Operationalizing postdischarge recovery from laparoscopic sacrocolpopexy for the preoperative consultative visit

Michael Heit, PhD, MD, Department of Obstetrics and Gynecology, School of Medicine, Indiana University, Indianapolis, IN

Janet S. Carpenter, PhD, RN, FAAN, Science of Nursing Care Department, School of Nursing, Indiana University, Indianapolis, IN;

Chen X. Chen, PhD, RN, Department of Community and Health Systems, School of Nursing, Indiana University, Indianapolis, IN;

Kevin L. Rand, PhD, Department of Psychology, School of Science, Indiana University-Purdue University Indianapolis

Financial support: Dr. Chen was supported by Grants Numbers KL2TR001106 and UL1TR001108 (A. Shekhar, PI) funded by the National Institutes of Health, National Center for Advancing Translational Sciences Clinical and Translational Sciences Award. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Corresponding author: Michael Heit MD PhD, email: mheit@iuhealth.org

Word Count: 3,688

This is the author's manuscript of the article published in final edited form as:

Heit, M., Carpenter, J. S., Chen, C. X., & Rand, K. L. (2021). Operationalizing Postdischarge Recovery From Laparoscopic Sacrocolpopexy for the Preoperative Consultative Visit. Female Pelvic Medicine & Reconstructive Surgery, 27(7), 427–431. https://doi.org/10.1097/SPV.0000000000000942

Abstract

Objective: The objective was to establish a threshold for postdischarge surgical recovery from laparoscopic sacrocolpopexy for the preoperative consultative visit to answer the "what is my recovery time?" question.

Methods: Study participants (N=171) with ≥ stage 2 pelvic organ prolapse undergoing laparoscopic sacrocolpopexy completed postoperative surveys at four time points. Postdischarge surgical recovery 13 (PSR13) scores were anchored to a global surgical recovery (GSR) tool (if 100% recovery is back to your usual health, what percentage of recovery are you now?). Weighted mean PSR13 scores were calculated as a sum of the products variable when patients considered themselves 80 to < 85, 85 to < 90, 90 to < 95, or 95 to 100 percent recovered on the GSR tool. Percent of study participants recovered at postdischarge day 7, 14, 42, and 90 were calculated based on a comparison between the GSR scores and weighted mean PSR13 scores.

Results: A PSR13 score ≥ 80, corresponding to ≥ 85% recovery, was seen in 55.6 % (42 days), and 50.9% (90 days) of study participants respectively, establishing this numeric threshold as representing "significant" postdischarge recovery after laparoscopic sacrocolpopexy. At 14 days post discharge only 16.4% of the study population achieved this PSR13 score.

Conclusion: The majority of study subjects were "significantly" recovered at 42 days following laparoscopic sacrocolpopexy using a PSR13 score of ≥ 80 as a numeric threshold. There is a need to determine the population percentage of recovered study subjects at 30, 60, and beyond 90 days from laparoscopic sacrocolpopexy.

Keywords: Postdischarge recovery, laparoscopic sacrocolpopexy, pelvic organ prolapse

Introduction

Postoperative recovery is defined as an energy-requiring process of returning to normality and wholeness, as evidenced by a return to preoperative levels of independence/dependence […] and psychological well-being [1]. One of the five most common symptom expectancies is an estimated duration of recovery which provides patients with a benchmark for self-assessment of their progress compared to others with similar symptoms or surgical procedures 2]. Unmet expectations and serious illness worry adversely affect patient satisfaction [2]. Patient dissatisfaction affects compliance with treatment regimens, follow-up recommendations, and certain disease outcomes including postdischarge surgical recovery, as well as predicting patients likely to leave a health care plan [2].

We have previously established the postdischarge surgical recovery trajectory for study subjects with pelvic organ prolapse after laparoscopic sacrocolpopexy as measured by the Postdischarge Surgical Recovery (PSR13) scale [3]. However, a continuous PSR13 score at any particular time point is incapable of answering the "what is my recovery time?" question, which is posed by many patients, family members, and significant others who are seeking a benchmark at the completion of the preoperative consultation visit. Establishing a threshold score for operationalizing postdischarge surgical recovery provides surgeon's with guidance about the population percentage of recovered individuals at salient time points after laparoscopic sacrocolpopexy, to estimate a duration of recovery, in an attempt to meet symptoms expectancies for the patient and maximize patient satisfaction.

The purpose of this study was to identify a PSR13 score and corresponding time point that corresponded to significant postdischarge recovery after laparoscopic sacrocolpopexy. We report the percentage of study subjects who met this important milestone at 7, 14, 42, and 90 days after surgery.

Material and Methods

This is a secondary analysis of data from 171 study subjects with Stage ≥ 2 pelvic organ prolapse. Study subjects were recruited from a university affiliated urogynecology practice between December 2013 and October 2016 for a prospective cohort study to establish predictors of postdischarge surgical recovery after laparoscopic sacrocolpopexy. The methodologies for study subject enrollment, and data collection have been previously published elsewhere [4].

In the parent study during the preoperative consultation visit, surgeons did not set recovery expectancies when study participants or family members asked "what is the recovery time?" during their preoperative surgical consultation visit. Patients were encouraged to "listen to their own bodies, and return to normal activities, including work responsibilities, when they felt up to it." No structured rehabilitation program was instituted as part of our recovery expectancy manipulative statement. On the contrary, we promoted liberalized postoperative instructions to prevent study subjects from embracing restrictive activities such as "no heavy lifting", or "no lifting greater than a gallon of milk. This allowed patients to self-regulate activity based on their perceived recover progress. Study subjects underwent conventional laparoscopic sacrocolpopexy using Amid classification type I ultra-lightweight polypropylene mesh (Restorelle® L or M Flat Mesh, Coloplast, Minneapolis, MN) and 2-0 polydioxanone suture (PDS® II, Ethicon, Inc., Somerville, NJ) in all cases, with concomitant procedures, including vaginal hysterectomy, retropubic midurethral sling, and posterior colporrhaphy, when indicated as previously described.

Preoperatively, study subjects completed a 30 minute survey that included, age, body mass index, race/ethnicity, prolapse stage, and Charlson co-morbidity index, among other sociodemographic and clinical variables. Postoperatively, study subjects completed a 15-minute survey to measure recovery on days 7, 14, 42, and 90 (± 3 days). Our research group previously reported on the psychometric properties of a validated version of the PSR13 [Cronbach's α's = .911-934, MID = 5, Clinical responsiveness to change, Cohen's d = 0.53 from 7 to 14 days, Cohen's d = 0.89 from 14 to 42 days,

Cohen's d = 0.08 from 42 to 90 days] in study subjects with pelvic organ prolapse undergoing laparoscopic sacrocolpopexy [3]. Study subjects also completed a single-item measure of perceived global surgical recovery (GSR) at the same time points as the PSR13 measurements for comparison. The GSR item asked: "If 100% recovery is back to your usual health, what percentage of recovery are you now?" Study subjects responded using a visual analogue slider scale from 0 to 100. The study subjects were randomized to the order of the two emailed surgical recovery questionnaires to minimize the risk of order bias and respondent fatigue.

Our research team established *a priori* GSR score bands (ranges) that represented varying degrees of recovery as follows; $80 \leq x < 85$, $85 \leq x < 90$, $90 \leq x < 95$, and $95 \leq x \leq 100$. We graphed the stacked frequency of study subjects within each GSR score band for all 4 time points that recovery data were collected. We defined "significant" recovery after laparoscopic sacrocolpopexy as the first GSR score band where the frequency distribution of study subjects (stacked bar height) varied with an inverted U-shaped dose-effect curve [5]. The inverted U-shaped dose-effect curve (IUSDEC) is the graphic representation of a quadratic function [$f(x) = ax^2 + bx + c$, where $a < 0$] where dosage effects increase up to a maximum after which the effects decrease. The IUSDEC may explain clinical observations where promotion of restrictive activity instructions (dose) does not generate optimal recovery (effect) [6]. Figure 1. Weighted mean PSR13 scores were anchored to each GSR score band by calculating the sum of the products of the mean PSR13 score*number of subjects within each GSR band, divided by the total number of patients for all 4 time points. Weighted rather than ordinary arithmetic means were calculated to allow data points with higher frequencies to contribute more to the mean than data points with lower frequencies. The weighted mean PSR13 score corresponding to the GSR score band where the frequency distribution of study subjects followed an inverted U-shaped dose-effect curve was considered the numerical threshold for "significant" recovery after laparoscopic sacrocolpopexy.

The database had been collected and managed using REDCap (Research Electronic Data Capture) hosted at Indiana University [7].

Study sample means with standard deviations were calculated after checking normality assumptions by visual inspection of the frequency distribution for each continuous variable. Study population percentages were calculated for each categorical predictor variable. IBM SPSS Statistics for Windows, version 24 (IBM Corp., Armonk, N.Y., USA) was used for all computational analyses.

Results

The 171 study subjects from the database had a mean age of 63.25 years ± 9.15, mean BMI of 28.05 ± 4.18 kg/m^2, and a mean Charlson Co-morbidity index score of 2.47 ± 1.85. The median length of hospital stay for all study subjects was 35.3 hours (interquartile range 32.3-53.7 hours). Seventy four percent of study participants had grade 0 complications while 13% had grade 1, 5% had grade II and 8% had Grade III as measured by the Clavien-DIndo classification system. Approximately 95% of study subjects self-classified themselves as non-Hispanic White with a preoperative POP-Q stage distribution of stage 2 (36.8%), stage 3 (58.5%) or stage 4 (4.7%).

Figure 2 is a stacked bar graph illustrating the frequency of study subjects within each GSR score band for all 4 time points. The first frequency distribution of study subjects (stacked bar height) following an inverted U-shaped dose-effect curve was the $85 \leq x < 90$ GSR recovery band, suggesting that the numeric threshold for "significant" recovery after laparoscopic sacrocolpopexy should approximate its corresponding anchored weighted mean PSR13 score. The weighted mean PSR13 score for the $85 \leq x < 90$ GSR recovery band was 79.26 (11*78.5 + 18*80.86 + 23* 78.31 + 14*79.35/66) suggesting that a PSR13 score above 80 represents "significant" recovery after laparoscopic sacrocolpopexy as defined in our study.

Figure 3 represents a comparison between similarly calculated sum of the product weighted mean PSR13 scores and the percent of study subjects who achieved these thresholds at each of the 4 data collection time points. The resultant weighted mean PSR13 scores of 70, 85, and 90 all likely represent clinically meaningful postdischarge recovery milestones after laparoscopic sacrocolpopexy given the established MID of 5 for this validated measure [3]. A PSR score of 90 could be considered a numeric threshold for "full" recovery after laparoscopic sacrocolpopexy because study subjects residing in the $95 \leq x \leq 100$ GSR recovery band showed improved recovery at all 4 time points at the expense of "significant" recovery after 42 days. The majority of study subjects reported "significant" recovery at 42 days (55.5%) and 90 days (50.9%). Of those, 25.2% reported "full recovery" at 42 days and 30.4% reported "full recovery" at 90 days after laparoscopic sacrocolpopexy.

Discussion

We established a PSR13 score of ≥ 80 as representing "significant" postdischarge surgical recovery after laparoscopic sacrocolopexy. Although this score does not reflect "full" or 100% recovery, this numeric threshold is achieved by the majority and similar percentages of study subjects (>50%) at two commonly accepted milestones reflecting the length of short term disability (42 days) [8-9] and the global surgical period (90 days). The categorical operationalization of postdischarge surgical recovery scores provides guidance to surgeons, surgical patients, and family members interested in establishing a benchmark for the "what is my recovery time?" question to aid surgical decision making after the preoperative consultative visit. Statisticians prefer continuous PSR13 scores when comparing interventions designed to optimize postdischarge surgical recovery because they lower the study's sample size burden. However a difference in the population percentage of recovered study subjects is favored by patients and surgeons because it is more clinically meaningful than differences in PSR13 scores.

We have previously established predictors of postdischarge surgical recovery after laparoscopic sacrocolpopexy using population mean PSR13 scores before establishing this numeric threshold for "significant" recovery [4]. Noordegraaf et al established a prediction model using return to work (RTW) rather than "recovery" at 6 weeks to identify the most important preoperative sociodemographic, medical, and work-related factors that predicted the risk of prolonged sick leave after gynecologic surgery. Interestingly, they found that 59% (87/148) of women had returned to work 6 weeks after surgery, suggesting that "significant" postdischarge recovery as measured by the PSR13 numeric threshold of 80 and RTW may be similar primary outcome measure constructs. The prediction model which included level of surgical invasiveness, preoperative return to work expectations, and functional status had a sensitivity of 89%, specificity of 86%, positive predictive value of 85%, and negative predictive value of 89% when a score of ≥ -2 was chosen as a threshold value for increased risk of prolonged sick leave (range -25 to 31) [8].

Evenson et al used the postdischarge surgical recovery scale to describe women's recovery during the first 6 weeks after hospital discharge from abdominal versus vaginal gynecologic surgery. They defined recovery as a response of 8, 9, or 10 (10 point scale) to the single item "I feel completely recovered from surgery" rather than establishing a numeric threshold from the validated questionnaire's composite score as established in our work. Recovery was similar for vaginal versus abdominal surgery at the two and 6 week assessment time points (vaginal vs abdominal; 2 week: 15.0 vs 17.0%, 6 week: 47.5 vs 48.8%). Population percentages of "significantly" recovered study subjects after laparoscopic sacrocolpopexy mirror these outcomes, suggesting that factors other than level of surgical invasiveness predict postdischarge recovery. Data collection beyond the 6 week time point, currently considered the classic "recovery period," did not increase the total percent of our study subjects reporting "significant" postdischarge recovery, as recommended by Evenson [9].

Taken together our present study and that of Vonk Noordegraaf [8] and Evenson [9] suggest that only 50-60% of surgical patients felt recovered 42 days postdischarge from surgery. Clearly these findings suggest a need for interventions designed to optimize recovery if we hope to increase the population percentage of recovered individuals by this time period.

The IUSDEC has been frequently reported in studies where the effects of increasing dosages of a given compound appear to increase up to a maximum and then the effects decrease. The mechanisms on which it is based have yet to be elucidated, and in many instances it has been described without attempted interpretation [5]. Restrictive postoperative activities such as “no heavy lifting” or “no lifting greater than a gallon of milk” may be effective in optimizing “significant” postdischarge recovery at 42 days after laparoscopic sacrocolpopexy with diminishing returns thereafter. We hypothesize that higher states or “full” recovery and satisfaction [10] only become achievable through promotion of liberal postoperative activity after surgery. Patients gain self-efficacy through self-regulation of physical activity rather than follow restrictive postoperative instructions leading to improved quality of life {11]. Our previous research promoting liberal postoperative activity while identifying predictors of postdischarge recovery [4] supports this hypothesis and the graphical representation of a sigmoid function to describe the shape of the recovery trajectory after laparoscopic sacrocolpopexy. Figure 4. The sigmoid function provides for a plateauing of the population percentage of recovered study subjects beginning at 42 days based solely on collected data from our study. Alternatively both the graphic representations of a positively sloped line [12] or cubic function [13] have been used to describe the shape of the recovery trajectory after hip replacement surgery.

We chose the IUSDEC because we felt it was the closest graphical representation of the frequency distribution of study subjects at our 4 chosen time points along the $85 \leq x < 90$, and $90 \leq x < 95$ GSR recovery bands. Decisions regarding the chosen graphical representation for the shape of our recovery trajectories is problematic and somewhat subjective [14] especially when PSR13 scores are

only measured at 4 time points postoperatively. Collection of PSR13 scores at 30, 60 and beyond 90 days postdischarge would be desirable for a better characterization recovery trajectory shape after laparoscopic sacrocolpopexy. However we had to weigh the benefit of adding two or more time points against the risk of study subject attrition attributable to the increased burden of prospective data collection. Our choice of the IUSDEC is consistent with the shape of the recovery trajectory labelled as "poor" recovery seen in 7% of patients after hip replacement surgery. Modest improvement was demonstrated during the first 6 months followed by rapid deterioration thereafter [13]. There are several limitations to our study that should be considered. Despite reports to the contrary, we did find a ceiling effect for postdischarge surgical recovery as measured by the PSR13 [Kluivers 2008]. However, we did not collect postdischarge recovery data beyond 90 days so we are unable to determine if the population percentage of "significantly" recovered study subjects increases beyond approximately 50% at a later time point after laparoscopic sacrocolpopexy. We believe the 4.6% decline in the population percentage of recovered patients at 90 days is reflective of the variability inherent in recovery measurement rather than a clinical significant difference from 42 days for the 7-8 study subjects who did not report a threshold score. Kluivers et al advised surgeons to apply the Post-Discharge Surgical Recovery Scale and the Quality of Recover-40 in future studies on postoperative recovery [15]. Neither of these instruments previously provided numeric thresholds to answer the "what is the recovery time?" question nor is there any accepted gold standard measurement of good quality postoperative recovery [16] to graphically plot receiver operating characteristic (ROC) curves of the discriminating threshold of scores for a binary classification system (recovered/not recovered).

Our "significant" recovery data, although similar to vaginal versus abdominal gynecologic surgical recovery, are only generalizable to laparoscopic sacrocolpopexy in patients with a similar mean age and co-morbidities as recruited for our study. We would expect postdischarge surgical recovery to be shorter for minimally invasive urogynecology procedures, such as midurethral sling, although this

remains to be studied. It would be interesting to determine if postdischarge surgical recovery differed in women undergoing native tissue versus mesh augmented procedures for pelvic organ prolapse.

In conclusion, we established a PSR13 score of 80 as a numeric threshold for "significant" postdischarge surgical recovery after laparoscopic sacrocolpopexy. This milestone was achieved by over 50% of our study subjects no later than 42 days. Future research is necessary to determine the population percentage achieving this milestone at 30, 60, and beyond 90 days accepting the risk of study subject attrition from increased measurement burden. Findings described in this paper will be used in power analysis calculations to determine sample sizes in prospective longitudinal studies describing recovery over time or in behavioral, medical device, and/or pharmaceutical clinical trials.

References

1. Allvin R, Berg K, Idvall E, et al. Postoperative recovery: a concept analysis. J Adv Nurs 2007;57(5):552–558.
2. Jackson JL, Kroenke K, Chamberlin J. Effects of physician awareness of symptom-related Expectations and mental disorders. Arch Fam Med. 1999;8:135-142.
3. Carpenter JS, Heit M, Chen CX, et al. Validating the Postdischarge Surgical Recovery Scale 13 as a measure of perceived postoperative recovery after laparoscopic sacrocolpopexy. Female Pelvic Med Reconstr Surg. 2017;23 (2):86–89.
4. Heit M, Carpenter J, Chen CX, et al. Predictors of postdischarge surgical recovery following laparoscopic sacroclopopexy: a prospective cohort study. Female Pelvic Med Reconstr Surg. June 19, 2018 - Volume Publish Ahead of Print - Issue -doi: 10.1097/SPV.0000000000000599.
5. Baldi E, Bucherelli C. The inverted “u-shaped” dose-effect relationships in learning and memory: modulation of arousal and consolidation. Nonlinearity Biol Toxicol Med. 2005 Jan;3(1):9-21.
6. Engineer ND, Engineer CT, Reed AC, et al. Inverted-U function relating cortical plasticity and task difficulty. Neuroscience. 2012 Mar 15;205:81-90.
7. Harris PA, Taylor R, Thielke R, et al. Research Electronic Data Capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377–381.
8. Vonk Noordegraaf A, Anema JR, Louwerse MD, et al. Predication of time to return to work after gynaecological surgery: a prospective cohort study in the Netherlands. BJOG. 2014:121:487-497
9. Evenson M, Payne D, Nygaard I. Recovery at home after major gynecologic surgery: how do our patients fare? Obstet Gynecol. 2012 Apr;119(4):780-4.

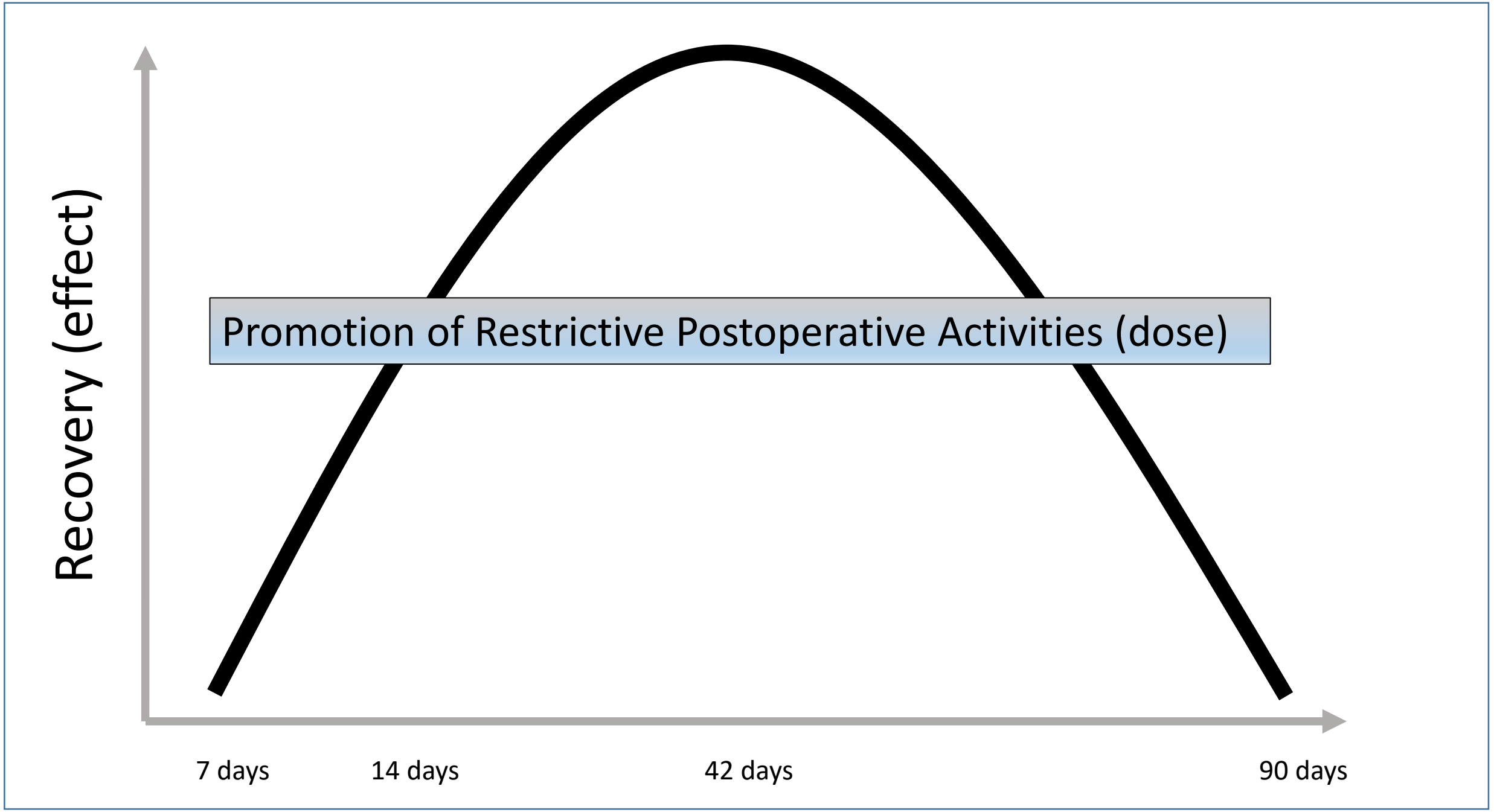
10. Mueller MG, Lewicky-Gaupp C, Collins SA, Abernethy MG, Alverdy A, Kenton K. Activity restriction recommendations and outcomes after reconstructive pelvic surgery: a randomized controlled trial. Obstet Gynecol. 2017;129(4):608–14.
11. Arunachalam D, Heit M. Impact of postoperative instructions on physical activity following pelvic reconstructive surgery: a randomized controlled trial. Int Urogynecol J. 2020 Feb 15. doi: 10.1007/s00192-020-04239-y. [Epub ahead of print].
12. Shyu YIL, Liang J, et al. Two-year effects of interdisciplinary intervention for hip fracture in older Taiwanese. JAGS. 2010;58:1081-1089.
13. Tseng MY, Shyu YIL, Liang J. Functional eecovery of older hip-fracture patients after interdisciplinary intervention follows three distinct trajectories. The Gerontologist. 2012;52(6):833-842.
14. Yang HY, Losina E, Lange JK, Katz JN, Collins JE. Longitudinal trajectories of pain and function improvement following total knee replacement. ACR Open Rheumatology. 2019;1(5):308-317.
15. Kluivers KB, Riphagen I, Vierhout ME, et al. Systematic review on recovery specific quality-of-life instruments. Surgery. 2008 Feb;143(2):206-15.
16. Myles PS, Weltkamp B, Jones K, et al. Validity and reliability of a postoperative quality of recovery score: the QoR-40. Br J Anaesth. 2000;84:11-15.

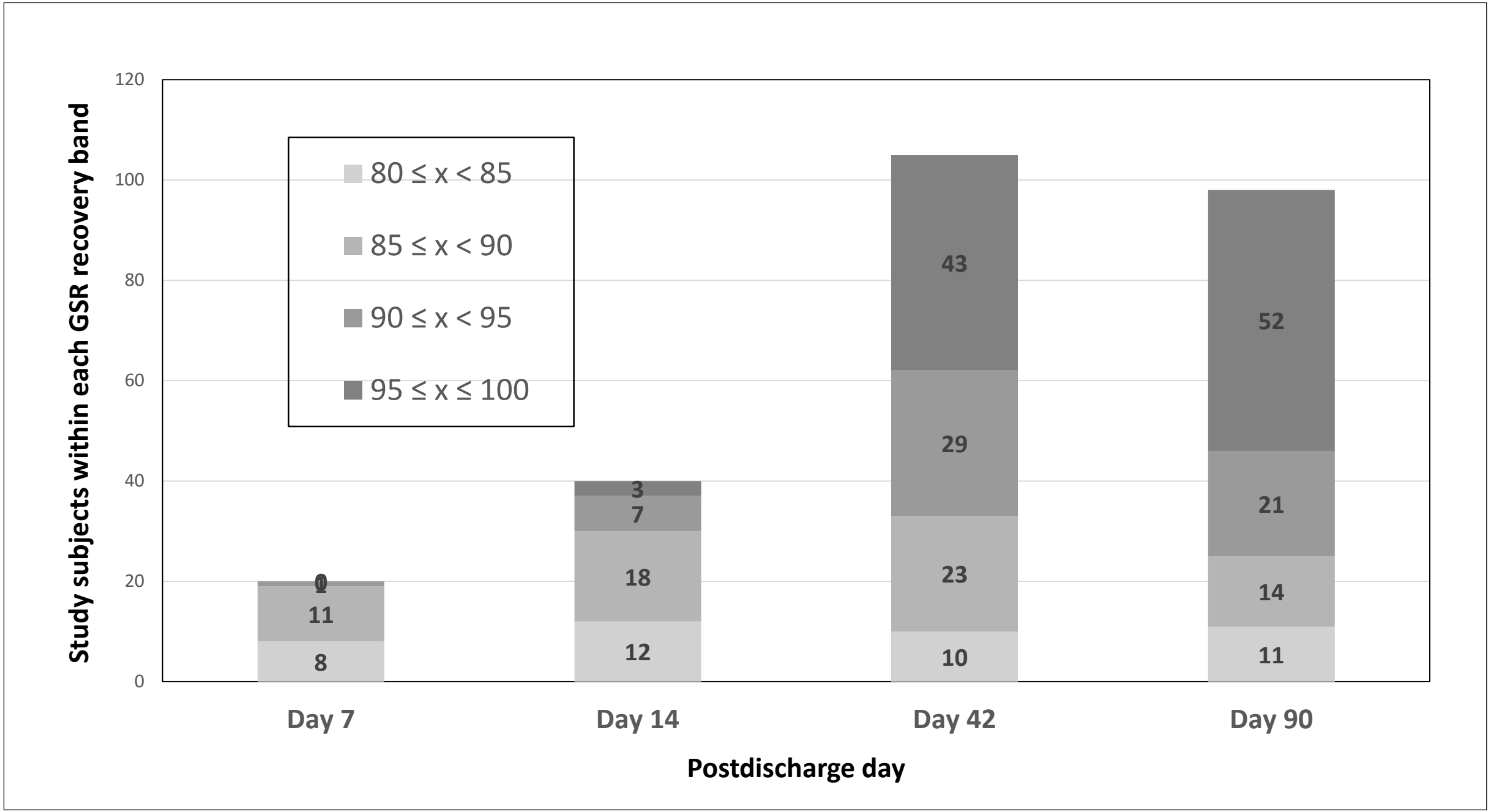
Figure 1 An Idealized model of the Inverted U-shaped dose-effect curve

Figure 2 Case frequency of study subjects within each single-item General Recovery Score (GSR) band at all 4 time points. Only study subjects who achieved these a priori established GSR scores are included.

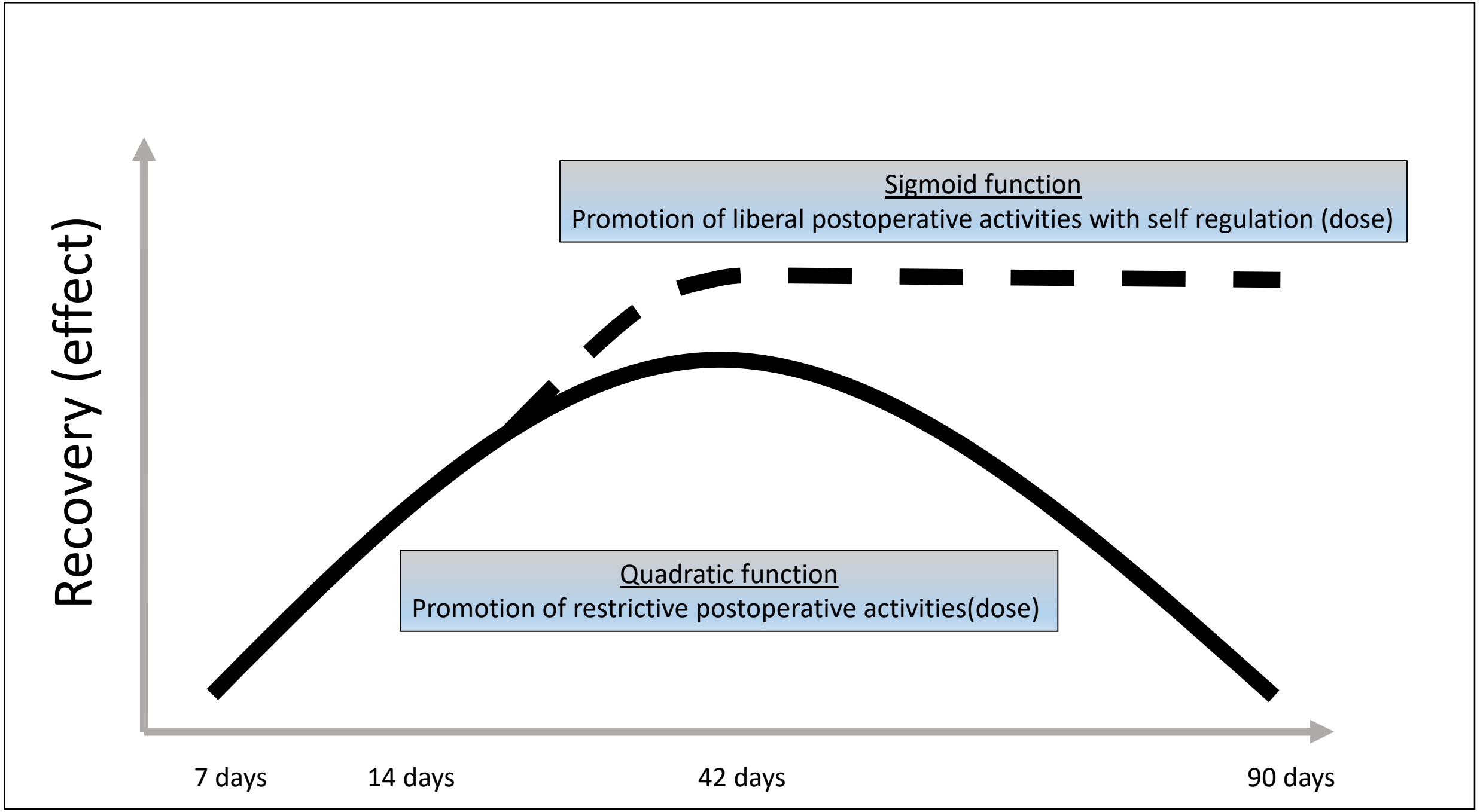
Figure 3 Single item General Recovery Score (GSR) Band, weighted mean Postdischarge Surgical Recovery 13 (PSR13) scores [sum of the products of the mean PSR13 score*number of subjects within each GSR band, divided by the total number of patients for all 4 time points], and % achievement by postdischarge day [the case frequency of study subjects within each GSR band divided by the total number of study subjects *100 for all 4 time points]

Figure 4 Hypothesized shape of the recovery trajectories after laparoscopic sacrocolpopexy.. **Solid line**: Quadratic function representing the diminishing effect of restrictive postoperative activity promotion on recovery after surgery. **Dotted line**: Sigmoid function representing the beneficial effect of liberal postoperative activity promotion through self-regulation with plateau at 42 days after surgery [from reference 4].


Recovery (effect)
Promotion of Restrictive Postoperative Activities (dose)
7 days
14 days
42 days
90 days


Study subjects within each GSR recovery band
120
100
80
60
40
20
0
80 ≤ x < 85
85 ≤ x < 90
90 ≤ x < 95
95 ≤ x ≤ 100
8
11
1
0
12
18
7
3
10
23
29
43
11
14
21
52
Day 7
Day 14
Day 42
Day 90
Postdischarge day

Single-Item Recovery Range	Weighted Mean PSR13	Day 7 %	Day 14 %	Day 42 %	Day 90 %
80 ≤ x < 85	70.29	4.68	7.02	5.85	6.43
85 ≤ x < 90	79.26	6.43	10.53	13.45	8.19
90 ≤ x < 95	85.17	0.58	4.09	16.96	12.28
95 ≤ x ≤ 100	90.97	0.00	1.75	25.15	30.41
			16.37%	55.56%	50.88%


Recovery (effect)
Sigmoid function
Promotion of liberal postoperative activities with self regulation (dose)
Quadratic function
Promotion of restrictive postoperative activities(dose)
7 days
14 days
42 days
90 days