Evaluating the Safety of the Hand Surgery Procedure Room: A Single-Center Cohort of 1,404 Surgical Encounters

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Purpose Performing hand surgeries in the procedure room (PR) setting instead of the operating room effectively reduces surgical costs. Understanding the safety or complication rates associated with the PR is important in determining the value of its use. Our purpose was to describe the incidence of medical and surgical complications among patients undergoing minor hand surgeries in the PR. Methods We retrospectively reviewed all adult patients who underwent an operation in the PR setting between December 2013 and May 2019 at a single tertiary academic medical center by 1 of 5 fellowship-trained orthopedic hand surgeons. Baseline patient characteristics were described. Complication rates were obtained via chart review.

Results For 1,404 PR surgical encounters, 1,796 procedures were performed. Mean patient age was 59 ± 15 years, 809 were female (57.6%), and average follow-up was 104 days. The most common surgeries were carpal tunnel release (39.9%), trigger finger release (35.9%), and finger mass or cyst excision (9.6%). Most surgeries were performed using a non-pneumatic wrist tourniquet (58%), whereas 42% used no tourniquet. No patient experienced a major medical complication. No procedure was aborted owing to intolerance. No patient required admission. No intraoperative surgical or medical complications occurred. Observed complications included delayed capillary refill requiring phentolamine administration after a trigger thumb release performed using epinephrine without a tourniquet (n = 1; 0.1%), complex regional pain syndrome (n = 3; 0.2%), infection requiring surgical debridement (n = 2; 0.2%), and recurrent symptoms requiring reoperation (n = 8; 0.7%).

Conclusions In this cohort of patients in whom surgery was performed in a PR, there were no major intraoperative surgical or medical complications. There was a low rate of postoperative infection, development of complex regional pain syndrome, and a low need for revision surgery. These observations do not support the concern for safety as a barrier to performing minor hand surgery in the PR setting. (*J Hand Surg Am. 2021;46(7):623.e1-e9. Copyright* © 2021 by the American Society for Surgery of the Hand. All rights reserved.)

Type of study/level of evidence Therapeutic IV.

Key words Complications, elective hand surgery, procedure room.



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0363-5023/21/4607-0015\$36.00/0 https://doi.org/10.1016/j.jhsa.2020.11.018 HE EMPHASIS ON IMPROVING THE value of health care delivery has increased in importance in recent decades, in part owing to policies that allow for value-based payment models. The value of care may be thought of as the outcome or level of improvement per unit cost. One means of improving the value of care is through decreasing surgical costs while maintaining comparable clinical, functional, and safety outcomes.

There is no question that performing minor hand surgery in the procedure room (PR) setting leads to reduced surgical costs, compared with using the operating room. Performing hand surgery in the PR with local-only anesthesia has been shown to decrease the need for costly preoperative medical testing.⁶ Recent literature also demonstrated that moving minor hand surgeries out of the operating room and into the PR is an effective means of directly decreasing surgical encounter costs.^{7–11} Direct surgical costs for carpal tunnel release (CTR) in the operating room range from sixfold to 29-fold higher than the cost of performing open CTR in the PR. A similar trend was reported for trigger finger release (TFR), for which performing surgery in the operating room was 2.2-fold to 3.2-fold more costly than in the PR. 8 Other studies with similar observations exist. 9,11-14

Less is known about the second component of value in relation to the PR: safety and outcomes. Several published reports exist in which CTR, TFR, hardware removal, nail ablation, tendon repair, de Quervain release, and Dupuytren open palmar fasciectomy were successfully performed under widelocal-only anesthesia, awake, no tourniquet (WALANT) protocol in the PR setting.^{7,8,11,15–17} Multiple studies have reported complications associated with performing hand surgery in the PR. 14,18-20 Some of these studies are limited in that they evaluated only specific procedures such as CTR18,19 or TFR. 14 Therefore, information regarding the safety of additional hand procedures performed in the PR could be informative.

Given the absence of detailed information regarding complication rates associated with performing minor hand surgeries in the PR, the purpose of this study was to describe the rate of major and minor complications for a large cohort of patients treated by fellowship-trained hand surgeons in the PR setting.

MATERIALS AND METHODS

This study was approved by our institution's review board. We retrospectively reviewed all patients

treated in the PR setting by 1 of 5 fellowship-trained orthopedic hand surgeons at our tertiary academic medical center between December 2013 and May 2019. Any patient meeting the indications for minor hand surgery during the study period was potentially a candidate for the PR instead of the operating room. Surgical setting selection was determined using shared decision-making. Although patients with decompensated medical comorbidities were considered ineligible for elective surgery in general, American Society of Anesthesiologists scores and comorbidities were not used as exclusion criteria for eligibility for the PR. Therefore, patients with substantial but stable medical comorbidities were available for inclusion in the study. Manual chart review of all clinic, emergency room, and hospital visits and procedural notes by the first author (A.R.S.) identified the procedures performed, associated diagnoses, use of epinephrine or tourniquets, intraoperative medical and surgical complications, and postoperative complications. All postoperative follow-up visits were conducted in person. Through review of the medication reconciliation in the electronic medical record, we also recorded whether diazepam was ordered before surgery and whether narcotics were prescribed after surgery.

Wide-awake, local-only anesthesia, no tourniquet protocol

Preoperative medical or anesthesia evaluation was not required for patients regardless of comorbidities. The WALANT surgeries were performed in a PR located adjacent to the operating rooms in an ambulatory surgical center. From the waiting room, patients were brought directly to the PR and placed supine. The patient's arm or arms were placed on an adjacent mobile hand table and a 5-mL injection of local anesthesia was administered in a sterile fashion at the appropriate operative site before formal draping, using a formulation of 4.5 mL 1% lidocaine and 4.5 mL 0.5% bupivacaine buffered with 8.4% sodium bicarbonate. The addition of epinephrine depended on the surgeon and procedure, and the use of phentolamine was available in case critical digital ischemia occurred. 15,21,22 Tourniquet usage was likewise surgeon-dependent.

Patients were not required to disrobe; the arm was prepped and sterilely draped. Fasting and/or holding of home medications, including anticoagulation agents, was not required in preparation for the operation. Cardiovascular monitoring was not used and an intravenous line was not placed. Intraoperative antibiotics (intravenous or oral) were not administered. Procedure room staffing included the attending hand

Variable	Level	Summary $(N = 1,404)$	Missing,
Age	Mean (SD)	59 (15)	0
	Median (IQR)	61 (49-71)	
	Range	(17–96)	
Sex	Female	809 (57.6%)	0
	Male	595 (42.4%)	
Race	White or Caucasian	1,202 (85.6%)	0
	Hispanic/Latino	103 (7.3%)	
	Other	30 (2.1%)	
	Asian	29 (2.1%)	
	Black or African American	12 (0.9%)	
	Patient refused	11 (0.8%)	
	American Indian and Alaska Native	7 (0.5%)	
	Native Hawaiian and other Pacific Islander	6 (0.4%)	
	Choose not to disclose	4 (0.3%)	
ody mass index	Mean (SD)	29.64 (7.56)	29
,	Median (IQR)	28.20 (24.60-32.90)	
	Range	(14.90-77.80)	
moking	Yes	70 (5%)	9
	No	1,325 (95%)	
Diabetes	Yes	161 (11.5%)	0
	No	1,243 (88.5%)	ŭ
Opioids	Yes	169 (12%)	0
	No	1,235 (88%)	
Follow-up, d	Mean (SD)	105 (222)	0
	Median (IQR)	14 (13–63)	V
	Range	(0-1,617)	
Death	Yes	14 (1%)	0
	No	1390 (99%)	U
ita	1	1,124 (80.1%)	0
Site	2	254 (18.1%)	U
	3	26 (1.9%)	
ttanding provider	A	12 (0.9%)	0
ttending provider			U
	В	354 (25.2%)	
	C	156 (11.1%)	
	D	617 (43.9%)	
	E	265 (18.9%)	7.6
isurance	Commercial	784 (59%)	76
	Medicare	439 (33.1%)	
	Medicaid	54 (4.1%)	
	Self-pay	18 (1.4%)	
	Workers' compensation	17 (1.3%)	
	Other government	13 (1%)	
	Other	3 (0.2%)	

Variable	Level	Summary $(N = 1,404)$	Missing, r
American Society of Anesthesiologists score	0	506 (49.7%)	385
	1	54 (5.3%)	
	1E	1 (0.1%)	
	2	289 (28.4%)	
	2E	2 (0.2%)	
	3	157 (15.4%)	
	3E	2 (0.2%)	
	4	7 (0.7%)	
	5	1 (0.1%)	

surgeon, a medical assistant whose primary role was to help maintain sterility, a hand surgery fellow or resident, and a registered nurse. After completion of the procedure, patients received postoperative care instructions and were discharged with self-care directly to home.

Variables of interest were descriptively summarized at the visit level (n=1,404). For continuous variables, mean, SD, median, interquartile range, and range were summarized. For categorical variables, frequency and percentage were calculated. Statistical significance was assessed at .05 using 2-tailed tests.

Based on the overall complication rate of 2.5% as reported in the study by Lipira et al,²³ with a sample size of 1,400 we expected a 95% confidence interval of 1.7% to 3.5% (a width of 1.8%) to describe the complication rate of the current study. Because the infection rate was 0.6%, the 95% confidence interval had greater precision, at 0.3% to 1.2% (a width of 0.9%).

RESULTS

A total of 1,796 procedures were performed for 1,263 patients within 1,404 unique procedural encounters. Considering that 127 patients had multiple procedure encounters over the study period, the cohort was 57.6% female, average age 59 years (SD, ± 15 years). Additional demographic data are presented in Table 1. The maximum number of procedures performed at a single encounter was 6; a single surgical procedure was performed for 1,083 of the encounters (Table 2). Median follow-up was 14 days (interquartile range, 13–63 days). Local anesthetic with epinephrine was used in 35.8% of encounters and

plain local anesthetic was used in the remainder. A nonpneumatic tourniquet (HemaClear, Grandville, MI) was used in 58% of encounters; no tourniquet was used in the remainder. The top 3 procedures were CTR (717), TFR (645), and digital mass excision (173). Numbers of procedures performed are shown in Figure 1. Postoperative narcotics were prescribed to 559 patients (39.8%).

Of the 1,404 procedural encounters, no patients required admission to the hospital and no procedures had to be aborted owing to patient intolerance or surgeon inability to complete the procedure for any reason. No intraoperative medical complications were observed.

No evidence of iatrogenic nerve, artery, or tendon laceration was observed during surgery or at subsequent follow-up visits. Only one surgical complication was identified: delayed capillary refill requiring phentolamine administration after a trigger thumb release. During the procedure, a tourniquet and local anesthetic with epinephrine was used; this patient had normal capillary refill after the procedure. About 6 hours after surgery, the patient noticed that the finger appeared blue. She was instructed to come back to clinic immediately. Upon examination, the tip of the operative digit had a blueish discoloration, decreased turgor, and absent Doppler arterial signals. After subcutaneous administration of phentolamine, perfusion normalized within minutes and was normal at the 2-week postoperative visit.

During the study period, 14 of the 1,263 patients died: 10 deaths occurred more than 1 year after surgery, one death was between 6 and 12 months after surgery, one occurred between 3 and 6 months after surgery, and 2 patients died less than 3 months after

Variable	Level	Summary $(N = 1,404)$	Missing, n
Procedures in single visit (continuous), n	Mean (SD)	1.28 (0.59)	0
	Median (interquartile range)	1.00 (1.00-1.00)	
	Range	(1.00-6.00)	
Total procedures in single visit (categorical), n	1	1,083 (77.1%)	0
	2	265 (18.9%)	
	3	41 (2.9%)	
	4	13 (0.9%)	
	6	2 (0.1%)	
Unilateral vs bilateral surgeries	Unilateral	1,226 (87.3%)	0
	Bilateral	178 (12.7%)	
Tourniquet use	Yes	817 (58.2%)	0
	No	587 (41.8%)	
Epinephrine use	Yes	503 (35.8%)	0
	No	901 (64.2%)	
Preoperative valium ordered	Yes	35 (2.5%)	0
	No	1,369 (97.5%)	
Postoperative narcotics ordered	Yes	559 (39.8%)	0
	No	683 (48.6%)	
	Already taking	162 (11.5%)	

surgery (one at 3 weeks and one at 4 weeks). The patient who died 4 weeks after surgery for TFR had known coronary artery disease with ischemic cardiomyopathy and was doing well at the 2-week postoperative visit with the hand surgeon. Although this patient had prescheduled coronary bypass grafting surgery performed 3 weeks after the PR visit, the cause of death is unknown. The patient who died 3 weeks after surgery after TFR had known diabetes, chronic obstructive pulmonary disease, and heart failure with reduced ejection fraction. Documented oxygen saturations were within normal limits within the week before hand surgery, no complications were noted during surgery, and the patient reported doing well when contacted by phone on postoperative day 1. The cause of death, or whether the procedure was contributory, is unknown for this individual.

Of the 1,207 visits for 1,070 patients who had recorded follow-up encounters, 7 patients had superficial skin infections requiring administration of oral antibiotics (0.6%), 2 of which went on to require surgical debridement in the operating room (0.2%). There was one CTR patient with an infection (0.2%) and 5 TFR patients (1.0%). Recurrence of symptoms occurred in 14 patients: 6 were observed after a needle aponeurotomy, 3 after TFR, 4 after mass excisions, and one after a nail ablation. Five required

reoperations in the operating room (3 needle aponeurotomies and 2 mass excisions) and 3 had reoperation in the PR (one nail ablation, one mass excision, and one TFR). Postoperative development of complex regional pain syndrome was noted in 3 patients at follow-up (0.2%). All had undergone CTR. The symptoms of one of these patients resolved by 4 months after surgery and one patient was doing well after a stellate block 6 months after CTR. The final patient continued to have symptoms at 12 months after surgery despite multiple stellate injections. A comprehensive summary of all major and minor complications is shown in Table 3.

DISCUSSION

The main finding of this study was that surgical procedures performed in the PR setting had a low rate of overall complications. No major intraoperative medical or iatrogenic surgical complications were observed in 1,404 procedural encounters and 1,796 individual surgical procedures. Observed rates of postoperative complications, including those requiring unplanned reoperation, were low. Taken together, these findings suggest that performing minor hand surgeries in the PR setting is safe. Although the PR at our institution is located in an office-like room within an ambulatory surgery center, we

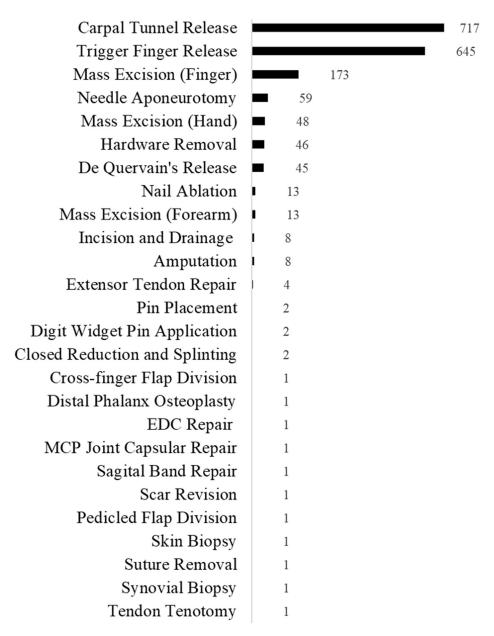


FIGURE 1: Number of procedures performed. EDC, extensor digitorum communis; MCP, metacarpophalangeal.

believe our findings are likely generalizable to any PR setting: the common denominator for the PR, whether in-office, associated with a surgery center, or within a tertiary or community hospital, is the use of surgeon-administered local anesthesia outside the operating room and a lack of anesthesia support.

Our results with respect to a low rate of complications are consistent with prior literature for minor hand surgeries. Bismil et al²⁰ also demonstrated no major intraoperative medical or surgical complications for 1,000 procedures performed in the PR. Leblanc et al¹⁹ and Halvorson et al¹⁸ both demonstrated low infection rates (0.4% and 2.2%, respectively) after CTR performed in the PR. The use of

WALANT for larger surgeries such as distal radius fracture fixation and trapeziectomies has also been shown to be safe. 24–26 Our findings are notable in that this is the first large cohort study to evaluate complication rates of all elective hand surgeries in addition to CTR and TFR (de Quervain, mass excision, needle aponeurotomy, etc) in the United States. Our results demonstrate that many small hand procedures can be safely performed in the PR setting. The results of our study are also consistent with rates previously demonstrated for similar procedures performed in the operating room. The risk for major medical and surgical complications in the current cohort is similar to that seen for hand surgery

Complication	n (%)
Major complications	
Had to abort procedure owing to patient intolerance	0
Phentolamine use	1 (0.1%)
Intraoperative surgical complication	1 (0.1%)
Intraoperative medical issue	0
Admitted on date of surgery	0
Nerve, artery, or tendon transection complication in follow-up	0
Recurrence and reoperation in operating room	5 (0.4%)
Recurrence and repeat surgery in PR	3 (0.3%)
Infection requiring surgical debridement in operating room	2 (0.2%)
Complex regional pain syndrome	3 (0.2%)
Minor complications	
Flexion contracture 0° to 10°	61 (5.0%)
Flexion contracture 11° to 20°	11 (0.9)
Flexion contracture 21° to 30°	3 (0.2%)
Flexion contracture >30°	1 (0.1%)
Infection total	7 (0.6%)
Infection necessitating administration of antibiotics	5 (0.4%)
Lacks 5° full flexion of proximal interphalangeal joint	1 (0.1%)
Persistent numbness	9 (0.7)
Persistent pain	3 (0.2%)
Persistent catching	2 (0.2%)
Persistent symptoms (pronator release)	1 (0.1%)
Recurrence no reoperation	6 (0.5%)
Stiffness	1 (0.1%)
Persistent numbness, steroid injection given	1 (0.1%)

performed in the operating room. Lipira et al²³ demonstrated that the risk for myocardial infarction, pulmonary embolism, shock, stroke, hemorrhage, or nerve injury for outpatient hand surgery all was less than 0.1%. The minor complication rate for the current cohort was similar and often qualitatively lower than published operating room values. In this study, we observed an overall rate of infection requiring operative debridement of 0.5%. This is similar to the findings of Tosti et al²⁷ and Lipira et al,²³ both of whom demonstrated overall infection rates after elective hand surgeries to be approximately 0.7%.; however, the findings were contrary to those of Platt et al,²⁸ who found the rate of surgical site infections for elective hand surgeries to be around 11%, which

sum of complications does not represent the sum of patients with complications.

is questionably high. Previous literature indicated that the infection rate is 1% to $11\%^{29,30}$ for CTR and 5% to 6%. TFR, values qualitatively higher than the current rates of 0.2% and 1%, respectively. Although limitations exist regarding diagnosis, the incidence of complex regional pain syndrome after CTR was previously demonstrated to be 2.1% to 8.3%, 33,34 which is qualitatively greater than the 0.3% rate observed in the current cohort. Recurrence of CTS requiring reoperation has been shown to be 2% to 8%, 35,36 which is qualitatively greater than the 0.2% in the current study. Finally, a Cochrane review of 14 randomized controlled trials found the recurrence of trigger finger after surgery to be approximately 7%, 37 in contrast to the 0.2% rate observed in

the current study. Rhee et al¹¹ found the complication rate of clinic-based WALANT for a spectrum of minor hand surgeries to be 3%. In their study of 100 consecutive patients, the postoperative infection rate was 1%. Phentolamine use was not required and the patients in that study did not experience major medical complications or require hospital admission or monitoring after surgery. However, the strength of this finding was limited by the low sample size of the study (100 patients). In total, the current results indicated that the use of the PR for hand surgery is comparably safe in terms of low complication rates in relation to those described in the literature for minor hand surgeries.

Our study had several limitations that warrant discussion. The retrospective nature of the study makes it susceptible to selection bias. Our study did not evaluate patient-level factors that might have an impact on a surgeon's likelihood to offer the PR or the patient's preference in selecting the PR versus the operating room. It is likely that differences exist between patients who opted to be treated in the PR and those who declined. These differences might have biased our results, which highlight the benefits of a randomized study design. Our study design and results do not allow us to comment on the potential for litigation or liability related to potential major intraoperative complications that occur in the PR compared with those in the operating room; these issues likely vary by country, state, and the specific medicolegal milieu of each hospital system. Although these concerns may still pose a barrier for some surgeons or health care administrators to implement the PR, our results and those of other published studies on PR complications do not support a level of complications that exceeds that of the operating room. Although we conclude that the PR is safe with a low complication rate that is comparable to that of historical complication rates among operating room patients, a formal statistical comparison between the current observed rates and internal (eg, a control group) or historic complication rates was not performed. A subjective comparison of our results with historical published complications is also limited given possible discrepancies in defining and reporting complications, in addition to differences in the perioperative and operative management and follow-up course. A large sample would be needed to evaluate differences in safety adequately between procedures performed in the PR versus the operating room. Future work possibly using administrative data is needed to clarify further differences in safety and complications between surgical settings. Given that the median follow-up duration of the study was 14 days, it is likely that our study might not have captured all possible complications such as recurrences and the need for reoperation. In addition, 193 patients had no follow-up visits. It is unknown whether these patients had major complications and decided to pursue care elsewhere. The short mean follow-up of 14 days limits the strength of the analysis of reoperation rates for recurrent or persistent symptoms. Finally, this study did not evaluate the clinical or functional outcomes of patients treated in the PR.

Given that the complication rates seen in our study are low and comparable to or lower than those reported for similar procedures performed in the operating room, we conclude that concern for major medical and surgical complications should not be a barrier to performing minor hand surgeries in the PR setting. In fact, in light of these findings and literature supporting patient satisfaction and overall lower costs associated with the PR, we recommend the use of the PR for appropriately qualified patients when performing minor hand surgeries.

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