcomes in older women (≥ 65 years) participating in the ASPIRe trial. The primary objective of FAST is to determine the impact of preoperative age, multi-morbidity, frailty and decreased mobility on postoperative outcomes in older women (≥ 65 years old) undergoing surgery for POP.

Methods—The selection of the preoperative assessments, primary outcome measures, and participant inclusion is described. Frailty and mobility measurements will be collected at the preoperative visit and include the six Robinson frailty measurements and the Timed Up and Go

mobility test. The main outcome measure in the FASt supplemental study will be moderate to severe postoperative adverse events according to the Clavien-Dindo Severity Classification.

Conclusion—This trial will assess impact of preoperative age, multi-morbidity, frailty and decreased mobility on postoperative outcomes in older women (≥ 65 years old) undergoing surgical procedures for the correction of apical POP. Information from this trial may help both primary care providers and surgeons better advise/inform women on their individual risks of surgical complications and provide more comprehensive postoperative care to women at highest risk of complications.

Keywords

Frailty; Mobility; Pelvic Organ Prolapse; Surgical Outcomes

Introduction

Female pelvic floor disorders (PFDs) including urinary incontinence (UI), pelvic organ prolapse (POP) and fecal incontinence, are common and increase with age.(1–3) PFDs cause distressing symptoms with significant impact on women's quality of life and perceived overall health.(4–8) PFDs are also the most common indication for gynecologic surgery in women ≥ 65 years old with 150,000 procedures currently performed annually in this demographic.(9) Treatment of PFDs is elective and can include either surgical or non-surgical interventions, making surgeries for PFDs preference-sensitive procedures.(10) Treatments for PFDs are offered with the primary intention of symptom improvement and improving a women's overall quality of life.

Surgery for POP correction is generally well tolerated with few major adverse events. In an American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP) database analysis, the overall prevalence of composite 30-day major postoperative complications, which excluded superficial surgical site infections and urinary tract infections, following POP surgery for women at any age was 3.1% (n/N = 1,028/33,416). (11) There were 13 perioperative deaths (0.04%) with no difference between the surgical approaches (p=.55). In a stratified analysis examining women aged ≥ 80 years compared with younger women (18 to 80 years old), the occurrence of 30-day major postoperative complications was 4.3% vs. 2.9%, respectively (p = .01).

The age-related onset of PFD symptoms in women suggests that many women seeking treatment for these disorders may have a high prevalence of other conditions of aging, namely frailty, cognitive impairment and functional disabilities. These co-morbid geriatric conditions could potentially impact the risks and benefits of different treatment options for PFDs.

Postoperative functional decline

As older women undergo elective gynecologic surgery, strategies to identify women at risk for postoperative functional decline need to be better understood to prevent this loss of function and optimize the intended benefit of these procedures. The majority of women undergoing POP surgery are independent in basic and instrumental activities of daily living

(BADLs, IADLs) at baseline.(12) In a prospective study of women 60 years or older undergoing surgical correction of PFDs, the prevalence of a preoperative functional limitation was 50% for stooping or kneeling, 25% for strenuous activities (e.g. climbing stairs, lifting heavy groceries), 10% for light activities and fine motor skills (e.g. picking up a dime, walking 1 block) and 8.7% for IADLs.(12). In a separate study of 890 women 65 years old identified with POP by claims data and linked to the Health and Retirement Study Survey data, the presence of functional limitations was 13.6% in IADLs and 4.5% in BADLs.(13) Few studies have evaluated the impact of elective gynecologic surgery on postoperative functional status in older women. Baseline and postoperative mobility and functional status were assessed using the life-space assessment (LSA) in a prospective study of 102 older women (aged > 65 years) who underwent surgery for PFDs and gynecologic cancer.(14) Patients in both surgical groups had a significant decline in LSA score at 6 weeks postoperatively, but saw return to baseline LSA score at six months.

While women with overt functional disability may be easily recognized, many facets of frailty and mild cognitive impairment are often unrecognized in clinical encounters unless specifically measured.(15, 16) As increasing numbers of older women in the United States undergo surgical procedures for PFDs, tools to identify and counsel patients at risk for postoperative adverse events and improve outcomes are critical.(9, 17, 18) There is a growing body of evidence demonstrating preoperative measurements of frailty and mobility predict surgical outcomes in older patients better than measurements of medical multi-morbidities or the American Society of Anesthesiologists (ASA) status alone.(19–27) Robinson et al. first examined the impact of preoperative frailty in male patients undergoing cardiovascular surgery with anticipated postoperative intensive care unit admission and these types of investigations have expanded to colorectal and vascular surgery literature as well. (19–21, 26, 28) More recently, the Successful Aging after Elective Surgery (SAGES) study demonstrated the impact of preoperative frailty on postoperative outcomes (length of stay, discharge to post-acute care and readmissions) in older adults undergoing elective procedures.(29)

Frailty

Frailty is a biologic syndrome of decreased reserve and resistance to stressors and increases with age. Frailty is common, present in >20% of adults over the age of 65 years old, and has been shown to be an important predictor of adverse outcomes (long-term nursing home stay, injurious falls and death) independent of medical multi-morbidity and age in community-dwelling older adults.(15) Frailty has been recognized as a distinct clinical entity that is independent of medical multi-morbidity and functional disability, although these commonly co-exist.(15) Frailty may be measured in a number of ways with different frailty indices having between 1 and 90 items. (30) Regardless of the measure of frailty used, the principal of elucidating a covert process, not always obvious to the primary care provider or surgeon, through measurement remains.

Frailty has been demonstrated as an important predictor of surgical outcomes in older adults undergoing major surgeries (cardiac and colorectal surgery) requiring admission to intensive care units.(19, 21, 26) Robinson et al. developed a preoperative predictive index using six

measures of frailty (Mini-Cog score, Charlson comorbidity index, functional disability, history of falls, preoperative serum albumin and preoperative serum hematocrit) to predict mortality after major surgery in older patients (aged ≥ 65 years). In 2013, the six measures of the Robinson frailty index combined with the Timed Up and Go (TUG) test were demonstrated to predict postoperative complications, better than standard risk-adjustment calculators, across surgical specialties including cardiac and colorectal surgeries.(26, 28) Of note, these prospective cohort studies were performed at Veteran's Administration Hospitals in an almost entirely male population.

To date, the impact of preoperative frailty on postoperative outcomes (both adverse events and treatment success) has not been prospectively studied in older women undergoing elective surgery for the treatment of PFDs. In a cohort of older women (≥ 65 years) seeking treatment for PFDs, 16.7% of women met the stricter phenotypic/Hopkins criteria for frailty.(31) In this cohort, unaware of their frailty status, similar percentages of women with and without frailty chose surgical management for the treatment of their PFDs.(31) This cross-sectional study did not follow women through the perioperative period to assess the impact of frailty on postoperative outcomes. This pilot work, and a recent systematic review of frailty assessments in women with PFDs, has brought to light that women with frailty seek surgery for PFDs, but it is not clear whether frailty is considered when deciding on a treatment plan.(32)

METHODS

Investigating how measures of preoperative frailty and mobility can predict outcomes in low-risk elective surgeries in women is an important next step in aging research. The Pelvic Floor Disorders Network (PFDN), a multi-centered surgical network funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), has been successfully conducting randomized surgical trials that have advanced the field of pelvic floor disorders since 2001. The Apical Suspension Repair for Vault Prolapse In a Three-Arm Randomized Trial Design (ASPIRe), is a multi-centered randomized trial being conducted by the PFDN that began recruitment in February, 2016. The primary aim of ASPIRe is to determine which of three surgical approaches to correct apical prolapse provides the best anatomic and subjective outcomes in women of all ages. The Frailty ASPIRe Study (FASt), is a supplementary study to ASPIRe, examining the impact of preoperative frailty and mobility on surgical outcomes in older women (≥ 65 years) participating in the ASPIRe trial. The FASt study specifically seeks to gather meaningful data on the impact of preoperative frailty, mobility and multi-morbidity in older women undergoing elective surgery for PFDs.

The primary objective of FASt is to determine the impact of preoperative age, multi-morbidity, frailty and decreased mobility on postoperative outcomes in older women (≥ 65 years old) randomized to 3 different surgical procedures for the correction of apical POP. We hypothesize that older women (≥ 65 years old) with frailty and slow baseline mobility are at increased risk of postoperative adverse events compared to older women without frailty.

ASPIRe study design

The ASPIRe study is a multi-center, randomized, surgical trial of women undergoing surgical correction of apical prolapse remote from prior hysterectomy. Women are randomized to one of three arms: abdominal sacrocolpopexy with mesh placed abdominally using laparotomy, laparoscopy or robotic-assisted laparoscopy, vaginal apical native tissue suspension to the uterosacral ligament or sacrospinous ligament, or vaginal mesh apical suspension with Uphold™ Lite (*Boston Scientific, Boston MA*).

Frailty ASPIRe study (FASt) supplemental trial design

The FASt supplemental trial is a prospective cohort trial of women ≥ 65 years old entering into the ASPIRe trial and undergoing surgical correction of apical prolapse. Preoperative baseline measurements of frailty and mobility are collected and women are followed at the scheduled ASPIRe study follow-up visits to determine postoperative complications and treatment success. (Figure 1)

Frailty ASPIRe (FASt) population

The FASt study population includes women participating in ASPIRe who are ≥ 65 years old at the time of their baseline preoperative visit and who elected to participate in additional evaluations required for FASt participation. Baseline demographic information and clinical characteristics of women who elected to participate in this supplement study will be compared to those who opted out of participation.

BASELINE PREOPERATIVE VISIT

The six Robinson frailty measurements and the TUG mobility test are collected at the baseline preoperative study visit. (Table 1) These assessments include the Mini-Cog exam, Katz BADLs, the functional co-morbidity index (FCI) (as a substitution for the Charlson Comorbidity Index), a question on reported falls in the last 6 months, measurements of preoperative serum albumin and hematocrit, and the TUG mobility test.(19, 33–36)

The Mini-Cog exam, a screening test for cognitive impairment, requires a participant to remember 3 words (e.g. Bicycle, Honesty, Yellow) and then draw the face of a clock at a specified time (e.g. 10 minutes to 11).(33) The participant is given a maximum of 2 minutes to draw the clock and at this time is also asked to recall the 3 words previously given to her.

The Timed Up and Go (TUG) Test requires an armless chair and a place for the patient to walk 10 feet and turn around and sit down.(34) Walking aids are allowed and no instructions are given to the patient about the use of their arms. Patients are asked to rise from a seated position, walk 10 feet, turn around, return to the chair and sit down. Examiners note if a patient walks unsteadily or requires the use of a walking aid (e.g. cane or walker) to complete the task.

Calculation of frailty will be the same as proposed by Robinson et al. (Table 1) Each of the seven items (Mini-Cog, Katz BADLs, Comorbidity Index, history of falls, preoperative serum albumin, preoperative serum hematocrit, and TUG mobility test) will count as 1 point.

Frailty scale range will be from 0 to 7. Scores of 0–1, 2–3, and 4 will be classified as non-frail, pre-frail, and frail, respectively.(19, 26)

OUTCOME VISITS

Postoperative visits are scheduled every 6 months for all ASPIRe participants up to a maximum of 60 months. These visits are scheduled to assess for both the primary outcome measures of the ASPIRe protocol (treatment failure) and secondary outcome measures (e.g. efficacy, safety and complication monitoring). In addition to the standard monitoring, the FAST protocol will specifically inquire about standard geriatric morbidity including falls, living arrangements, admission to a skilled nursing facility (SNF) and mortality through the 60-month follow-up.

OUTCOME MEASURES

Postoperative complications

The main outcome measure in the FAST supplemental study will be moderate to severe postoperative adverse events according to the Clavien-Dindo Severity Classification.(37, 38) Common geriatric perioperative complications (falls,discharged to a skilled nursing facility (SNF) and social support needed after discharge) and postoperative complications (surgical site infections, urinary tract infections, all cause readmission and mortality) will be assessed. Mid and long-term follow-up will be obtained with validated measures of pelvic floor symptom distress and impact at the 6, 12, 24 month visits. A comparison of complications depending on assigned prolapse surgery (e.g. sacrocolpopexy, vaginal apical native tissue suspension or vaginal mesh suspension) is also planned as a secondary analysis. In addition to the planned assessments of the functional activity scale and Quality of Life measures for all ASPIRe participants, assessments of geriatric morbidity in FAST participants will include specific questions at 6 to 60 months postoperatively regarding new admission to SNF/long-term care (LTC), falls, all-cause hospital admissions, and mortality.

Treatment success

Participants in the ASPIRe trial will undergo surgical treatment of POP for relief of bothersome POP symptoms. Validated subjective and objective outcome measures will be used to define treatment success from this surgical procedure. (39) Treatment failure for ASPIRe POP surgery will be defined as (1) return of bothersome vaginal bulge symptoms on validated questionnaires, (2) retreatment for prolapse (surgery or pessary) and (3) any prolapse measure (Ba, C, Bp from the standardized Pelvic Organ Prolapse-Quantification exam) that is beyond the vaginal hymen.

Social Support/Living arrangements

Participants will be asked preoperatively about their living arrangements prior to surgery. At the six-week study visit, they will be asked what their current living arrangements are. They will also be asked about their need for support after surgery and if a friend/family member stayed with them or if they stayed at a friend/family member's house. The duration of this extra needed social support after surgery will also be measured.

STATISTICAL CONSIDERATIONS AND ANALYTICAL PLAN

The total expected sample size for the ASPIRe protocol is 363 women. Prior PFDN multi-center surgical trials have been highly successful in recruiting older women. Thirty-nine percent ($n/N = 550/1407$) of women who participated in prior 4 PFDN surgical trials were 65 years.(40–43) Therefore, we expect approximately 142 women ($39.2\% \times 363$ women) recruited for the ASPIRe trial to be 65 years old.

In a combined analysis of two prior multi-centered surgical trials, the CARE and SISTER trials, moderate to severe postoperative complications (Clavien-Dindo Grade 2, 3 or 4) occurred in 34% of women.(38) Using the strict Fried/Hopkins frailty phenotype definition, prior work demonstrates that frailty is present in 17% of older women seeking treatment for PFDs.(31) The Robinson frailty score is much more liberal, however, as it incorporates both cognitive function as well as serum laboratory values. In previously published work using this frailty score 58% and 56% of patients 65 years old undergoing elective colorectal surgery and cardiac surgery, respectively, were considered frail.(26) If we estimated that between 40% and 60% of women (65 years old) in the ASPIRe cohort would meet the Robinson definition of frailty and that the occurrence of postoperative complications among frail women will be 34%, we would need between 130 and 139 women to detect a 20% difference in postoperative complications between frail and non-frail women ($\alpha = 0.05$; power = 0.8, one-sided). We estimate that 142 subjects recruited in the ASPIRe protocol will be 65 years old at the time of their baseline preoperative assessment, which will allow us adequate power for the projected number of FAST participants. FAST enrollment has been completed which included 144 women, with one participant withdrawing prior to her six-week appointment.

ETHICAL CONCERNS AND INFORMED CONSENT

Individual IRB approval was obtained at each participating site. Written consent was obtained from all ASPIRe participants. Participants who were 65 years old at the time of consent were given the option of participating or declining additional screening for the FAST study as a part of this consent process.

Preoperatively, it was assumed that different surgeons may or may not advise and treat women differently knowing the results of their baseline preoperative frailty measurements. As frailty had not been prospectively studied in women undergoing elective gynecologic surgery including pelvic floor surgery, the impact of frailty on postoperative outcomes in older women undergoing these elective procedures is not known. To mitigate surgeon bias, all ASPIRe surgeons recruiting women into the FAST study will be blinded to the baseline preoperative frailty measurements of all participants.

DISCUSSION

The FAST study seeks to determine the impact of baseline frailty status on postoperative adverse events and overall treatment success in older women undergoing surgical correction of POP. There are many proposed measurements for preoperative frailty assessment including the Fried frailty phenotype, the Edmonton Frail Scale, TUG test, the FRAIL scale,

the NSQIP Modified frailty index and the Robinson Index.(15, 20, 23, 30, 32, 44) The Robinson frailty measurements were selected due to their demonstrated value in predicting postoperative complications in patients undergoing cardiac and colorectal surgery.(26, 28) In addition, we sought to include both a measure of mobility (TUG test) and cognition (Mini-Cog) in order to best capture the deficit accumulation frailty markers proposed by the National Institutes of Aging (NIA) conference on frailty for the specialist.(30) We deviated from the Robinson frailty index only by substituting the FCI for the Charlson comorbidity index. The FCI was selected for use for the larger ASPIRe trial as it is a comorbidity index that performs better for assessments of physical function, a valued outcome after surgical intervention, when compared directly to the Charlson comorbidity index. (36) We chose to use the FCI for both its strengths in measuring of physical function and to reduce participant burden in this supplemental trial.

Our study has several strengths. As a supplemental study to a large multi-center RCT, the FAST study will provide prospectively collected high quality data on post-operative outcomes following on three different surgical procedures for POP from nine centers, and will have wide generalizability. In the proposed work, we are only studying women who have selected to undergo surgical intervention for POP correction; therefore, we are limited by the lack of control group of similar aged frail women choosing expectant management or other non-surgical treatment options. Further, women with overt limitations may not be recruited for this trial of 3 restorative surgeries for prolapse repair and may elect to undergo colpocleisis. To minimize this recruitment bias for women without overt limitations, surgeons were blinded to pre-operative frailty, mobility, and cognitive function status to avoid biasing study recruitment and postoperative management and outcome evaluation. Due to the conscious intention to limit participant burden with limited funding resources, we will not have baseline comprehensive neurocognitive testing or inflammatory biomarkers. We also will not have repeated frailty, mobility or cognitive function measures in the postoperative period. However, data that will be collected before surgery and at regular follow-up visits are the Short-Form 12 and the Functional Activity Scale as well as standardize questions on living arrangements. However, the FAST study remains the first of its kind to prospectively determine the role of frailty on postoperative outcomes in a large population of older women undergoing elective gynecologic surgery for benign indications.

CONCLUSIONS

Preoperative identification of older women with frailty may identify some women who are at highest risk for adverse events after surgery and may consider non-surgical treatment, but will also identify frail women who may benefit from more intensive support and active management in the hospital and with transitions of care to avoid postoperative complications. Well-selected well-managed older women undergoing surgery for the correction of POP may realize tremendous benefit in quality of life improvements following these elective procedures. Considering medical multi-morbidities, frailty and functional status in addition to age can help surgeons better lead discussions with women on their individual risk of complications after surgery, provide more comprehensive postoperative care plans and inform to the expectations of women at highest risk of complications.

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Conflict of Interest

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References

1. Nygaard I, Barber MD, Burgio KL, Kenton K, Meikle S, Schaffer J, et al. Prevalence of symptomatic pelvic floor disorders in US women. *JAMA*. 2008 9 17;300(11):1311–6. [PubMed: 18799443]
2. Rortveit G, Hannestad YS, Daltveit AK, Hunskaar S. Age- and type-dependent effects of parity on urinary incontinence: the Norwegian EPINCONT study. *Obstet Gynecol*. 2001 12;98(6):1004–10. [PubMed: 11755545]
3. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S, Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trondelag. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. *Epidemiology of Incontinence in the County of Nord-Trondelag. J Clin Epidemiol*. 2000 11;53(11):1150–7. [PubMed: 11106889]
4. Yip SO, Dick MA, McPencow AM, Martin DK, Ciarleglio MM, Erekson EA. The association between urinary and fecal incontinence and social isolation in older women. *Am J Obstet Gynecol*. 2013 2;208(2):146.e1,146.e7. [PubMed: 23159696]
5. Melville JL, Fan MY, Rau H, Nygaard IE, Katon WJ. Major depression and urinary incontinence in women: temporal associations in an epidemiologic sample. *Am J Obstet Gynecol*. 2009 11;201(5):490.e1,490.e7. [PubMed: 19716547]
6. Melville JL, Delaney K, Newton K, Katon W. Incontinence severity and major depression in incontinent women. *Obstet Gynecol*. 2005 9;106(3):585–92. [PubMed: 16135592]
7. Fialkow MF, Melville JL, Lentz GM, Miller EA, Miller J, Fenner DE. The functional and psychosocial impact of fecal incontinence on women with urinary incontinence. *Am J Obstet Gynecol*. 2003 7;189(1):127–9. [PubMed: 12861150]
8. Sung VW, West DS, Hernandez AL, Wheeler TL 2nd, Myers DL, Subak LL, et al. Association between urinary incontinence and depressive symptoms in overweight and obese women. *Am J Obstet Gynecol*. 2009 5;200(5):557.e1,557.e5. [PubMed: 19236869]
9. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. *Obstet Gynecol*. 2014 6;123(6):1201–6. [PubMed: 24807341]
10. Birkmeyer JD, Reames BN, McCulloch P, Carr AJ, Campbell WB, Wennberg JE. Understanding of regional variation in the use of surgery. *Lancet*. 2013 9; 382(9898): 1121–9. [PubMed: 24075052]
11. Erekson E, Murchison RL, Gerjevic KA, Meljen VT, Strohbehn K. Major postoperative complications following surgical procedures for pelvic organ prolapse: a secondary database

analysis of the American College of Surgeons National Surgical Quality Improvement Program. *Am J Obstet Gynecol*. 2017 11;217(5):608.e1,608.e17. [PubMed: 28578172]

12. Greer JA, Harvie HS, Andy UU, Smith AL, Northington GM, Arya LA. Short-term postoperative functional outcomes in older women undergoing prolapse surgery. *Obstet Gynecol*. 2015 3;125(3):551–8. [PubMed: 25730215]
13. Sanses TV, Schiltz NK, Couri BM, Mahajan ST, Richter HE, Warner DF, et al. Functional status in older women diagnosed with pelvic organ prolapse. *Am J Obstet Gynecol*. 2016 5;214(5):613.e1,613.e7. [PubMed: 26704893]
14. Stewart CM, Wheeler TL 2nd, Markland AD, Straughn JM Jr, Richter HE. Life-space assessment in urogynecology and gynecological oncology surgery patients: a measure of perioperative mobility and function. *J Am Geriatr Soc*. 2009 12;57(12):2263–8. [PubMed: 19874406]
15. Fried LP, Tangen CM, Walston J, Newman AB, Hirsch C, Gottdiener J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci*. 2001 3;56(3):M146–56. [PubMed: 11253156]
16. Fried LP, Ferrucci L, Darer J, Williamson JD, Anderson G. Untangling the concepts of disability, frailty, and comorbidity: implications for improved targeting and care. *J Gerontol A Biol Sci Med Sci*. 2004 3;59(3):255–63. [PubMed: 15031310]
17. Wu JM, Kawasaki A, Hundley AF, Dieter AA, Myers ER, Sung VW. Predicting the number of women who will undergo incontinence and prolapse surgery, 2010 to 2050. *Am J Obstet Gynecol*. 2011 9;205(3):230.e1,230.e5. [PubMed: 21600549]
18. Wu JM, Hundley AF, Fulton RG, Myers ER. Forecasting the prevalence of pelvic floor disorders in U.S. Women: 2010 to 2050. *Obstet Gynecol*. 2009 12;114(6):1278–83. [PubMed: 19935030]
19. Robinson TN, Eiseman B, Wallace JI, Church SD, McFann KK, Pfister SM, et al. Redefining geriatric preoperative assessment using frailty, disability and co-morbidity. *Ann Surg*. 2009 9;250(3):449–55. [PubMed: 19730176]
20. Robinson TN, Wallace JI, Wu DS, Wiktor A, Pointer LF, Pfister SM, et al. Accumulated frailty characteristics predict postoperative discharge institutionalization in the geriatric patient. *J Am Coll Surg*. 2011 7;213(1):37,42; discussion 42–4. [PubMed: 21435921]
21. Robinson TN, Wu DS, Stiegmann GV, Moss M. Frailty predicts increased hospital and six-month healthcare cost following colorectal surgery in older adults. *Am J Surg*. 2011 11;202(5):511–4. [PubMed: 21890098]
22. Hamel MB, Henderson WG, Khuri SF, Daley J. Surgical outcomes for patients aged 80 and older: morbidity and mortality from major noncardiac surgery. *J Am Geriatr Soc*. 2005 3;53(3):424–9. [PubMed: 15743284]
23. Dasgupta M, Rolfson DB, Stolee P, Borrie MJ, Speechley M. Frailty is associated with postoperative complications in older adults with medical problems. *Arch Gerontol Geriatr*. 2009 Jan-Feb;48(1):78–83. [PubMed: 18068828]
24. Makary MA, Segev DL, Pronovost PJ, Syin D, Bandeen-Roche K, Patel P, et al. Frailty as a predictor of surgical outcomes in older patients. *J Am Coll Surg*. 2010 6;210(6):901–8. [PubMed: 20510798]
25. Kim SW, Han HS, Jung HW, Kim KI, Hwang DW, Kang SB, et al. Multidimensional frailty score for the prediction of postoperative mortality risk. *JAMA Surg*. 2014 7;149(7):633–40. [PubMed: 24804971]
26. Robinson TN, Wu DS, Pointer L, Dunn CL, Cleveland JC Jr, Moss M. Simple frailty score predicts postoperative complications across surgical specialties. *Am J Surg*. 2013 10;206(4):544–50. [PubMed: 23880071]
27. Cooper Z, Rogers SO Jr, Ngo L, Guess J, Schmitt E, Jones RN, et al. Comparison of Frailty Measures as Predictors of Outcomes After Orthopedic Surgery. *J Am Geriatr Soc*. 2016 12;64(12):2464–71. [PubMed: 27801939]
28. Robinson TN, Wu DS, Sauaia A, Dunn CL, Stevens-Lapsley JE, Moss M, et al. Slower walking speed forecasts increased postoperative morbidity and 1-year mortality across surgical specialties. *Ann Surg*. 2013 10;258(4):582,8; discussion 588–90. [PubMed: 23979272]

29. Schmitt EM, Marcantonio ER, Alsop DC, Jones RN, Rogers SO Jr, Fong TG, et al. Novel risk markers and long-term outcomes of delirium: the successful aging after elective surgery (SAGES) study design and methods. *J Am Med Dir Assoc*. 2012 11;13(9):818.e1,818.10.
30. Robinson TN, Walston JD, Brummel NE, Deiner S, Brown CH 4th, Kennedy M, et al. Frailty for Surgeons: Review of a National Institute on Aging Conference on Frailty for Specialists. *J Am Coll Surg*. 2015 12;221(6):1083–92. [PubMed: 26422746]
31. Erekson EA, Fried TR, Martin DK, Rutherford TJ, Strohbehn K, Bynum JP. Frailty, cognitive impairment, and functional disability in older women with female pelvic floor dysfunction. *Int Urogynecol J* 2015;26:823–30. [PubMed: 25516232]
32. Zeno A, Alvarez P, Yazdany T. A Systematic Review of Frailty Assessments in Women With Pelvic Floor Disorders: Are We Following the American College of Surgeons National Surgical Quality Improvement Program/American Geriatric Society Guidelines? *Female Pelvic Med Reconstr Surg*. 2018 Mar-Apr; 24(2):135–41. [PubMed: 29474287]
33. Borson S, Scanlan JM, Chen P, Ganguli M. The Mini-Cog as a screen for dementia: validation in a population-based sample. *J Am Geriatr Soc*. 2003 10;51(10):1451–4. [PubMed: 14511167]
34. Podsiadlo D, Richardson S. The timed “Up & Go”: a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc*. 1991 2;39(2):142–8. [PubMed: 1991946]
35. Katz S Assessing self-maintenance: activities of daily living, mobility, and instrumental activities of daily living. *J Am Geriatr Soc*. 1983 12;31(12):721–7. [PubMed: 6418786]
36. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. *J Clin Epidemiol*. 2005 6;58(6):595–602. [PubMed: 15878473]
37. Clavien PA, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, et al. The Clavien-Dindo classification of surgical complications: five-year experience. *Ann Surg*. 2009 8;250(2):187–96. [PubMed: 19638912]
38. Gutman RE, Nygaard IE, Ye W, Rahn DD, Barber MD, Zyczynski HM, et al. The pelvic floor complication scale: a new instrument for reconstructive pelvic surgery. *Am J Obstet Gynecol*. 2013 1;208(1):81.e1,81.e9. [PubMed: 23131463]
39. Barber MD, Brubaker L, Nygaard I, Wheeler TL 2nd, Schaffer J, Chen Z, et al. Defining success after surgery for pelvic organ prolapse. *Obstet Gynecol*. 2009 9;114(3):600–9. [PubMed: 19701041]
40. Brubaker L, Cundiff GW, Fine P, Nygaard I, Richter HE, Visco AG, et al. Abdominal sacrocolpopexy with Burch colposuspension to reduce urinary stress incontinence. *N Engl J Med*. 2006 4 13;354(15):1557–66. [PubMed: 16611949]
41. Wei JT, Nygaard I, Richter HE, Nager CW, Barber MD, Kenton K, et al. A midurethral sling to reduce incontinence after vaginal prolapse repair. *N Engl J Med*. 2012 6 21;366(25):2358–67. [PubMed: 22716974]
42. Barber MD, Brubaker L, Burgio KL, Richter HE, Nygaard I, Weidner AC, et al. Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial. *JAMA*. 2014 3 12;311(10):1023–34. [PubMed: 24618964]
43. Amundsen CL, Richter HE, Menefee SA, Komesu YM, Arya LA, Gregory WT, et al. OnabotulinumtoxinA vs Sacral Neuromodulation on Refractory Urgency Urinary Incontinence in Women: A Randomized Clinical Trial. *JAMA*. 2016 10 4;316(13):1366–74. [PubMed: 27701661]
44. Amrock LG, Neuman MD, Lin HM, Deiner S. Can routine preoperative data predict adverse outcomes in the elderly? Development and validation of a simple risk model incorporating a chart-derived frailty score. *J Am Coll Surg*. 2014 10;219(4):684–94. [PubMed: 25154667]

Figure 1: Study design for Frailty ASPIRe study (FASt) supplemental study

Planned preoperative and postoperative evaluations of patients participating in the FASt supplemental study

BADLs = Basic Activities of Daily Living; SNF = skilled nursing facility; LTC = long-term care; QOL = quality of life

Table 1:**Preoperative Assessments: The Robinson Frailty Index**

Frailty	Scale explanation	Score	Cut-off	Points
Mini-Cog(33)	3-item recall (1 point per item) paired with clock drawing test (2 points)	Scores range from 0 (impaired cognition) to 5 (normal cognition)	<4	1
Katz Basic Activities of Daily Living (BADLs) Score(35)	1 point for each of six basic ADLs that patient performs independently (bathing, dressing, toileting, transferring in/out of bed, walking, and feeding)	Scores range from 0 (totally dependent) to 6 (independent)	<6	1
Functional Comorbidity Index (FCI)(36)	18 items medical comorbidity assessment	Scores range from 0 (no comorbid conditions) to 18 (severe co-morbidity)	3	1
History of falls	Recorded answer to the question "How many times have you fallen in the last 6 months?"		1 fall	1
Preoperative serum albumin	Indicative of poor nutritional status		3.3 g/dL	1
Preoperative serum hematocrit	Indicative of anemia of chronic disease		<35%	1
Mobility	Scale explanation	Score	Cut-off	
Timed Up and Go ^{*(34)}	Patient sits in an armless chair and is timed to: 1) Rise from chair 2)Walk 10 feet 3)Turn around 4)Walk 10 feet 5) Sit back down in chair	10 seconds (fast) 11-14 seconds (intermediate) 15 seconds (slow)	15 seconds	1

* walking aids are allowed and no instructions are given to the patient about the use of her arms