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Research Article

Interest of Drainage in Shoulder Arthroplasty: A Prospective Multicenter Study

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Abstract

Objectives of the study: It is common to drain the operative wound to limit the occurrence of postoperative hematoma after shoulder prosthesis (TSA). The interest of drainage has been questioned in hip and knee replacement surgeries for the sake of blood saving. Rapid recovery protocols after surgeries are suitable for shoulder surgery and the usefulness of drainage is a determining factor. A prospective, multicenter controlled study was performed on shoulder prostheses with or without drainage to analyze blood loss, mean length of stay (SMD) and complications.

Hypothesis: the drain increases the length of hospitalization and does not decrease the risk of complications.

Material and Method: A continuous prospective study was carried out on 6 centres in France for a total of 139 TSA over a year divided into 2 groups, the first 6 months with drainage (AD: 80 TSA) and the following 6 months without drainage (SD: 59 TSA). The study compared the 2 groups with clinical scores in preoperative and at 6 months postoperatively (M6): Constant, SST, SSV and ASES. Blood loss was assessed on the evolution of hemoglobin (Hb) levels, the volume of the redon on the 1st and^{2nd} day and any transfusions. SMD and postoperative complications were identified. The groups with and without drain are comparable in age, ASA score and types of prosthesis.

Results: No significant difference on the constant (M6) AD scores: 62 points (pts), SD: 60 pts p = 0.37, ASES, SST, SSV nor on the rate of change in preoperative hemoglobin and J2 AD (-1.87g/dL) SD (-1.83g/dL). No significant difference on the SMD (3.9d – 4.1d) with extremes of 2 to 15 days. A difference in SMD is found depending on the etiology: fractures vs other causes (6.06days - 3.7 days) p = 0.015. Analysis of complications was less hematoma collected in the drain group AD 2.5%, SD 8.5%, not significant p = 0.13, 4 times in the group with drain vs 2 times in the group without drain.

Discussion: Drainage did not increase blood loss, lack of drainage did not decrease SMD in our study. The main factor in increasing SMD is traumatic etiology with a SMD that is often greater than a week. Drainage does not influence the recovery rate. Systematic drainage is above all a matter of practice.

Conclusion: Drainage does not appear to be essential for shoulder prostheses in patients who do not have a coagulation abnormality.

Level of Evidence: III

Keywords: Drainage; Shoulder Arthroplasty; Multicenter

Introduction

Drainage is commonly used after prosthetic surgery to limit the risk of postoperative hematoma. Drainage in knee (TKA) and hip (THA) surgery [1,2] has been studied for 30 years but is still relevant. The theoretical benefits of drainage are better healing, a decrease in the risk of hematoma, seepage and infection [3]. These theoretical benefits have not been proven in studies on hip and knee prostheses, on the contrary, they find an increase in blood loss and an increased number of transfusions with drainage [4]. Drainage does not appear to have positive effects on the fate of patients [5,6]. Only one prospective study investigated the immediate postoperative effects of drainage in shoulder prosthetic surgery without finding a significant difference in blood loss, postoperative anemia, mean length of stay and cost [7]. No prospective studies on drainage in shoulder prosthetic surgery investigate medium-term complications and clinical scores. We developed a prospective study to study immediate postoperative data: blood loss, average length of stay and remote: clinical scores with a record of complications (hematomas, surgical repeats) up to the 6th month postoperatively. The tendency to «no drainage» after prosthetic surgery in the protocols of rapid recovery after surgery (RRAC) and outpatient surgery [8] are all arguments for studying the need for drainage in total shoulder prostheses.

Hypothesis

The drain increases the length of hospitalization and does not decrease the risk of complications.

Materials and Methods

A continuous prospective multicenter study was carried out on six centers in France from January to December 2018 by operators with experience in these techniques. All patients operated on shoulder replacement (PTE) from January to June 2018 were drained (80 PTE), the following six months patients had no drainage (59 PTE).

The inclusion criteria included all types of shoulder replacement regardless of etiology (osteoarthritis, traumatic and other etiologies), the signed consent of the patient participating in the study. The exclusion criteria include all coagulation abnormalities, preoperative hemoglobin (Hb) less than 10 g/dL, patient on anticoagulant therapy or with a medical history that may disrupt coagulation. The inclusion and exclusion criteria are grouped in (Table 1) and the flowchart (Table 2).

Inclusion criteria
Patient programmed for a shoulder prosthesis: anatomical, inverted and hemi arthroplasty
Patient who gave written consent to participate in this study
Critères d'exclusion
Patient nécessitant une autotransfusion
Patient with preoperative platelet count < 100000
Patient with preoperative hemoglobin < 10gdL
Patient with a history of venous thrombosis
Patient with deficient coagulation
Patient requiring anticoagulant therapy
Patient with metabolic bleeding history
Patient with a history of heparin thrombocythemia
Patient with a history of vascular, renal, hepatic insufficiency
Patient ayant des antécédents néoplasiques

Table 1: Inclusion and exclusion criteria.

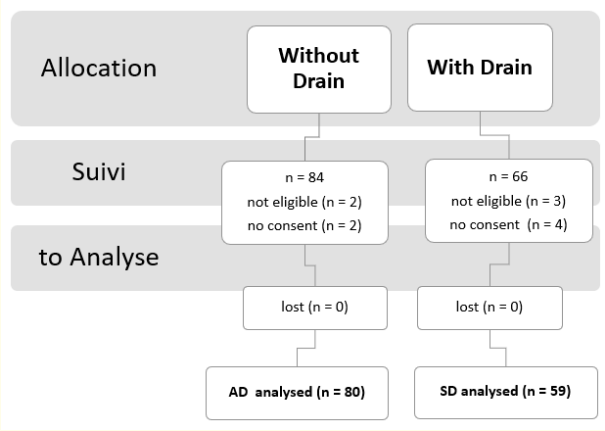

Table 2: Flowchart.

The CHU Nantes France ethics committee, the CNIL 2129700 v 0 and the CPP ID RCB: 2017-A00660-53 have issued a favorable opinion for the conduct of the study.

Comparability of groups

The average age in both groups was comparable, with Drain (AD) 74.52 (+/- 9.8) and Without Drain (SD) 74.37 (+/- 9). The groups were comparable in sex, BMI and ASA score Eccentric omarthrosis was the main etiology in both AD groups: 39 (47%) SD: 28 (47%). The demographic criteria are summarized (Table 3).

		With Drain		Without Drain	
		n	average (DS) ou %	n	average (DS) ou %
		80		59	
Gender	man	57		34	
	Wife	23		25	
Average age			74,52(+/- 9,8)		74,37(+/- 9)
Etiology	out-of-the-way omarthrosis	39	(47%)	28	(47%)
	omarthrosis centered	13	(16%)	21	(36%)
	Fracture	14	(18%)	3	(5%)
	post-trauma	7	(9%)	4	(7%)
	necrosis	4	(5%)	1	(2%)
	Other	3	(4%)	2	(3%)
BMI (kg/m2)	Medium	26.5		28.7	
	Median	26		27	
	<19	4	(5%)	1	(2%)
	[19-25]	30	(38%)	13	(22%)
	[25-30]	27	(34%)	23	(39%)
	[30-35]	12	(15%)	14	(24%)
	[35-40]	6	(8%)	3	(5%)
	≥ 40	1	(1%)	5	(8%)
ASA	1	16	(20%)	5	(8%)
	2	30	(38%)	28	(47%)
	3	34	(43%)	26	(44%)
Prosthesis	HSA	1	(1%)	1	(2%)
	RSA	63	(79%)	50	(85%)
	TSA	16	(20%)	8	(14%)

Table 3: Demographic characteristics.

DS: Standard Deviation; BMI: Body Mass Index; ASA: American Society of Anesthesiologist; HAS: Anatomical Humeral Prosthesis; PTEI: Inverted Shoulder Total Prosthesis; PTEA: Anatomical Total Shoulder Prosthesis

Surgical technique

The surgeon had the free choice of prosthesis: Reverse shoulder arthroplasty (RSA), anatomical total shoulder prosthesis (TSA) and anatomical humeral prosthesis (HSA), the first route (delto-pectoral or superero-lateral), immobilization, and the rehabilitation protocol.

In group AD, only one drain of Charrière 10 was used, the drain was systematically removed on J2. Administration for all tranexamic acid (ATX) 1g IV or BMI-adapted arthroplasties at the time of incision.

Evaluation and scores

Patients were assessed by their operator preoperatively and at 6 months postoperatively by the constant score, SSV (Subjective Shoulder Value), SST (Simple Shoulder Test), ases score (American Shoulder and Elbow Surgeons) and EVA (Échelle Visuelle

Analogique). During hospitalization, pain (EVA) was assessed on the 1st postoperative day (D1) and on the 2nd postoperative day (D2), blood loss was assessed by the difference in hemoglobin (Hb) levels preoperatively and on Day 2, the volume of blood collected by the drain (group AD) on Day 1 and Day 2 and the number of red blood cells (GC) transfused if transfusion was necessary. The average length of stay and complications from J1 to 6 months postoperative (M6) (hematomas, oozing on scar, surgical resumption) were collected.

Statistical analysis

The statistical analysis was done with calculation of means and standard deviations, Chi2 tests for qualitative variables and by exact Fisher tests and t student test for quantitative variables, P < at 0.05 was the threshold of significance. All statistical analyses were performed on the SPSS statistics software (SPSS for windows 14.0.0, SPSS, Inc, Chicago, IL)

Results

Scores

The Constant score in the sixth postoperative month (M6) shows no significant difference AD: 62 points (pts), SD: 60 pts p = 0.37, the evolution of constant's score is significantly greater in the AD group: 38pts, SD: 30 pts p = 0.01. The SSV score a M6 shows no significant difference SSV AD: 75, SSV SD: 72 p = 0.23, the evolution of SSV is significantly greater in the AD group:49, SD: 42 p = 0.04. No significant difference in OSH, ASES and pain assessments on Day 1 and Day 2 between the 2 groups (Table 4).

		With Drain	Drainless	Value of p
EVA	EVA J1	2,98	3,23	0,5
	EVA 2	1,64	1,88	0,42
Score Constant				
	Initial	24	29	0.04
	Final	62	60	0.37
	Evolution	38	30	0.01
SSV	Initial	26	30	0.19
	Final	75	72	0.23
	Evolution	49	42	0.04
SST	Initial	2.4	2.8	0.30
	Final	7.6	7.4	0.68
	Evolution	5.2	4.6	0.22
ASES	Initial	75,43	72,55	0.30
	Final	26,28	29,8	0.68
	Evolution	49,15	42,75	0.07

Table 4: Douleur en postopératoire immédiat et évolution des scores cliniques.

EVA, Analogue Visual Scale; Day 1, 1st day postoperative; Day 2, 2nd postoperative day; initial, preoperative; final, 6th month postoperatively; SSV: Subjective Shoulder Value; SST: Simple Shoulder Test; ASES: American Shoulder and Elbow Surgeons.

Blood loss

Analysis of the decrease in preoperative hemoglobin and J2 levels does not show a significant difference in the 2 groups AD (-1.87g/dL) SD (-1.83g/dL), all patients have a significant decrease in Hb (P< to 0.001) (Table 5). Group AD had an average collection at J1 144cc +/-103 and the cumulative collection (CR) J1+J2 is 180 cc +/- 130. No significant difference on the CR according to the type of prosthesis CR RSA 183+/- 133 vs CR TSA and HSA 167.9 +/-120 p = 0.32 nor according to the trauma etiology 140+/-107 or not 188 +/-133 p = 0.079 (Table 6). No significant difference on the number of red blood caps transfused, 2 caps in each group.

		With Drain	Drainless	P-value
Hb (g/dL)	Hb preop	13,24 (+/- 1,19)	13,77 (+/- 1,38)	
	Hb postop /J2	11,38 (+/- 1,41)	11,94 (+/- 1,25)	
	preop difference/J2	1,87	1,83	P = 0,423

Table 5: Blood Loss, Hemoglobin Levels.

Calculation of average with standard deviation; Hb: Hemoglobin level in g/dL; preop, preoperative; postop, postoperative; Day 2, 2nd postoperative day

	n	J1 cc	J2 cc	RC J1+J2 cc	p value
Group With Drain	80	144,4 (+/-103)	35,6 (+/-26,7)	180 (+/-130,1)	
Volume drain TSA +HSA	63	143,2 (+/-98,1)	24,7 (+/-21,2)	167,9 (+/-120,3)	0,328
Volume drain RSA	17	145 (+/-105)	38 (+/-31,3)	183 (+/-133)	
Volume drain outside trauma	66	152,3 (+/-106)	36 (+/-28,6)	188,3 (+/-103,6)	0,079
Volume drain trauma	14	106,7 (+/-80)	33,3 (+/-23,5)	140 (+/-107,5)	

Table 6: Blood loss: volume of collection of the drain on Day 1 and Day 2 of group AD.

Day 1 cc, volume collected in cm3 on the 1st day postoperatively; Day 2 cc, volume collected in cm3 on the 2nd postoperative day; RC, Cumulative Collection; PTEI: Inverted Total Shoulder Prosthesis; PTEA: Anatomical Total Shoulder Prosthesis; HAS: Anatomical Humeral Prosthesis; trauma, prosthesis on fracture

SMD et complications

There is no significant difference in mean length of stay (SMD) AD 3.9 - SD 4.1 (P = 0.7) with extremes of 2 to 15 days. The SMD is significantly longer in patients operated on in a fracture context (6.06d +/-3.54) compared to scheduled surgery 3.7d (+/-1.44d) p = 0.015. RSA (4.23 days +/- 2.04d) have a significantly longer SMD than other prostheses 2.96d +/- 1.18 p < 0.01 (Table 7).

		n	Mean (DS) in j	Value of p
Drainage	With drain	80	3.9j (+/- 1,82)	P = 0.7
	Without drain	59	4.1 (+/-2,17)	
Etiology	Scheduled surgery	122	3,7(+/-1,44)	P = 0,015
	Traumatology	17	6,06(+/-3,54)	
Type of prosthesis	RSA	113	4,23(+/-2,04)	P < 0,01
	TSA + HSA	26	2,96(+/-1,18)	

Table 7: Average length of stay.

Average with standard deviation in days.

Hematoma not collected in the arm is the most common complication AD: 8 (10%), SD:9 (13.6%); hematoma collected is more common in the SD group, SD: 5 (8.5%), AD: 2 (2.5%) but not significant p = 0.13. Scar seeps are more common in the AD group, AD:5 (6.3%), SD: 2 (3.4%)) but not significant p = 0.69.

6 patients were re-enrolled in the 6 months postoperative AD:4, SD:2. In the AD group: sepsis on scar, hematoma infection collected at 2 months of surgery (Figure 1), fall at 2 months of surgery with rupture of the tendon of the subscapular us and pectoralis major and instability on glenoid descellement. In the SD group: a deep infection a cuti bacterium acnes, an episode of dislocation in a patient with Parkinson's disease (Table 8).

Figure 1: Hematoma collected after shoulder prosthesis.

	With Drain		Drainless		
	n	%	n	%	value of p
Seepage on scar	5	(6.3%)	2	(3.4%)	0.69
Uncollected hematoma on the arm	8	(10.0%)	8	(13.6%)	0.5
Hematoma collected	2	(2.5%)	5	(8.5%)	0.13
Complication during hospitalization	1	(1.3%)	1	(1.7%)	0,83
Resumption until the6th month	4	(5.0%)	2	(3.39%)	0,63

Table 8: Complications.

Discussion

Contrary to our initial hypothesis, drainage does not increase the length of stay, the hypothesis suggesting that the drain does not decrease complications is validated. Blood loss and transfusion rate are significantly greater in case of drainage on THA and TKA [5,6]. This result was not confirmed by our study on shoulder arthroplasty and is consistent with the literature [7,10]. Gerstman., *et al*. [9] conducted in 1997 a prospective study on 300 patients on all open shoulder surgeries including rotator cuff repair, glenohumeral stabilizations and arthroplasty, the authors found no difference in hematoma formation, seepage, transfusion with or without drainage. The transfusion risk is probably greater in hip and knee replacements. RSA appear to be at higher risk of blood loss with older patients, Makhni., *et al*. [10] find a significantly larger volume of collection in the CIPTs (200 mL vs 168 mL) We have in our study an average difference of 15 mL (not significant). Other transfusion risk factors found in studies [11-13] are low hemoglobin (< 10g/dL), female sex, high age. The low transfusion rate in our study of 2.8% is certainly related to the exclusion criterion (Hb < 10g dL) preoperatively compared to studies published in the literature 4.3 to 43% [11-13] and by the use of systematic ATX [14-16]. Anemia is a major transfusion risk factor [10,17]. For every 1g/dL increase in preoperative hemoglobin levels, it is a 57% decrease in the risk of transfusion. The average drainage in our study (140-183 mL) is comparable to other studies [7]. We were able to see that 80% of the volume collected was done from the 1st day of operation. An ablation of the redon drain from Day 1 can be an alternative to study.

The mean length of stay (SMD) was not shorter in undrained patients unlike retrospective studies (2) but we do not have the preoperative or intraoperative selection bias that could justify or not the placement of the drain, this is confirmed by the study of Trofa., *et al.* [7]. Fracture prosthesis has a significantly longer SMD than scheduled surgery.

We do not find a significant difference in the number of complications, hematomas or relapses with or without drainage this is in agreement with the literature [18].

The long-term consequences of drainage on the risk of infection that can develop at low noise in shoulder surgery should be studied in the long term, with cuti Bacterium acnes being the germ most often involved with slow growth [19,20].

The limitations of our study were marked by the absence of randomization and the lack of power. Moreover, the groups were not strictly comparable in number of prostheses in each group and in number of fracture prostheses in the two groups. The strength of our study was related to its prospective controlled nature with a follow-up over 6 months.

Conclusion

There has been no evidence of superiority of drainage in shoulder prosthetic surgery. Drainage does not appear to significantly increase the average length of stay or blood loss. Drainage also does not seem to bring gain, so it could be abandoned in patients who do not have a coagulation abnormality. Systematic drainage is above all matter of habits. The shift to outpatient surgery is likely to change practices.

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Authors' Contribution

KB study design and article writing.

All authors contributed to study validation, patient data and proofreading.

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