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Efficacy of postoperative drainage after arthroscopic rotator cuff repair: a randomized controlled trial

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Background: Arthroscopic rotator cuff repair is the standard treatment in patients with symptomatic reparable rotator cuff tear. It brings good to excellent postoperative outcomes. Postoperative suction drainage is the method to theoretically reduce postoperative shoulder swelling and hematoma formation, which is still commonly used in clinical practice, yet its efficacy remains unproven.

Methods: This is a nonblinded prospective randomized controlled study. A sample of 43 shoulders were simply randomized without replacement across drain and nondrain groups, allocated by sealed envelope before skin closures. The preoperative, intraoperative, and postoperative data were analyzed. The difference of oblique (O) and horizontal (H) shoulder circumference between before and after operation is the primary parameter indicating swelling and hematoma formation. The preoperative reliability of O and H dimensions were evaluated by 2 independent evaluators. The visual analog scale, estimated blood loss, and Disabilities of Arm, Shoulder, and Hand score were analyzed.

Results: There was no significant difference of circumference between drain and nondrain groups in both O and H methods. For method O, the mean difference between drain and nondrain groups at 24 hours was -0.25 (95% CI: -2.09 to 1.59, $P = .783$), at 1 week was -0.54 (95% CI: -2.05 to 0.96, $P = .470$), at 1 month was -0.39 (95% CI: -2.06 to 1.28, $P = .639$) and at 3 months was -0.01 (95% CI: -1.49 to 1.46, $P = .987$). Method H: Mean difference between groups at 24 hours was 0.29 (95% confidence interval [CI]: -0.61 to 1.20, $P = .520$), at 1 week was 0.004 (95% CI: -0.99 to 1.002, $P = .993$), at 1 month was -0.53 (95% CI: -1.62 to 0.56, $P = .333$), and at 3 months was -0.07 (95% CI: -0.91 to 0.77, $P = .862$). The preoperative O and H parameters showed strong to almost perfect agreement (intraclass correlation coefficient for A = 0.858 [95% CI: 0.738 to 0.923, $P < .001$], intraclass correlation coefficient for B = 0.955 [95% CI: 0.918 to 0.976, $P < .001$]). No significant difference of visual analog scale, estimated blood loss, and Disabilities of Arm, Shoulder, and Hand score was recorded between groups.

Conclusion: No difference was found between drain and nondrain placement for shoulder swelling, visual analog scale, estimated blood loss, and functional outcome in 3 months after surgery. Drain placement after arthroscopic rotator cuff repair is of unproven benefit in routine clinical practice.

Introduction

Drain placement after orthopedic surgery has been generally used in the past to reduce hematoma in the operative site, intra-articular hematoma and to perhaps reduce risk of infected hematoma postoperative.[13] Placement of a drain may increase risk of contamination, tube-tract infection, and increased bleeding owing to loss of compression effect around the shoulders. Results of drain placement after orthopedic surgery are inconclusive.[6,9,10]

Many shoulder procedures can be performed arthroscopically, which provides the benefit of the decreasing complications from open procedure, shorten hospital stay, and reduce postoperative pain. Shoulder swelling and hematoma formation are the common early postoperative complications.[3,8] Postoperative suction drainage is the method to theoretically reduce postoperative shoulder swelling and hematoma formation and is still used in clinical practice although efficacy is unproven. The efficacy of drain placement after shoulder surgery is still doubtful with limited studies especially in shoulder arthroscopy.[4]

Approval for this study was received from the Human Ethics Committee of Thammasat University (no. MTU-EC-OT-1-120/61). Consent for study and publication have been received from all participants.

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The main purpose of this study is to evaluate the efficacy of drain placement after arthroscopic rotator cuff repair compared with nondrain placement in terms of shoulder swelling and hematoma formation. We developed simple measurement methods to evaluate the shoulder swelling using measurement tape. Other outcomes after surgery have been analyzed including visual analog scale (VAS) score, estimated blood loss, and the functional score using Disabilities of the Arm, Shoulder, and Hand (DASH) score, Thai version.[12]

Materials and methods

Study design

This study is a nonblinded prospective randomized controlled trial of 44 patients undergoing arthroscopic rotator cuff repair, divided into postoperative drain placement and nondrain placement groups of 22 patients each. After complete surgical interventions, the patients were sampling and allocated using simple randomization without replacement by the sealed envelope before skin closures. One of patient in drain group had canceled the surgery, so the drain (DA) group had 21 patients and the nondrain (NDA) group had 22 patients. This study was conducted with the official approval of the Human Ethical Committee of Thammasat University MTU-EC-OT-1-120/61 and was registered with the Thai Clinical Trial Registry (www.clinicaltrials.in.th) No.TCTR20180 927003. The arthroscopic rotator cuff repair was performed by a single orthopedic surgeon (AA).

Inclusion criteria

We included patients with rotator cuff tear, older than 20 years of age who underwent arthroscopic rotator cuff repair in Thammasat University Hospital between 2017 and 2018. All rotator cuff tears were confirmed preoperatively by physical examination and magnetic resonance imaging (MRI) of the affected shoulders. The concomitant procedures such as the subacromial decompression, ACJ resection, long-head biceps procedures were included and analyzed.

Exclusions

Patients with bleeding disorder or coagulopathy and patients who were unable to follow the postoperative rehabilitation protocols were specific criteria for exclusion.

Sample size estimation

Based on the result from our pilot study, we assumed a Cohen's d effect size of 0.98. The required sample size to achieve 80% power and type I error of 0.05 with equivalence bounds of ±2 mm is 18 per group. The sample size was calculated using R package "TOSTER" with built-in command powerTOSTtwo. We allowed for 20% dropout of the sample size, therefore we required at least 22 participants per group.

Blinding

The patients were simply randomized without replacement and allocated by sealed envelope before skin closures. Surgeon and patients were not able to be blinded between with or without drain placement. Blinding would have been possible by the evaluators after drain was removed (24 hours postoperatively).

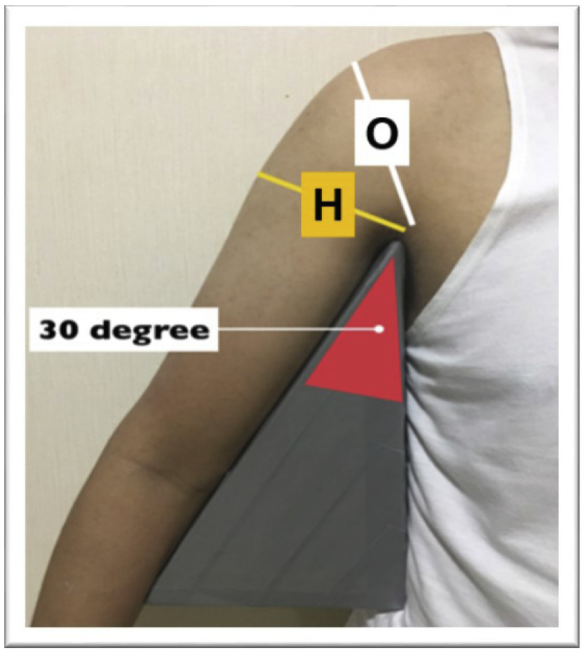

Figure 1 Measurement of right shoulder circumference in shoulder abduction 30-degree, neutral rotation. **O,** measure the diameter of affected shoulder, oblique from axillary crease to lateral border of the acromion; **H**, line perpendicular to the anatomical axis of arm, measure the horizontal diameter of the affected shoulder at the level of axillary crease.

Data collection and outcome measurement

The preoperative data were collected including the preoperative DASH score, hemoglobin (Hb), hematocrit, shoulder circumference as (O) by measuring the diameter of affected shoulder from axillary crease to lateral border of the acromion and (H) by measuring the horizontal diameter of the affected shoulder at the level of axillary crease (Fig. 1).

Intraoperative data were recorded including the operative time, operative procedures, and volume of normal saline used through the arthroscopic pump.

Postoperative data were collected including the DASH score at 1 month and 3 months; hematocrit at postoperative 24 hours; VAS at 24 hours, 1 week, 1 month, and 3 months; shoulder circumference (O and H) at 24 hours, 1 week, 1 month, and 3 months; volume of blood transfusion administered (transfusion thresholds were set at Hb 8 g/dL); and length of stay including preoperative days and length of stay in hours starting from the time of admission.

The CONSORT flow diagram of the study is shown in Fig. 2.

Outcome measurement

The primary outcome is the shoulder swelling measured by calculating the shoulder circumference change from preoperative measurement in 24 hours, 1 week, 1 month, and 3 months after surgery between both groups.

The inter-rater reliability of the shoulder circumference measurement is evaluated using preoperative data of shoulder circumference (O and H within 24 hours before surgery) from 2 independent orthopedic surgeons as the evaluators.

Secondary outcomes including pain (VAS score), hematocrit and Hb level, DASH score, drainage volume in the DA group, blood transfusion, length of hospital stay between both groups are

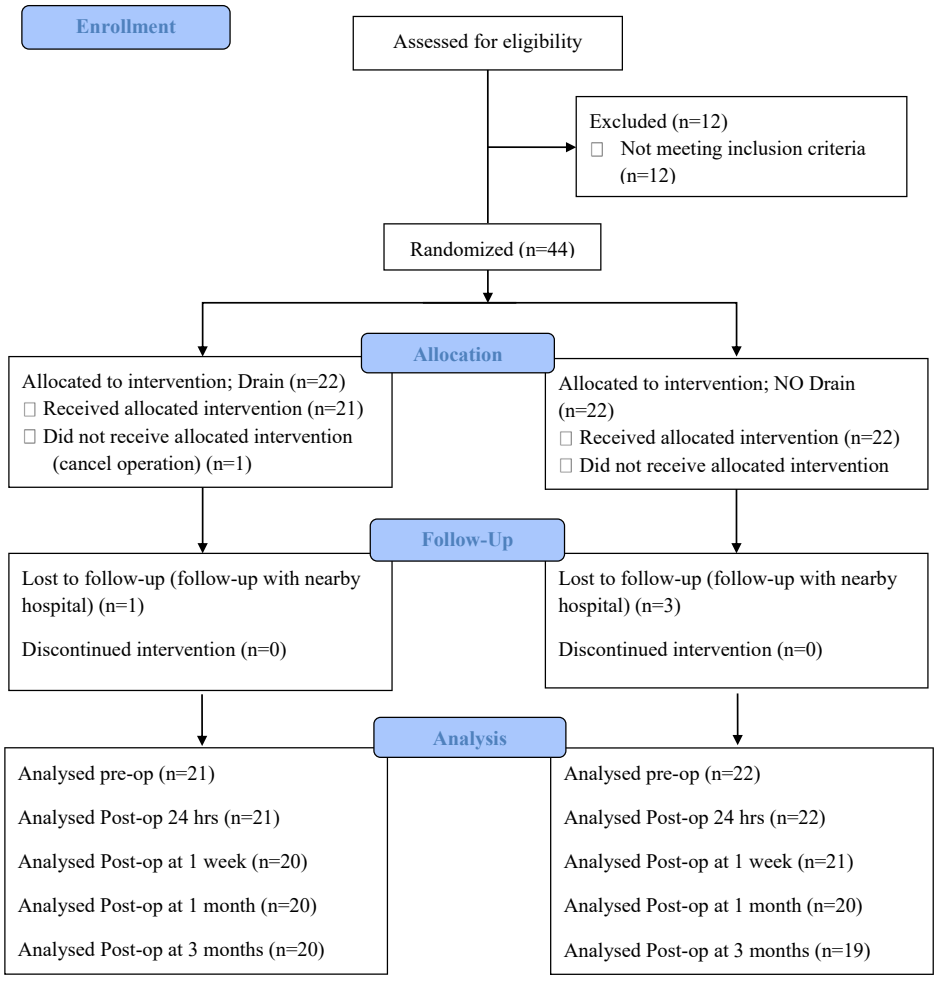

Figure 2 The CONSORT flow diagram.

collected. The blood volume (BV) is estimated following the Nadler formula [7] based on gender, body mass, and height. The Hb loss (in grams) is calculated using formula: Hbloss = BV×(Hbi−Hbe) ×0.001+Hbt ; Hbloss (g) is the amount of Hb lost, Hbi (g liter^{-1}) is the Hb concentration before surgery, Hbe (g liter^{-1}) is the Hb concentration on second day after surgery, and Hbt (g) is the total amount of allogeneic Hb transfused. Then, the blood loss is calculated following the formula: Blood loss = 1000×Hbloss/Hbi.[5]

Surgical techniques

All patients were operated on using all-arthroscopic rotator cuff repair technique in the beach-chair position about 70 degree upright under general anesthesia and ultrasonographic-guided brachial plexus block with bupivacaine. The standard posterior viewing portal was used to assess the glenohumeral compartment and performed the articular works using the anterior working portal. The long head of biceps (LHB) was assessed for tenotomy or tenodesis if indicated including significant LHB tear/subluxation, inflamed hypertrophic LHB, or combined with significant superior labrum anterior to posterior lesion. LHB tenodesis using all-arthroscopic LHB transfer[1] to conjoint tendon was performed in the active patients younger than 50 years of age, the others were LHB tenotomy. We decided to repair the subscapularis in all cases having more than 10% tear size using single-row repair (1 or 2 double-loaded suture anchors [5.5-mm CrossFT-BC, ConMed-Linvatec, Largo, FL]) depending on the tear size.

After finishing the glenohumeral compartment procedures, the arthroscope was reinserted through the posterior portal into the subacromial space. Subacromial bursectomy was routinely performed. Acromioplasty was performed in the shoulder with significant preoperative radiographic evidence of acromial spur on the supraspinatus outlet or Rockwood tilt view or from the MRI. The acromioclavicular joint was resected [2] with patients having preoperative acromioclavicular joint tenderness and significant osteoarthritic change. The supraspinatus and infraspinatus were repaired using double-row suture-bridge technique in all cases using 1-2 medial-row anchor sutures (5.5-mm CrossFT-BC, ConMed-Linvatec, Largo, FL) and 1-2 lateral-row anchor sutures (4.5-mm PopLok Knotless Suture Anchors, ConMed-Linvatec, Largo, FL) depending on the tear size. An arthroscopic pump with pressure about 50 to 80 mmHg was used for expanding the working space and control bleeding using the 10K fluid system (CONMED, US) and the normal saline solution without additional adrenaline.

On completion of surgical procedures, a sealed envelope for DA or NDA grouping was opened for randomization without replacement. A Redivac drain tube size 9 French in diameter with 1 end hole and 5 side holes (Redon drainage tube 9 FG/50 cm length; Polymed, Poly Medicure Ltd., India) was inserted through the anterolateral working portal into the subacromial space in the DA group and connected with a 400-ml vacuum bottle (PRIVAC,

Table I
Baseline characteristics.

	DA (n = 21 shoulders)		NDA (n = 22 shoulders)		*P* value
Age (yr) – mean (SD)	63.14	(7.14)	62.45	(7.65)	.762
Sex					.850
Male	8	(38.10%)	9	(40.91%)	
Female	13	(61.90%)	13	(59.09%)	
BMI – mean (SD)	26.85	(5.15)	25.82	(4.78)	.501
Side					.370
Right	16	(76.19%)	14	(63.64%)	
Left	5	(23.81%)	8	(36.36%)	
Diagnostic					
RC tear	21	(100.00%)	22	(100.00%)	NA
Biceps tendinitis	9	(42.86%)	16	(72.73%)	.047
Biceps rupture	1	(4.76%)	1	(4.55%)	1.000
ACJ arthritis	4	(19.05%)	1	(4.55%)	.185
Operation					
Subacromial decompression	18	(85.71%)	21	(95.45%)	.345
ACJ resection	2	(9.52%)	1	(4.55%)	.607
SSp/ISp repair	18	(85.71%)	22	(100.00%)	.108
SSc repair	7	(33.33%)	12	(54.55%)	.161
Biceps tenotomy	10	(47.62%)	16	(72.73%)	.092
Biceps tenodesis	2	(9.52%)	1	(4.55%)	.607
DASH score – mean (SD)	30.35	(15.38)	34.77	(21.42)	.444
Preoperative VAS pain – median (Min, Max)	3.00	(0, 10)	2.00	(0, 7)	.657

ACJ, acromioclavicular joint; *D*, drain; *DASH*, Disabilities of the Arm, Shoulder, and Hand; *ISp*, infraspinatus; *NA*, not available; *NDA*, no drain; *SD*, standard deviation; *SSc*, subscapularis; *SSp*, supraspinatus; *VAS*, visual analog scale.

Primed, Germany). No tube was placed in the NDA group, then the portal wounds were simply sutured using nonabsorbable suture (No.3-0 Ethicon ETHILON Nylon Suture, US)

After surgery, all patients received the same of the following medications during hospitalization: morphine 3 mg intravenous injection as needed for pain every 3 hours, ondansetron 4 mg intravenous injection as needed for nausea or vomiting every 6 hours, acetaminophen (500 mg) 2 tablets orally every 6 hours, omeprazole (20 mg) 1 tablet orally once daily before meals, naproxen (250 mg) 1 tablet orally twice daily after meals, and cefazolin 1 gm intravenous injection every 6 hours for 24 hours. All of the patients were admitted because of the standard practice at our facility.

The Redivac drain was removed in about 24 hours in every patient in the DA group after recording the amount of fluid drainage. The surgical wounds were routinely attended with simple dry dressing. All patients in both groups received the same postoperative rehabilitation protocol that involved the total immobilization protocol with simple arm sling of the operated shoulder for 4 weeks while promoting the early active range of motion exercise of the elbow, wrist, and hand.

Statistical analysis

Statistical analysis was conducted using SPSS for Window, version 25.0. Independent t-test or Mann-Whitney U test was performed for comparing the difference of continuous variables between groups, depending on their distribution. Chi-square test was performed for comparing categorical variables between groups. Intrarater reliability was carried out using intraclass correlation coefficient. All statistical tests were performed at an a priori significance level of 0.05.

Results

The 44 patients with rotator cuff tear who underwent arthroscopic rotator cuff repair in Thammasat University Hospital between 1st February 2017 and 1st February 2019 were divided into 2 groups; 22 were postoperative drainage tube placement groups and 22 were without postoperative drainage tube placement. One of the patient in the DA group canceled the surgery, so the DA group had 21 patients and NDA group had 22 patients.

Baseline demographic and characteristic data revealed no significant differences between both groups including age, gender, body mass index, the procedures, and the preoperative DASH and VAS score (Table I).

The preoperative Hb/hematocrit level, calculated blood loss, operative time, length of hospital stays, and intraoperative usage of normal saline (mL) showed no significant difference between both groups (Table II).

The shoulder circumference change using both O and H methods showed no significant difference within 24 hours, 1 week, 1 month, and 3 months postoperatively (Table III). The inter-rater reliability of the shoulder circumference measurement, evaluated using preoperative data of shoulder circumference (O and H within 24 hours before surgery) from 2 independent orthopedic surgeons has correlation with statistical significance. For method O, intraclass correlation coefficient = 0.858 (95% CI: 0.738 to 0.923); $P < .001$, and for method H, intraclass correlation coefficient = 0.955 (95% CI: 0.918 to 0.976); $P < .001$.

No significant difference of postoperative VAS was evident at 24 hours, 1 week, 1 month, and 3 months (Table IV). The postoperative DASH score at 1 month and 3 months was not significantly different (Table V).

Discussion

The necessity and safety of insertion of postoperative tube drainage is debatable. The tube drainage has theoretically reduced the amount of fluid collection and hematoma formation around the surgical portions but has not been proven. In our current practices, the routine placement of postoperative tube drainage in the subacromial space after arthroscopic rotator cuff repair has been performed by many shoulder surgeons.

This study aims to compare the postoperative outcomes between patients with arthroscopic rotator cuff repair with and without postoperative tube drainage placement. We focus on shoulder swelling after surgery that may indicate the formation of

Table II
Compare the hemoglobin/hematocrit change, calculated blood loss, operative time, normal saline used, and length of hospital stays between drain and nondrain groups.

	DA (n = 21)		NDA (n = 22)		*P* value
Hemoglobin – mean (SD)					
Preoperative	12.83	(1.49)	12.93	(1.12)	.807
Postoperative 24 h	11.62	(1.57)	11.81	(1.41)	.672
Hematocrit – mean (SD)					
Preoperative	38.50	(4.45)	39.10	(2.84)	.602
Postoperative 24 h	34.87	(4.46)	35.60	(4.57)	.595
Calculated blood loss (mL) – median (min, max)	391	(0, 828)	322	(0, 1192)	.627
Operative time – mean (SD)	128.14	(35.87)	136.27	(46.45)	.526
NSS used (Liter) – mean (SD)	37.95	(16.32)	39.50	(18.09)	.770
LOS – median (min, max)	3.00	(2, 4)	3.00	(2, 9)	.893
Drain volume at 24 h (mL) – median (min, max)	90	(0, 250)	-		-

DA, drain; *LOS*, length of hospital stays; *NDA*, nondrain; *NSS*, normal saline.

Table III
The shoulder circumference changed from baseline (preoperative) using O method and H method within 24 hours, 1 week, 1 month, and 3 months postoperatively.

	DA			NDA			Mean difference (DA – NDA) (95%CI)	*P* value
	n	Mean	(SD)	n	Mean	(SD)		
Oblique (O) method								
Postoperative 24 h	21	3.84	(3.16)	22	4.10	(2.80)	−0.25 (−2.09, 1.59)	.783
Postoperative at 1 week	20	0.50	(2.84)	21	1.04	(1.83)	−0.54 (−2.05, 0.96)	.470
Postoperative at 1 mo	20	0.00	(2.91)	20	0.39	(2.26)	−0.39 (−2.06, 1.28)	.639
Postoperative at 3 mo	20	−0.68	(2.85)	19	−0.66	(1.45)	−0.01 (−1.49, 1.46)	.987
Horizontal (H) method								
Postoperative 24 h	21	2.40	(1.64)	22	2.10	(1.28)	0.29 (−0.61, 1.20)	.520
Postoperative at 1 week	20	0.49	(1.85)	21	0.49	(1.27)	0.004 (−0.99, 1.002)	.993
Postoperative at 1 mo	20	−0.55	(1.74)	20	−0.01	(1.68)	−0.53 (−1.62, 0.56)	.333
Postoperative at 3 mo	20	−0.43	(1.29)	19	−0.35	(1.30)	−0.07 (−0.91, 0.77)	.862

DA, drain; *NDA*, nondrain.

Table IV
The visual analog scale between the drain and nondrain groups at preoperative, 24 hours, 1 week, 1 month, and 3 months postoperatively.

VAS	DA			NDA			*P* value
	n	Median	(Min, Max)	n	Median	(Min, Max)	
Preoperative	21	3.00	(0, 10)	22	2.00	(0, 7)	.657
Postoperative 24 h	21	6.00	(2, 10)	22	7.50	(3, 10)	.563
Postoperative at 1 week	20	3.00	(0, 6)	21	3.00	(0, 10)	.642
Postoperative at 1 mo	20	2.00	(0, 5)	20	3.00	(0, 7)	.310
Postoperative at 3 mo	20	1.50	(0, 8)	19	2.00	(0, 6)	.395

DA, drain; *NDA*, nondrain.

Table V
The DASH score between the drain and nondrain groups at preoperative, 1 month, and 3 months postoperatively.

DASH	DA			NDA			Mean difference (DA – NDA) (95% CI)	*P* value
	n	Mean	(SD)	n	Mean	(SD)		
Preoperative	21	30.35	(15.38)	22	34.77	(21.42)	−4.42 (−15.95, 7.11)	.444
Postoperative at 1 mo	20	45.89	(17.13)	20	42.06	(17.00)	3.84 (−7.09, 14.76)	.482
Postoperative at 3 mo	20	24.81	(14.72)	19	23.49	(8.95)	1.32 (−6.64, 9.27)	.739

CI, confidence interval; *DA*, drain; *NDA*, nondrain.

hematoma or fluid collection around the surgical site. There is no gold standard in the measurement method of hematoma formation around the shoulder. Although an ultrasound or MRI evaluation would have been much more compelling measurement methods than a simple tape measure, we used the shoulder swelling to estimate the amount of postoperative hematoma formation and/or fluid collection.

The prospective randomized controlled trial by Straw et al [11] reported no statistical difference in functional outcomes including knee swelling, range of movement, pain, and knee strength within 6 months after arthroscopically assisted anterior cruciate ligament reconstruction between 49 patients with and without intra-articular drain placement postoperatively. Another prospective randomized study [4] evaluated the effectiveness of closed wound drainage in 300 patients after elective shoulder surgeries (open rotator cuff repair, open anterior reconstruction for instability, and arthroplasty) and found no difference in outcomes for wound hematoma and infection between 3 groups.

From our study, there are no statistical differences in demographic data of the patients, calculated blood loss, operative time, length of hospital stay, intraoperative usage of normal saline, the shoulder circumference change within 24 hours to 3 months

postoperatively, postoperative VAS about 24 hours to 3 months, postoperative DASH score at 1 month and 3 months, and complications between the DA and NDA groups. The reliability of shoulder circumferential measurement is also tested, which showed good to excellent correlation with statistical significance.

Although the shoulder circumference could not directly represent of the amount of hematoma formation or fluid collection, other parameters such as ultrasonography or MRI area are still not the gold standard for evaluation. We used a simple method to evaluate which may help the physician to evaluate the degree of shoulder swelling which has not been previously reported.

Strengths and limitations

This study has used prospective randomized design and is the first study to focus on postoperative drainage in arthroscopic rotator cuff repair. The surgeries were performed by a single shoulder surgeon, and the reliability of the outcome measurement methods has also been tested.

The postoperative care of arthroscopic rotator cuff repair without drain placement has potential benefits including reduced cost of unnecessary equipment, less time for nursing care surrounding the drain, evocate the ambulatory surgery concept about the arthroscopic rotator cuff repair, and no pain during tube drainage removal. The limitations of this study include the small sample size, hematoma formation measurement using an indirect method, the reliability test of shoulder circumference measurement had been performed using only the preoperative shoulder circumferential data, short period of follow-up, and blinding of the patients and the surgeon could not be performed.

Conclusion

Drain placement after arthroscopic rotator cuff repair reveals no benefits compared with the patient group without drain placement. The shoulder swelling based on circumferential change, calculated blood loss, DASH score, VAS scale, and overall complications shows no significant difference between both groups within 3 months postoperatively. Drain placement after arthroscopic rotator cuff repair is of unproven usefulness in routine clinical practice.

Disclaimers:

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