

Feasibility of recruiting elective spinal surgery patients in the preoperative anesthesia clinic for a tele-health behavioral pain management intervention study during the COVID-19 pandemic

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Introduction:

In anticipation of a surge of SARS-CoV-2 (COVID-19) infections and demand for personal protective equipment, the American College of Surgeons recommended postponing or canceling elective procedures in March 2020 [1]. As elective surgery restrictions changed, researchers had to adjust strategy on conducting perioperative trials [2]. Emerging literature suggested that study investigators consider ethical principles, local/national guidelines, local pandemic risk, limited study staffing, and participant exposure to COVID-19 to decide the best course of action [2,3]. The purpose of this report was to describe the feasibility of continuing with a study of a HIPAA-compliant telehealth behavioral pain management and opioid tapering program for post-surgical spine patients. We examined the process of recruiting patients, retention of consented patients for the 1st post-surgical telehealth intervention appointment and predictors of retention.

Methods:

The study is a prospective parallel arm study examining the effects of weekly telehealth behavioral therapy on opioid naive (no opioid exposure in the last 30 days) and opioid tolerant (taking an opioid at least once during the last 30 days) patients. Recruitment was planned in the preoperative anesthesia clinic of a large urban hospital that serves mixed socioeconomic communities. Due to local COVID-19 restrictions temporarily halting the in-person clinic for a period, recruitment was attempted on the morning of surgery until clinic activities slowly resumed. Within the bustle of preoperative preparation, recruitment on the day of surgery was challenging given limitation of adequate time for subjects to consider participation. Medical students on a clinical research rotation and an external investigator were available for recruitment as their schedule allowed so was unintentionally random. Inclusion criteria

included adults (aged 18+ years) undergoing elective spine surgery with 4 identified surgeons who would be receiving postoperative opioids. Subjects needed access to a smartphone or computer with video capabilities and agreed to have therapy summaries shared with their surgical team. Outcomes of interest include number of patients consented and number of consented patients that successfully engaged in their 1st post-surgical telehealth appointment. Binary logistic regression was used to determine odds ratios for successful first appointment.

Results:

From August 2020, 72 patients scheduled for elective spine surgery were approached. 37 (51.4%) consented to participation of which, 15 (40.5%) successfully attended the 1st post-surgical intervention appointment to date (demographics shown in Table 1). The likelihood of attending the 1st appointment did not differ by prior opioid use, gender, ethnicity or age (Table 2).

Conclusion:

In this preliminary report of a small cohort of an ongoing study of postsurgical telehealth interventions to assist patients with postoperative opioid weaning, we describe challenges with recruitment during the COVID-19 pandemic. Although elective surgery resumed, appropriate safety considerations for the preoperative clinic and increased use of virtual assessment likely impacted subject follow-up to the 1st post operative appointment. In a behavioral study, adequate time is necessary to perform baseline survey instruments, engage the subject and reinforce the potential mental health benefits of postoperative participation. We suggest that in the current pandemic, limited preoperative anesthesia clinic availability may not be ideal for recruitment for perioperative clinical studies. Given the expansion and success of telehealth platforms in the preoperative setting, use of a HIPAA-compliant telehealth platform for study recruitment would allow for adequate time to increase recruitment for a clinical study [2].

In the small cohort, there were no differences in likelihood of attending the 1st post-surgical telehealth intervention. Further data on the impact of the intervention program on postoperative patient outcomes are awaited as enrollment continues to accrue.

Reference(s):

1. American College of Surgeons. COVID-19: recommendations for management of elective surgical procedures. 2020. March 13
2. Padala PR, Jendro AM, Padala KP. Conducting clinical research during the COVID-19 Pandemic: Investigator and participant perspectives. *JMIR Public Health and Surveillance*. 2020;6(2):e18887.
3. Byrd JB, Bello N, Meyer MN. Pandemic Pandemonium: Pausing Clinical Research During the COVID-19 Outbreak. *Circulation*. 2020 Apr 22.

Table 1.

Demographics and length of opioid use on consented patients ($n = 37$)

	<i>n</i> (%)
Opioid Use- Tolerant	12 (32.4)
Attended 1st Appointment	16 (43.2)
Ethnicity	
White	17 (45.9)
Black	10 (27.0)
Hispanic	10 (27.0)
Gender- Female	24 (64.9)
	<i>M</i> (<i>SD</i>)
Age (years)	55.3 (11.8)

Table 2.

Odds-ratios of attending 1st appointment

	<i>OR</i>	95% <i>CI</i> [LL, UL]
Opioid Use (Tolerant)	1.50	[.38, 6.00]
Ethnicity (White)	1.17	[.316, 4.32]
Gender (Female)	.74	[.187, 2.92]
Age	1.00	[.95, 1.06]

Note. *OR* = odds ratio; predictor reference value is noted in parentheses for categorical variables