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Research article

Achievement of the minimal clinically important difference following open proximal hamstring repair

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ABSTRACT

There is a paucity of literature on patient-reported outcome measures (PROMs) following proximal hamstring repair beyond return to play, patient satisfaction and pain improvement. The minimal clinically important difference (MCID) defines the minimum degree of quantifiable improvement that a patient can perceive, but the MCID and predictors of this measure have not been defined for this patient population. This study aimed to define the MCID and determine the efficacy of open proximal hamstring repair through achievement of MCID and identify characteristics predictive of achieving MCID. A retrospective cohort review of an institutional hip registry was conducted, analyzing the modified Harris Hip Score (mHHS) and International Hip Outcome Tool (iHOT-33). MCID was calculated using a distribution-based method. Demographic and clinical variables predictive of achieving MCID were analyzed using univariable and multivariate logistic regression analyses. Thirty-nine patients who underwent open proximal hamstring repair were included. The mean patient age was 48.5 ± 12.4 years, with a mean follow-up of 37.1 ± 28 months. The MCID was determined for each PROM (mHHS—11.8; iHOT-33—12.6). A high percentage of patients achieved MCID for both PROMs (mHHS—85.7%; iHOT-33—91.4%). Univariate logistical regression demonstrated increased age ($P = 0.163$), increased body mass index (BMI; $P = 0.072$), requirement for inpatient admission ($P = 0.088$) and pre-operative iHOT-33 ($P = 0.104$) trended towards clinically significant predictors of not achieving MCID. A high percentage of patients achieved MCID while age, BMI, inpatient admission and pre-operative iHOT-33 appear to influence the achievement of clinically significant outcome in patients undergoing open proximal hamstring repair.

INTRODUCTION

Hamstring strains account for 25–30% of all muscle strains, making this injury the most common muscle strain in the body [1–6]. A majority of these injuries occur at the myotendinous junction and can be treated non-operatively; however, up to 12% involve a tear or avulsion at the proximal hamstring origin [7–9]. Non-operative treatment of retracted and/or complete tears can result in intractable pain, atrophy, weakness and scarring to the sciatic nerve resulting in radicular pain patterns [10, 11]. As a result, surgical intervention is often recommended, especially for young and athletic populations. Furthermore, the frequency of proximal hamstring injuries appears to be on the rise as the middle-aged population has become more physically active and now represents a larger percentage of the patients presenting with a proximal hamstring injury [3].

Patient-reported outcome measures (PROMs) are now established as standard for defining treatment success. As previously defined in the literature, minimal clinically important difference (MCID) is the smallest change in the outcome that a patient is able to appreciate clinically [12–15]. When deciding which is the best treatment for a patient undergoing a surgical proximal hamstring repair, little research has been conducted on patient outcomes beyond patient satisfaction, return to play and pain improvement [16–18]. More specifically, psychometric measures such as MCID of patient-reported hip outcomes have not been determined in this patient population.

Assessing the achievement of meaningful outcome for the operative treatment of proximal hamstring tendon injury is important in order to allow for a more accurate assessment of the efficacy of treatment interventions. The purpose of this study is to (i) define the MCID of patient-reported hip outcomes and determine the efficacy of open proximal hamstring repair and (ii) identify patient and injury characteristics predictive of achieving MCID post-operatively.

METHODS

Patient enrollment and data collection

After institutional review board approval, a retrospective review was performed on a consecutive series of patients who underwent open proximal hamstring repair between September 2010

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and April 2019. Patient and operative demographics, clinical data, and patient-reported outcomes were prospectively collected in a secure institutional registry. Indications for proximal hamstring repair were as follows: partial avulsions that have failed non-operative management for a minimum of 6 months, 2-tendon tears with >2 cm of retraction in young active patients and 3-tendon tears [19]. Exclusion criteria included: incomplete pre-operative or 1-year post-operative PROMs, concomitant procedures beyond hamstring repair and prior operative treatment of the ipsilateral proximal hamstring. Acuity of the injury was defined as follows: acute ($\leq$6 weeks) and chronic (>6 weeks).

Operative technique

All open proximal hamstring repairs were performed by one of three fellowship-trained sports medicine surgeons at a high-volume tertiary care hospital. Patients are placed in the prone position with the operative leg free allowing knee flexion to relieve hamstring tension during repair. A microvascular trained co-surgeon (hand or plastic surgeon) is frequently used to assist with exposure, especially for chronic cases where significant scar tissue is expected and for cases where a neurolysis was indicated. The decision to use a transverse gluteal incision versus a longitudinal incision is largely dictated by the co-surgeons preference. The gluteal fascia is opened and the gluteus maximus is retracted proximally. The hamstring fascia is then opened and the retracted tendon is identified. Prior to the placement of deep retractors around the ischium, the sciatic nerve is identified and protected, and a neurolysis is performed when indicated. Care is taken to protect the posterior femoral cutaneous nerve, which can be traced proximally to aid in identification of the sciatic nerve. The ruptured proximal hamstring tendon is identified and mobilized. Deep Hohmann retractors are placed to expose the ischial tuberosity, which is then debrided of soft tissue to create a bleeding bony surface to facilitate biological healing. The number of anchors placed in the ischial tuberosity for repair depends on the size of the tear and quality of the tendon. Once the anchors are placed, the free sutures from the anchors are passed through the tendon edges. The knee is flexed to relieve tension on the hamstring tendon while the sutures are tied. Adequate re-approximation of the tendon to the ischial tuberosity is confirmed. The wound is copiously irrigated and closed in layers. Patients are placed in a hinged knee brace to maintain knee flexion in order to prevent tension on the repair.

Post-operative rehabilitation protocol

The post-operative rehabilitation regime was standardized for all proximal hamstring repairs. A full-time knee brace is used for 6 weeks to keep the knee flexed to 30°, limiting tension on the repair site and weight bearing is limited to toe touch weight bearing. During the next 6 weeks, patients are progressed to full weight bearing, weaned from their brace and assistive devices as tolerated. At 12 weeks post-operatively, patients are permitted to begin strengthening exercises. Patients are allowed to return to activities as tolerated no sooner than 16 weeks post-operatively. Return to sport criteria is defined based on (i) dynamic neuromuscular control with multi-plane activities at high velocity without pain or swelling; (ii) less than 10% deficit for side-to-side hamstring comparison on Biodex testing and (iii) less than 10% deficit on functional testing profile.

Patient-reported clinical outcomes

The modified Harris Hip Score (mHHS) and International Hip Outcome Tool (iHOT-33) were obtained pre-operatively and at final follow-up. To identify differences in meaningful outcome improvement in patients undergoing open proximal hamstring repair, the MCID was calculated using the distribution-based method. This method involved calculating the half standard deviation for the mHHS and iHOT-33 in the current study, consistent with previous studies [12–15, 20].

Statistical analysis

Patient demographics assessed included length of follow-up, laterality, sex, age, BMI, smoking history and history of diabetes. Injury demographics assessed included mechanism, number of tendons involved, tendon retraction, presence of neurological symptoms, acuity, number of anchors used for repair, presence of a plastic surgeon for exposure, disposition and length of stay. The mean and standard deviation were reported for continuous variables. Continuous data were analyzed with paired *t*-tests. Univariate logistical regression analysis was performed to assess associations between achieving MCID and demographic variables. Multivariate conditional logistic regression analysis was performed on variables demonstrating a P-value < 0.15 during univariate logistic regression analysis. Statistical analyses were conducted using SPSS statistical software (IBM SPSS Statistics for Windows, version 25.0.0; Armonk, NY: IBM Corp).

RESULTS

One hundred and sixteen patients were identified in the Hospital for Special Surgery Hip Registry, with 39 patients included in this study after the application of the inclusion/exclusion criteria (Fig. 1). The mean follow-up was 37.1 $\pm$ 28.0 months. A majority of the patients were female (66.7%), with a relatively even distribution in laterality. The mean patient age was 48.5 $\pm$ 12.4 years. No patients were diabetic, while 12.8% of patients reported a smoking history (Table I).

Running was the mechanism of injury in 15.4% of the cases, with 28.2% of all injuries resulting from a traumatic mechanism. Tendon retraction was noted in 46.2% of cases, and 10 patients (25.6%) had 5 cm or more of tendon retraction at the time of presentation. A previous study indicated increased difficult to perform the proximal hamstring repair when tendon retraction was >5 cm [21]. Only two patients (5.1%) presented with neurological symptoms. A majority of the repairs were performed using a two (43.6%) or three (28.2%) anchor repair. Patients were frequently admitted overnight and discharged on Post-operative Day 1 (Table II).

Minimal clinically important difference analysis

Patients in the cohort experienced a statistically significant mean improvement in their pre- (53.7 $\pm$ 19.8) to post-operative (90.1 $\pm$ 14.7) mHHS (P-value < 0.01). The distribution-based MCID for the mHHS was 11.8. Post-operatively, 30 patients (85.7%) achieved MCID (Table III). Similarly, patients experienced a statistically significant mean improvement in their

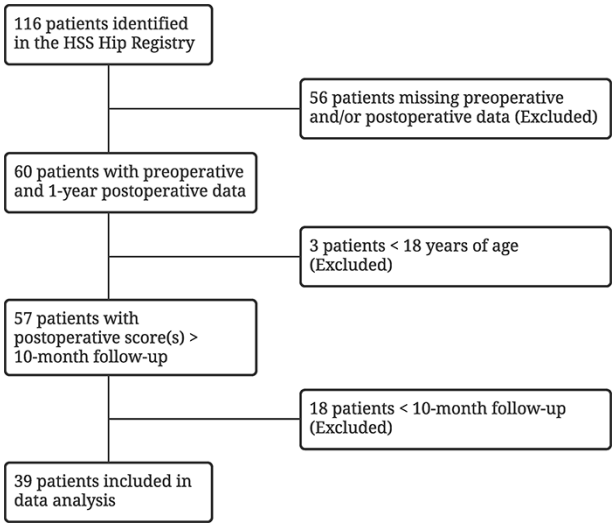

Fig. 1. CONSORT diagram of patient inclusion into the current retrospective study.

Table I. Patient demographics

	N	*Percentage*	*Mean*	*SD*	*Range*
Age (years)			48.5	12.4	19–68
BMI (kg/m^2)			25.3	3.9	18.9–33.9
Follow-up (months)			37.1	28.0	10–112
Total	39	100.0			
Laterality					
Right	21	53.8			
Left	18	46.2			
Sex					
Female	26	66.7			
Male	13	33.3			
Smoking status					
Yes	5	12.8			
No	31	79.5			
Unknown	3	7.7			
Diabetic					
Yes		0.0			
No	37	94.9			
Unknown	2	5.1			

Abbreviations: *N*, total number; SD, standard deviation.

pre- (37.9 ± 16.2) to post-operative (84.4 ± 20.5) iHOT-33 (P-value < 0.01). The distribution-based MCID for the iHOT-33 was 12.6. Post-operatively, 32 patients (91.4%) achieved MCID (Table III).

Logistic regression analysis

On univariate logistic regression analysis, no variables were found to have a statistically significant association with achieving the MCID on the mHHS; however, age (P-value = 0.163) and BMI (P-value = 0.072) were near-significant predictors for not achieving MCID. Multivariate logistic regression analysis of these variables did not reach statistical significance for an association between age (P-value = 0.564) and BMI (P-value = 0.518) and achieving post-operative mHHS MCID (Table IV).

Table II. Injury demographics

	N	*Percentage*
Mechanism (Running)		
Yes	6	15.4
No	27	69.2
Unknown	6	15.4
Mechanism (Traumatic)		
Yes	11	28.2
No	22	56.4
Unknown	6	15.4
Tendons involved		
1–2	10	25.6
3	10	25.6
Unknown	19	48.7
Retraction		
Yes	18	46.2
No	6	15.4
Unknown	15	38.5
Retraction distance		
<5 cm	14	35.9
≥5 cm	10	25.6
Unknown	15	38.5
Neurological symptoms		
Yes	2	5.1
No	35	89.7
Unknown	2	5.1
Acuity		
Acute	15	38.5
Chronic	22	56.4
Unknown	2	5.1
Number of anchors		
1	5	12.8
2	17	43.6
3	11	28.2
Unknown	2	5.1
Microvascular surgeon assistance		
Yes	31	79.5
No	6	15.4
Unknown	2	5.1
Disposition		
Inpatient	35	89.7
Outpatient	2	5.1
Unknown	2	5.1
Length of stay		
0–1	30	76.9
2–6	7	17.9
Unknown	2	5.1

On univariate logistic regression analysis, no variables were found to have a statistically significant association with achieving the MCID on the iHOT-33; however, requirement for inpatient admission (P-value = 0.088) and pre-operative iHOT-33 (P-value = 0.104) were near-significant predictors for not achieving MCID on the iHOT-33. Multivariate logistic regression analysis of these variables did not reach statistical significance for an association between requirement for inpatient admission (P-value = 1.00) and pre-operative iHOT-33 (P-value = 0.437) and achieving post-operative iHOT-33 MCID (Table V).

Table III. PROM MCID analysis

	N	*Percentage*	*Mean*	*SD*	*Range*
mHHS					
Pre-operative			53.7	19.8	7.7–95.7
Post-operative			90.1	14.7	42.9–100
Net change			37.0	23.5	−14.3–84.6
P-value	<0.01				
Distribution-based MCID	11.8				
Patients achieving MCID					
Yes	30	85.7			
No	5	14.3			
iHOT-33					
Pre-operative			37.9	16.2	15.2–72.7
Post-operative			84.8	20.5	17.5–100
Net change			46.6	25.2	−37.1–83.4
P-value	<0.01				
Distribution-based MCID	12.6				
Patients achieving MCID					
Yes	32	91.4			
No	3	8.6			

Table IV. Logistic regression analysis for variables associated with achieving MCID for mHHS

	Univariate analysis (P-value)	*Multivariate analysis (P-value)*
Attending surgeon	0.380	
Laterality	1.000	
Sex	0.337	
Age	0.163*	0.564
BMI	0.072*	0.518
Smoking	1.000	
Mechanism (Running)	1.000	
Mechanism (Traumatic)	1.000	
Tendons involved	1.000	
Retraction	0.537	
Retraction distance	1.000	
Neurological symptoms	1.000	
Acuity	0.625	
Implant	0.454	
Number of anchors	0.572	
Microvascular surgeon assistance	1.000	
Disposition	0.284	
Length of stay	1.000	
Follow-up	0.394	
Pre-operative mHHS	0.394	

*Multivariate logistic regression was performed on variables that achieved a *P*-value < 0.15 during univariate analysis.

Complications

Six patients (15.4%) experienced a total of seven post-operative complications (Table VI). Deep infection (two patients, 5.1%) and superficial vein thrombophlebitis (two patients, 5.1%) were the most common complications. One patient (2.6%) experienced a pudendal nerve injury post-operatively.

Table V. Logistic regression analysis for variables associated with achieving MCID for iHOT-33

	Univariate analysis (P-value)	*Multivariate analysis (P-value)*
Attending surgeon	0.712	
Laterality	0.234	
Sex	1.000	
Age	0.241	
BMI	0.747	
Smoking	1.000	
Mechanism (Running)	0.446	
Mechanism (Traumatic)	0.532	
Tendons involved	0.474	
Retraction	0.486	
Retraction distance	0.429	
Neurological symptoms	1.000	
Acuity	1.000	
Implant	1.000	
Number of anchors	0.392	
Microvascular surgeon assistance	0.453	
Disposition	0.088*	1.000
Length of stay	1.000	
Follow-up	0.729	
Pre-operative mHHS	0.104*	0.437

*Multivariate logistic regression was performed on variables that achieved a *P*-value < 0.15 during univariate analysis.

Table VI. Complications

	N	*Percentage*
Superficial infection	1	2.6
Deep infection	2	5.1
SVT	2	5.1
DVT	1	2.6
Pudendal nerve injury	1	2.6

Abbreviations: SVT, superficial vein thrombosis; DVT, deep vein thrombosis.

DISCUSSION

To the best of our knowledge, this is the first study defining the MCID values for the mHHS (11.8) and iHOT-33 (12.6) PROMs in patients undergoing open proximal hamstring repair. We demonstrated that open proximal hamstring repair is associated with significant improvement in these PROMs at an average follow-up of over 3 years. Furthermore, 85.7% of patients achieved MCID for mHHS and 91.4% achieved MCID for iHOT-33 post-operatively. Age and BMI were near-significant predictors for achieving MCID for the mHHS, while inpatient admission and pre-operative iHOT-33 were near-significant predictors for achieving MCID for the iHOT-33; however, these variables did not reach statistical significance on multivariate logistic regression analysis.

Studies comparing non-operative to operative management of proximal hamstring ruptures have demonstrated superior outcomes following operative intervention [11, 16]. Shambaugh *et al.* compared outcomes following non-operative and operative management of complete, retracted proximal hamstring ruptures in a cohort of 25 patients, concluding that patients treated operatively had a greater likelihood of returning to pre-injury activities [11]. In a systematic review, Harris *et al.* reported significantly better strength testing, endurance levels and return to sport with operative intervention [22]. More recently, Bodendorfer *et al.* published a systematic review and meta-analysis of outcomes following operative and non-operative treatment of proximal hamstring avulsions in 24 studies (795 proximal hamstring avulsions) [16]. The authors concluded that operative intervention resulted in superior outcomes, with significantly higher patient satisfaction, hamstring strength, single-legged hop test and Lower Extremity Function Scale score [16].

Current studies assessing outcomes following proximal hamstring repair largely focus on patient satisfaction, endurance, strength and return to sport [5, 7, 23–28]. There remains a paucity of literature reported on analysis of specific PROMs in this population, with current studies limited to small case series [2, 11, 29–32]. In a case series of 13 patients, at a mean follow-up of 36.9 months, Chahal *et al.* reported a high mean post-operative HHS (90.7 ± 13.9), with nine patients achieving a good or excellent result [2]. Mica *et al.* reported a case series of six patients at a mean follow-up of 31.83 ± 18.9 months, with a post-operative HHS ranging from 86 to 100 [29]. These studies are limited by their small sample size and lack of pre-operative PROMs. Furthermore, these studies do not address the proportion of patients achieving MCID for their reported outcome measure, precluding conclusions regarding the clinical relevance of such findings.

In our study, we found that patients experienced a significant improvement in their pre- to post-operative mHHS (P-value < 0.01) and iHOT-33 (P-value < 0.01) at the final follow-up. We determined the distribution-based MCID for the mHHS (11.8) and iHOT-33 (12.6). We found that a high percentage of patients achieved MCID post-operatively for both the mHHS (85.7%) and iHOT-33 (91.4%) (Table III). These data highlight the efficacy of proximal hamstring repair, with a high percentage of patients experiencing a clinically relevant and statistically significant improvement in PROMs post-operatively. Furthermore, the MCID values serve as useful reference numbers for future studies investigating the efficacy of open proximal hamstring repair.

Bowman *et al.* reported on predictors of clinical outcomes following proximal hamstring repair in 45 patients at a mean follow-up of 29 months [17]. The authors were unable to detect any significant differences in functional outcome scores based on patient age, sex, BMI, smoking status, medial comorbidities, tear grade, activity level or surgical technique [17]. Our data suggest that age and BMI were near-significant predictors for not achieving MCID on the mHHS (Table IV), while requirement for inpatient admission and pre-operative iHOT-33 were near-significant predictors for not achieving MCID on the iHOT-33 (Table V); however, these variables did not reach statistical significance in this cohort.

In a systematic review and meta-analysis, Bodendorfer *et al.* reported that despite finding superior outcomes with operative compared to non-operative management of proximal hamstring injuries, there was a complication rate of 23.17% with operative intervention [16]. A majority of these complications were neurologic in origin [16]. Cvetanovich *et al.* published on the anatomy of neural structures around the proximal hamstring origin, highlighting the close proximity of the pudendal, sciatic and posterior femoral cutaneous nerves [33]. In our series, six patients (15.4%) experienced a complication, with only one (2.6%) neurologic complication (Table VI). Notably, there were no sciatic-nerve-related complications in our cohort. Our only neurologic complication was a pudendal nerve injury, which typically occurs while placing a retractor too far medially around the ischial tuberosity [33]. A microvascular surgeon assisted with exposure in 79.5% of the cases, potentially explaining our low rate of neurological complication. We believe that utilizing a surgeon accustomed to nerve decompression is beneficial for avoiding complications, especially in chronic cases where the tendon may be scarred and in cases where a neurolysis is indicated [34].

A limitation of this study includes the study design as a retrospective case series. Due to crossover of institutional registry providers, a number of patients were lost to follow-up, yielding a final sample size of 39 patients. Despite our sample size being larger than many of the previously published articles reporting outcomes following proximal hamstring repair, the sample size may preclude the ability for variables to reach statistical significance, especially in the logistic regression analysis. Additionally, the discharge time variable may not have been determined by time needed for recovery, but by local arrangements and surgical times of the providing institution. Lastly, complication data are limited to follow-up at our institution and may fail to account for potential complications that were treated at outside facilities.

CONCLUSION

This is the first study defining the MCID for the mHHS and iHOT-33 in patients undergoing open proximal hamstring repair (distribution-based MCID: 11.8 and 12.6, respectively). A very high percentage of patients achieved MCID for both the mHHS (85.7%) and iHOT-33 (91.4%). Age, BMI, requirement for inpatient admission and pre-operative iHOT-33 were near-significant predictors for not achieving MCID; however, these variables did not reach statistical significance in logistic regression analysis. There was an overall complication rate of 15.4%, with only one patient (2.6%) experiencing a neurological complication.

DATA AVAILABILITY

The data underlying this article were provided by Hospital for Special Surgery by permission. Data will be shared on request to the corresponding author with permission of Hospital for Special Surgery.

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CONFLICT OF INTEREST STATEMENT

C.D.L., S.W.S., K.J.H., and J.A.B. have no conflicts of interest to declare. D.H.N. reports ownership interest in BetterPT and Engage Uni outside the submitted work. A.S.R. reports the editorial board for Springer and Saunder Mosby Elsevier, a consultant for Anika, Arthrex (Speakers Bureau), Bodycad, Enhatch, Smith & Nephew and Stryker - MAKO Surgical Corp., ownership interest in Conformis and Enhatch outside the submitted work. B.T.K. reports ownership interest and/or royalties in Arthrex, HS2, LLC., Parvizi Surgical Innovation LLC., and Vincera Institute, a consultant for Organicell (shareholder) and Smith & Nephew and serves on the advisory board for Relief Labs, Inc., outside the submitted work. B.U.N. reports ownership interest in BICMD (founder) outside the submitted work.

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