



The Role of Fibrin Tissue Sealant in Groin Dissection to Reduce Seroma Formation: A Prospective Study

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Abstract

Background: Prolong wound drainage and seroma formation has been classically associated with groin dissection affecting the quality of life of patients adversely. Recently, there has been growing interest in use of tissue sealants to reduce prolonged wound drainage and seroma formation.

Method: The present study was designed to evaluate the role of tissue sealant following groin dissection in reducing wound drainage and seroma formation. All the patients of age of 18-years and above undergoing groin dissection for various indications were included in the study as cases. Controls were recruited in the study from the computerized database of the patients. After completion of groin dissection and before the surgical wound closure, fibrin tissue sealant was applied in droplets locally in the groin wound in the cases.

Result: The prospective study involved 40 patients and evaluated 52 groin dissections. The cases and controls were comparable for age, gender, body mass index, Diabetes mellitus, and number of lymph nodes harvested. There was no statistically significant difference between the two groups with respect to median time (in days) required for drain removal (11 vs. 14, p value 0.75), number of clinically evident seroma formation (8 vs. 7, p value 0.76), frequency of surgical site infection or flap necrosis.

Conclusion: Fibrin tissue sealants are unlikely to decrease the wound drainage or number of clinically evident seromas following groin dissection.

Keywords: Groin dissection; Lymphadenectomy; Seroma; Tissue sealant; Morbidity

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Introduction

Groin dissection has been classically associated with significant postoperative morbidity of prolonged wound drainage, seroma formation, surgical site infection, flap necrosis and limb lymphedema [1,2] affecting the quality of life of patients adversely. Closed Suction Drains (CSDs) placed at the time of surgery, are usually kept for long due to prolonged wound drainage and to avoid seroma formation. However, around 20% of the patients still develop seromas after the CSDs are removed [3]. Other problems of prolonged CSDs include significant surgical site infections, restricted physical activity of the patients, and a delay in return to their normal life [4]. A number of surgical and non-surgical strategies have been employed to reduce the wound drainage and number of clinically evident seromas; however, none of the strategies has so far been able to address this problem effectively [5]. Recently, there has been growing interest in use of tissue sealants to reduce prolonged wound drainage and seroma formation. The rationale of using fibrin tissue sealant lies in its ability to improve hemostasis and tissue adherence. Theoretically, it should lead to decrease in postoperative serosanguinous fluid accumulation, the consequence of transecting multiple small blood vessels and lymphatics while performing lymphadenectomy [6]. The potential application of tissue adhesives to reduce seroma formations has been evaluated following a number of surgeries including axillary lymphadenectomy [7], groin dissection [3], and abdominal wall hernias [8]. The results have been conflicting in these studies [4,9-11]. The present study was designed to evaluate the role of tissue sealant following groin dissection in reducing wound drainage and seroma formation.

Method

A case-control study was conducted in a tertiary care cancer centre in North India. All the patients of age of 18-years and above undergoing groin dissection for various indications were

Table 1: Comparable characteristic of cases and controls.

Characteristics	Cases	Control	p value*
Median age	50.5 (43.8-60.0)	55.6 (39.0-58.5)	0.86
Gender (male:female)	8:18	7:19	0.76
Median BMI (IQR**)	20.7 (18.4-23.2)	21 (18.3-24.2)	0.34
Unilateral/Bilateral	20:6	20:6	1.0
Diabetes mellitus	3.8%	11.5%	0.29
Median lymph nodes harvested (IQR**)	18 (12-22)	20 (17-23)	0.41

*Chi square test for qualitative data, Wilcoxon sign rank test for quantitative data, ** Interquartile range

Table 2: Postoperative morbidity in two groups.

Characteristics	Cases	Control	p value*
Median time to drain removal in days (IQR**)	11 (15-17)	14 (10-18)	0.75
Clinically evident seroma	8 (30.8%)	7 (26.9%)	0.76
SSI	3 (11.5%)	2 (7.7%)	1.0
Flap necrosis	2 (7.7%)	1 (3.8%)	1.0

*Chi square test for qualitative data, Wilcoxon sign rank test for quantitative data, ** Interquartile range

included in the study. Controls were recruited in the study from the computerized database of the patients. They included the patients who had undergone groin dissection from various indications immediately preceding the start of the present study.

Technique of groin dissection

The patient is positioned supine with abduction and external rotation at hip joints. The surgical field was prepped in a standard manner with 5% Povidone iodine solution. Two curvilinear incisions - an inguinal incision, of approximately 7 cm length, 4 cm below and parallel to the inguinal ligament; and an iliac incision, of 5-7 cm length, 4 cm above and parallel to the inguinal ligament. During inguinal part of dissection, the skin flap is raised preserving the subcutaneous fat, just superficial to scarpa's fascia, with flap; the lateral limit of dissection is the medial border of Sartorius and the medial limit is the lateral border of adductor longus, the upper limit is 2-3 cm above the inguinal ligament, and lower limit is the apex of Scarpa's triangle. During the iliac part of the dissection - the external oblique muscle is divided along the skin incision, and the internal oblique and transversus abdominis muscles are split along the muscle fibres. Retroperitoneal space is entered thereafter. Inguinal and iliac lymphadenectomy is completed as per the standard technique. Margins of inguinal incisions are routinely freshened before closure. Sartorius flap is routinely used to cover the femoral vessels in all patients. The details of our procedure have been published in an earlier paper [12]. After completion of groin dissection and before the surgical wound closure, five millilitres of fibrin sealant (TISSEEL™: Baxter Healthcare Corp, Deerfield, IL, USA) which was reconstituted according to the manufacturer's instructions, was applied in droplets locally in the groin wound. A closed suction drain was inserted through a separate incision site and surgically secured to the skin in all patients. The surgical incision was then closed. A light pressure dressing is done. All the patients were prescribed elastic stockings within eight hours of the surgery. Antithrombotic prophylaxis was not routinely prescribed. The patients were discharged on 2nd postoperative days; they were explained about surgical site care and taught to measure daily drain output. The drain was removed in out-patient clinic after the drain output decreases to less than 40 ml/day. All patients received perioperative antibiotics for five days or till the drainage tube was not removed.

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) software (version 16, SPSS, Inc, Chicago, IL, USA). Parametric and non-parametric quantitative data was displayed as mean (standard deviation) and median (inter-quartile range) while qualitative data was represented as proportions/percentage [13-15] Chi-square test and Mann Whitney U test was used to compare qualitative variables and for quantitative variables in two groups.

Results

The study was approved by the institutional ethics committee for human research. After having received all the information, all the patients consented to participate in the study. The prospective study involved 20 patients and evaluated 26 groin dissections constituting cases. Another 20 patients undergoing 26 groin dissections were retrieved from the computerized patient-database - this constituted controls. The cases and controls were comparable for age, gender, body mass index, Diabetes mellitus, and number of lymph nodes harvested (Table 1). There was no statistically significant difference between the two groups with respect to median time (in days) required for drain removal, number of clinically evident seroma formation, frequency of surgical site infection or flap necrosis (Table 2).

Discussion

Groin dissection is an important part of surgical treatment of cutaneous and genitourinary cancer leading to accurate and regional control of the disease [16]. However, it is well known that prolonged wound drainage and seroma formation occurs in a significant number of patients delaying their postoperative recovery and affecting the quality of life adversely. There was recently quite enthusiasm to use fibrin tissue sealant over the raw area following lymphadenectomy to reduce the wound drainage. However, our study reveals that it is neither helpful in reducing the wound drainage nor the number of clinically evident seromas. In a recently conducted meta-analysis of six Randomized Controlled Trials (RCTs), Weldrick C et al concluded that Tissue fibrin sealant does not significantly reduce Surgical Site Infection (SSI) or number of seromas in patients undergoing groin dissection with tissue Fibrin Sealant (FS) compared to Standard Closure (SC) techniques. The overall incidence of SSI in the FS group was 32% (43/133) compared to 34% (45/132) in the

SC group (Pooled risk ratio = 0.0.94, 95% CI 0.68 - 1.32; P = 0.74). The incidence of seroma for the FS group (30/133) and the SC group (30/132) did not differ (Pooled risk ratio = 1.03, 95% CI 0.67-1.58; P value = 0.90) [9]. A RCT conducted in The University of Texas M D Anderson Cancer Centre involving 30 patients revealed that applying a fibrin sealant at the time of groin lymph node dissection did not reduce the median time to drain removal (control vs. fibrin sealant, 30 vs. 29 days) or postoperative morbidity in patients with melanoma [3]. Contrary to that, a prospective, single-center study from Italy concluded that the use of the tissue sealant resulted in a significant reduction in duration of drainage Seroma formation following radical lymph node dissection in patients with metastatic melanoma. The study included a total of 70 patients undergoing axillary (n=47) or ilio-inguinal (n=23) lymphadenectomy. There was significant reduction in mean duration of drainage in the tissue sealant group compared with standard treatment (ITT analysis: 20.1 ± 5.1 versus 23.3 ± 5.1 days; $p = 0.010$); the proportion of the drainage-free patients on day 21 was significantly higher in the tissue sealant group compared with the standard treatment group (86% versus 67%; $p = 0.049$). It should be noted that tissue sealant used in this study differed for the one used in other studies as it contained collagen fleece other than fibrin, which serves as an additional layer for sealing. The role of fibrin tissue sealant has also been questioned in reducing the seroma formation following axillary lymphadenectomy. In a meta-analysis of RCTs to evaluate the role of Fibrin Glue (FG) instillation under skin flaps in the prevention of seroma formation and related morbidities following breast and axillary surgery for breast cancer, Sajid et al [17] found that FG was statistically ineffective in reducing the incidence of postoperative seroma (RR= 1.02 95% CI 0.90 - 1.16; $z = 0.35$; $P = 0.73$); there was no heterogeneity [$\chi^2 = 16.50$, $df = 14$ ($P = 0.28$); $I^2 = 15\%$] among studies. Tissue fibrin sealant has also been evaluated to reduce seroma formation following ventral hernia repair; however, it has not been found to decrease seroma formation. A systematic review of the use of fibrin sealant in abdominal-wall repair surgery performed by Morales-Conde et al did not find any evidence to suggest decrease seroma formation following its use over the raw surface [18]. These studies clarify that there is little role of tissue fibrin sealant in reducing wound drainage when it is applied locally over a large raw surface.

Conclusion

Based on the findings of present study, we conclude that fibrin tissue sealants are unlikely to decrease the wound drainage or number of clinically evident seromas following groin dissection.

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