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Original Research

A Comparison of Open Carpal Tunnel Release Outcomes Between Procedure Room and Operating Room Settings



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Purpose: Carpal tunnel release (CTR) surgical costs are minimized when performed in the procedure room (PR) setting, compared with the operating room. However, it remains unclear whether outcomes differ between surgical settings. Our purpose was to compare outcomes at 1 year or greater follow-up after open CTR between patients treated in PR versus operating room settings using the Boston Carpal Tunnel Questionnaire (BCTQ).

Methods: A change in clinical care protocols at our institution occurred in 2014. Before this, all CTRs were performed in the operating room; thereafter, these were transitioned to the PR. Adult patients who underwent isolated unilateral or bilateral open CTR in either surgical setting were considered for inclusion, in which procedures were conducted between January 2014 and October 2018 for the PR group and January 2009 and March 2014 for the operating room group. The Functional Status Scale (FSS) and the Symptom Severity Scale (SSS) components of the BCTQ were collected for all eligible patients at a minimum of 1 year after surgery. We used univariate and multivariable linear regression to determine whether postoperative BCTQ scores were equivalent between PR and operating room groups within a threshold of one-fourth of the lowest estimates of the minimal clinically important difference.

Results: No differences in demographics, comorbidities, or insurance type were observed between the 104 PR and 112 operating room patients. Survey response rate was 25% and 25% for the PR and operating room patients, respectively. At a mean follow-up of 3 ± 1 years, FSS and SSS scores were equivalent between PR and operating room groups on bivariate analysis. The multivariable equivalence test also demonstrated equivalent FSS and SSS scores between PR and operating room groups within a one-fourth minimal clinically important difference threshold while controlling for age, sex, presence of diabetes or thyroid disease, unilateral versus bilateral CTR, and surgeon.

Conclusions: Clinical outcomes did not differ between PR and operating room settings after open CTR.

Type of study/level of evidence: Therapeutic III.

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Carpal tunnel syndrome is common, and frequently surgical management is indicated and offered.^{1,2} Traditionally, open carpal tunnel release (CTR) surgery has been performed in the

operating room. Recently, efforts have been made to transition from the operating room to the clinic or procedure room (PR) setting for CTR.^{3,4}

Previous literature demonstrated that performing CTR in an ambulatory or clinic-based PR with wide-awake local anesthesia no tourniquet⁵ is a safe option with few reported complications.^{3,4} The PR setting has also been shown to reduce costs by eliminating the need for preoperative medical testing, evaluation, and monitoring by anesthesia, the cost of the operating room, and postoperative care by postanesthesia care unit staff.^{6–9} Wide-awake local

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anesthesia no tourniquet was demonstrated to reduce health care costs at a medical center in Canada by Leblanc et al,³ and was since shown to provide opportunities for cost savings in the National Health Service,¹⁰ in the US Military Health Care System,¹¹ and among other US and European institutions.^{4,9,12–14} From these studies and additional studies evaluating the cost savings of other hand surgeries performed with wide-awake local anesthesia no tourniquet,^{15–17} it is clear that moving hand surgeries from the operating room into the PR has the potential to improve the value of care offered to patients by reducing costs.¹⁸

It is less clear, however whether long-term patient-reported outcomes differ between patients treated in the PR setting versus those treated in the operating room after CTR. White et al⁹ demonstrated no difference in postoperative pain scores in patients treated with CTR surgery in the clinic versus the operating room. The study by Rabonowitz et al¹⁹ comparing trigger finger releases (TFR) performed in the clinic versus the operating room showed that patients treated in the PR reported greater satisfaction with the experience than those treated in the operating room. Other studies demonstrated similar results.^{4,6,14,16} We are unaware of any studies in the literature that compared patient-reported functional outcomes between surgical settings for CTR. Value was previously described as outcome per unit cost.^{20,21} Because the literature comparing outcomes between the PR and the operating room is lacking, the results of this study have the potential to determine whether performing CTR in the PR truly has greater value than using the operating room.

The purpose of our study was to compare the clinical outcome, as measured by the Boston Carpal Tunnel Questionnaire (BCTQ) Symptom Severity Scale (SSS) and Functional Status Scale (FSS), between patients treated with open CTR in the PR versus the operating room. Our null hypothesis was that there would be no difference in the BCTQ score at a minimum of 1 year after surgery between open CTR performed in the PR compared with the operating room.

Materials and Methods

This study was approved by our institution's review board. Adult patients (aged 18 years or greater) who underwent isolated unilateral or bilateral CTR surgery by 1 of 5 fellowship-trained orthopedic hand surgeons at a single tertiary academic medical center were available for inclusion in the study. We excluded patients who underwent additional procedures simultaneous with the index CTR. The preoperative, operative, and postoperative protocols for both the PR and the operating room at our institution were previously described elsewhere.¹⁷

The PR was established at our center within an ambulatory surgery center in 2014 and was thereafter available for small hand procedure use. Before this date, all CTR surgeries occurred in the operating room. For the PR group, patients were identified by Current Procedural Terminology code 64721 with treatment dates between December 2013 and December 2018. Manual chart review was used to verify surgical procedures and the surgical setting. After initiation of the PR, 334 isolated unilateral and 81 isolated bilateral CTRs were performed in the operating room. Demographic data were obtained through a combination of electronic data acquisition and manual chart review. The BCTQ was administered through Research Electronic Data Capture. An e-mail link was sent to patients with instructions on how to complete the survey. Patients with missing or invalid e-mails were contacted by telephone in an attempt to obtain an updated working e-mail. Two additional follow-up e-mails were sent to patients with incomplete surveys 1 week apart, as needed. Patients who did not complete the survey were contacted by telephone to determine whether they had

received a working survey link or experienced technical difficulties with the survey. We attempted to contact patients by telephone only twice. Patients without a working e-mail were queried to complete the survey by telephone (n = 3).

For the operating room group, BCTQ responses were previously obtained for patients treated with CTR for a prior study²² conducted at our institution that had a wider scope. For the current study, we included only the subset of patients who had 1 year or greater follow-up after isolated open unilateral or bilateral CTR (eg, those undergoing additional simultaneous surgeries were excluded) performed by fellowship-trained orthopedic hand surgeons. Specific details regarding the approach to data collection can be found in the original study, which included telephone, e-mail, and verbal score acquisition.²²

Differences in patient and surgical encounter demographics between the PR and operating room groups were compared using *t* tests for continuous variables and chi-square or Fisher exact test for categorical variables. To assess whether postoperative BCTQ scores between the PR and operating room groups were equivalent, we employed the 2 one-sided *t* test (TOST) procedure at α , in which we tested whether the 90% confidence intervals (CIs) for the difference between PR and operating room groups fell within a prespecified range.²³ Under TOST, the null hypothesis (nonequivalence) is that the difference between means (*Diff*) is either below or above a prespecified threshold ($H_0: Diff \leq -\delta$ or $Diff \geq +\delta$) and the alternative hypothesis (equivalence) is that *Diff* is within the equivalence margin ($H_1: -\delta < Diff < \delta$). We determined an equivalence margin from the previously reported minimal clinically important difference (MCID) values for the 2 components of the BCTQ: 1.45 for the FSS and 1.60 for the SSS, based on the 6-month point with an SD of 0.7 for both the FSS and SSS.²⁴ We selected one-fourth of these MCID estimates as the detection threshold for potential differences between FSS and SSS scores for PR and operating room cohorts, such that if the 2 cohorts demonstrated equivalent outcomes, it would be a rigorous finding well below the threshold of clinical relevance. Thus, the threshold for equivalence on the FSS between PR and operating room groups was ± 0.36 points, and that for the SSS was ± 0.4 . We applied the TOST approach in both univariable and multivariable analyses, in which the multivariable analysis consisted of linear regression models that also adjusted for potential confounders (age, sex, diagnoses of diabetes and thyroid disease, unilateral vs bilateral CTR, and surgeon). In each case, we report the difference and the associated 90% CI and *P* value.²³ $P < .05$ rejects the null hypothesis of nonequivalence, suggesting that the difference falls within the equivalence margin $[-\delta, \delta]$.

An a priori power calculation was conducted based on the equivalence margins of ± 0.40 for the SSS and ± 0.36 for FSS, and SDs reported by Ozer et al²⁴ of 0.7. Based on these SDs and equivalence margins, we would have 90% power at an $\alpha = 0.05$ to detect equivalence with 134 total patients for SSS and 166 total patients for the FSS, in which PR and operating room patients were available at a 1:1 ratio.²⁴

Results

Of the 414 CTR patients treated in the PR, 47 were unable to be contacted and 104 completed the survey, for a response rate of 25%. We identified 443 open CTR patients treated in the operating room. Of these, 188 were unable to be contacted, 13 had an incomplete survey, and 112 completed the BCTQ, for a response rate of 25%. Overall mean follow-up was 3 ± 1 years after surgery (range, 1–6 years), with no significant difference in follow-up duration between PR and operating room groups ($P = .36$). There were significant differences in handedness and provider between PR and operating room groups. However, there were no differences in age,

Table 1
Comparison of Surgical Encounter Demographics: Procedure Room Versus Operating Room Settings

Variable	Levels	Procedure Room (n = 104)	Operating Room (n = 112)	P Value
Age, y*	Mean (SD)	58 (15)	55 (17)	.20
Male†	n (%)	37 (36%)	40 (36%)	.98
Handedness‡	Left	14 (13%)	6 (5%)	<.05
	Right	90 (86%)	67 (60%)	
	Not reported	0 (0%)	39 (34.8%)	
Body mass index*	Mean (SD)	31.8 (10.4)	30.7 (7.4)	.39
Race†	White	97 (94%)	101 (91%)	.38
Provider‡	A	29 (28%)	44 (39%)	<.05
	B	26 (25%)	41 (37%)	
	C	36 (35%)	2 (2%)	
	D	1(1%)	25 (22%)	
	E	12 (11%)	0	
Unilateral†	Y	85 (82%)	96 (86%)	.43
Follow-up, y*	Mean (SD)	3 (1)	3 (1)	.36
Insurance type‡	Commercial	58 (56%)	64 (57%)	.16
	Government other	4 (4%)	11 (10%)	
	Medicaid	2 (2%)	0	
	Medicare	39 (37%)	34 (30%)	
	Workers' compensation	1 (1%)	3 (3%)	
Diabetes†	Y	18 (17%)	20 (18%)	.92
Thyroid†	Y	12 (11%)	16 (14%)	.55
Rheumatoid†	Y	1 (1%)	3 (3%)	.62
Anesthesia‡	Bier block	0	18 (17%)	>.99
	General	0	4 (4%)	
	Local only	0	10 (10%)	
	Monitored anesthesia Care with local	0	74 (69%)	
	Unknown	0	1 (1%)	

* Based on *t* test.

† Based on chi-square test.

‡ Based on Fisher exact test.

sex, race, body mass index, insurance type, rates of unilateral versus bilateral releases, or comorbidities including diabetes, thyroid disease, or rheumatoid arthritis observed between PR and operating room groups (Table 1).

For the PR group, mean FSS score was 1.49 ± 0.74 (interquartile range [IQR], 1–1.75) and the mean SSS score was 1.57 ± 0.83 (IQR, 1–1.93). For the operating room group, mean FSS score was 1.54 ± 0.70 (IQR, 1–1.62) and mean SSS score was 1.61 ± 0.77 (IQR, 1–1.84).

The univariate TOST demonstrated that the FSS and the SSS were equivalent between the PR and the operating room cohorts. The differences were -0.06 (95% CI, -0.11 to 0.22) and -0.04 (95% CI, -0.14 to 0.22), respectively, which were well within the one-fourth MCID thresholds ($P < .05$ for both) (Table 2).

The multivariable TOST likewise showed that the FSS and the SSS were equivalent between the PR and the operating room cohort, in which the differences were 0.15 (95% CI, -0.05 to 0.35) and 0.06 (95% CI, -0.16 to 0.28), respectively, when controlling for age, sex, diagnoses of diabetes and thyroid disease, unilateral versus bilateral, and surgeon ($P < .05$ for both) (Table 3).

Discussion

The main finding of this study is that the clinical outcomes of open CTR surgery performed in either a procedure room or an operating room were equivalent as measured by the BTCQ, with at a minimum of 1 year follow-up after surgery. This was the case for both the SSS and FSS components of the BTCQ. In this study, equivalence thresholds were stringent and defined as one-fourth of the smallest MCID estimates for both scales. The sample size was sufficient to have ample power to detect these small potential differences between PR and operating room groups, which we found were absent. Furthermore, these findings were independent of a variety of clinically relevant comorbidities and surgical factors. Based on these findings, we conclude that patient-reported

outcomes after open CTR are not affected by the choice of surgical setting.

Our study is informative in light of previous literature that evaluated outcome, patient satisfaction, and variations in cost between the 2 surgical settings. We were unable to identify other studies that compared patient-reported functional outcomes for CTR patients treated in the PR versus the operating room. However, a recently published study by Rabinowitz et al¹⁹ evaluated Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire scores in TFR patients treated in the office versus the operating room, which demonstrated that both groups had statistically significant improvement in DASH scores after surgery. Although the patients treated in the clinic had lower postoperative DASH scores compared with those treated in the operating room (26.4 vs 36.5), the study did not directly compare results between in-office and operating room groups, and it is unknown whether this observed difference was statistically significant.

Regarding satisfaction, there is a paucity of literature comparing operating room and PR settings for CTR. However, Rabinowitz et al¹⁹ demonstrated that patients treated with TFR in the clinic were significantly more satisfied with the experience than were patients treated in the operating room. Other studies have likewise demonstrated high rates of satisfaction for clinic-based hand surgeries.^{4,11,14}

Prior literature also demonstrated a low rate of complications associated with the use of the PR or clinic for minor hand surgeries,^{4,15,19} such as Bismil et al,⁴ who noted no major intraoperative surgical complications for 1,000 consecutive hand procedures performed in the PR over 10 years. Although likely lacking enough power, a study by Halvorson et al²⁵ found similar rates of infection after CTR in the PR and operating room in the Veterans Administration setting. A recent database study with a large sample size also found similar rates of surgical and medical complications between CTR patients treated with local-only

Table 2
Univariate Equivalence Test*

Outcome	Procedure Room	Operating Room	PR – Operating Room Difference (90% CI)	Margin	P Value
FSS [†]	1.49	1.54	−0.06 (−0.11 to 0.22)	±0.39	<.05
SSS [‡]	1.57	1.61	−0.04 (−0.14 to 0.22)	±0.36	<.05

* According to the TOST. We conclude that there was equivalence between the PR and operating room for both FSS and SSS because the 90% CIs are within the specified margins. For equivalence testing, $P < .05$ allows us to reject the null hypothesis that there is a difference between the PR and operating room cohorts and resort to the alternative hypothesis of no equivalence.

[†] For the FSS, the equivalence TOST threshold was set at 0.39 based on one-quarter the MCID estimate of 1.55.

[‡] For the SSS, the equivalence TOST threshold was set at 0.36 based on one-quarter the MCID estimate of 1.45.

anesthesia versus other forms of anesthesia.²⁶ However, that analysis compared anesthesia types rather than surgical setting per se, which highlights the importance of defining complication rates by surgical setting for future studies.

Regarding cost, multiple studies demonstrated that performing hand surgery in the PR is substantially less costly than in the operating room. Kazmers et al¹² demonstrated that the total direct cost of performing CTR in the operating room was sixfold to 29-fold greater than performing CTR surgery in the PR, depending on the anesthesia type and operating room location (ambulatory surgery center vs main hospital). This was consistent with additional studies that estimated the cost of performing CTR in the operating room to be 3.7 to 6.7 times greater than in the clinic.^{3,9,11,13,14} When interpreted together, our finding of equivalent outcomes, combined with prior reports of cost-savings and low complication rates associated with the PR setting, suggests that the value of care for patients undergoing open CTR is greater in the PR setting than in the operating room.¹⁸

Several limitations of our study merit discussion. Our results were derived from 5 surgeons at a single academic institution; therefore, the ability to generalize the results to other practices deserves consideration. Our study examined outcomes between CTR patients treated in the operating room before the introduction of our PR, compared with those of patients treated in the PR after it became the mainstay setting for small hand procedures at our institution. The downside to this design is that there can be temporal changes in surgical practice or care that could potentially affect outcomes and confound results. However, to our knowledge, there were no major changes to our practice during the study period. Given the shared decision-making process employed when obtaining consent from patients in either surgical setting, we were unable to account for patient preference when both settings were offered. Although not a consideration for referring a patient to be treated in the PR or the operating room at our institution, it is possible that there were confounding differences between the 415 patients who selected to be treated in the operating room versus those treated in the PR. Although response rates and follow-up duration were similar between PR and operating room groups, our study was limited by a low response rate. It is unclear whether this affected the study results, because we lack data reflecting whether responders and nonresponders experienced different levels of benefit from surgery. Our response rates were consistent with recent findings that demonstrated decreased response rates for long-term follow-up studies.²⁷ Another limitation to our study was a lack of preoperative BCTQ scores available for comparison with the final scores. It is unclear whether the study findings would have differed if we had used the change in BCTQ scores (eg, the difference between postoperative and preoperative scores). Nevertheless, our study is consistent with the methods of Tang et al,²⁸ who compared final BCTQ scores between open and endoscopic CTR. Finally, our study did not directly compare the safety and complication rates between the 2 settings. A difference in safety would be an important consideration when determining the

Table 3
Multivariable Equivalence Test*

Outcome	PR – Operating Room Difference (90% CI)	P Value
FSS [†]	0.15 (−0.05 to 0.35)	<.05
SSS [‡]	0.06 (−0.16 to 0.28)	<.05

* According to the TOST. For equivalence testing, $P < .05$ allows us to reject the null hypothesis that there is a difference between the PR and operating room cohorts and resort to the alternative hypothesis of no equivalence.

[†] For the FSS, the equivalence TOST threshold was set at 0.39 based on one-quarter the MCID estimate of 1.55.

[‡] For the SSS, the equivalence TOST threshold was set at 0.36 based on one-quarter the MCID estimate of 1.45.

appropriate surgical setting, because small differences in rare but devastating injuries such as median nerve transection, if present, could strongly influence the value of one treatment strategy over another.

Our study demonstrated that patient-reported outcomes after open CTR performed in the PR and the operating room were equivalent on the BCTQ. Combining this finding with previous literature demonstrating the reduced cost of the PR compared with the operating room, performing open CTR in the PR has the potential to increase the value of care delivered to indicated patients.¹⁸

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