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Influence of fibrin sealant in preventing postoperative seroma and normalizing the abdominal wall after laparoscopic repair of ventral hernia

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Abstract
Background Seroma after laparoscopic ventral hernia repair (LVHR) has been related to certain complications of the technique, such as recurrences and postoperative pain. The aim of this study was to assess whether percutaneous application of fibrin sealant in the hernia sac after LVHR reduces the incidence and volume of the postoperative seroma, and to analyze whether the percentage of patients achieving complete normalization of the abdominal wall increases.
Methods Prospective and comparative study. Patients were distributed into 2 control–case groups. Group 1 comprised patients submitted to LVHR using the double crown technique and a compressing bandage as the only method for prevent seroma. Group 2 comprised patients admitted to LVHR using the same technique together with percutaneous injection of fibrin sealant in the sac, and later applying the same bandage. Patients were examined clinically and radiologically at 7 days, 1 month, and 3 months after surgery.
Results Twenty-five patients were included in each group. There were significant differences in the incidence of seroma by the day 7 after surgery (92 % in group 1 vs. 64 % in group 2, $p = 0.017$) and by 1 month (72 % in group 1 vs. 28 % in group 2, $p = 0.002$). The difference was also significant regarding the achievement of normalization of the abdominal wall by day 7 (24 % in group 1 vs. 52 % in group 2, $p = 0.041$) and by month 1 (64 % in group 1 vs. 88 % in group 2, $p = 0.047$) after operation. Volume of seroma was larger among patients of group 1 after the week ($p = 0.002$) and 1 month after operation ($p = 0.001$).
Conclusions Fibrin sealant application after LVHR reduces the incidence and volume of the seroma 7 days and 1 month after surgery. The treated patients obtain a larger normalization of the abdominal wall 1 week and 1 month after the operation.

Keywords Fibrin sealant · Laparoscopic repair · Seroma · Ventral hernia

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Laparoscopic repair of ventral hernias has been consolidated in the last decade as a safe and effective procedure to treat these defects of the abdominal wall [1, 2], offering lower morbidity rates and shorter hospital stays in comparison with the open approach. One of the great concerns of this technique has been the postoperative seroma, given the potential complications that might be derived from it. Susmallian et al. [3] have demonstrated that practically 100 % of patients develop a postoperative seroma between the hernia sac and the prosthesis. There is a wide range of consequences of this seroma and although most patients suffer no symptoms, in

35 % of cases it can cause abdominal pain and discomfort [3]. In a few cases, the seroma is a serious complication, although this might even be related to hernia recurrence or infection of the prosthesis.

Several authors in recent years have described treatments to prevent its formation. Tsimoyiannis et al. [4], for instance, favors cauterizing the sac and closing the hernia defect with sutures. This last surgical manoeuvre has also been defended by Chelala et al. [5], who described an incidence of seroma of just 2 % in his series of 400 patients, although they neither define nor describe whether this refers to clinical presence, radiological presence or complication. The aim of suturing the defect would be to reduce the space where the seroma might settle, but this surgical technique might not be possible in large hernia defects and might also go against the principle of hernia repair without tension. Other treatments, such as the use of suction drainage or repeated evacuating puncture, have been ineffective. However, there is an absence of comparative prospective studies that assess the efficacy of these treatments.

Tissue adhesives have been used successfully as sealants, hemostatics and adhesives, or even to prevent the formation of adhesions [6], and have been consolidated in ventral and inguinal hernia surgery as a possible means to fix the prosthesis. In this study, the intention was to assess the potential reduction of the seroma formation by percutaneous application of a heterologous fibrin sealant with the intention of collapsing the real space where the seroma settles.

Therefore, the objective of this study was to assess whether the percutaneous application of a heterologous fibrin sealant (Tissucol Duo, Baxter, Vienna, Austria) in the preprosthetic space after laparoscopic repair of a ventral hernia reduces the incidence and volume of the postoperative seroma in this space. It also analyzed whether the treatment with the adhesive reduces the clinical repercussion of the seroma and whether it increases the percentage of patients obtaining the subjective sensation of complete normalization of the abdominal wall.

Materials and methods

This is a simple blinded prospective and comparative study in which the patients were distributed into 2 control–case groups with a 1/1 distribution. The first 25 patients were assigned to group 1 and the second 25 patients to group 2. The criteria for inclusion and exclusion are listed in Table 1.

The sample size was determined by estimating a seroma incidence in group 1 of 98 % and in group 2 of 70 % (28 % difference). In order to detect statistically significant differences with $p < 0.05$, 25 patients are required in each group.

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Ventral hernia larger than 3 cm.
ASA I, II, or III compensated.
Provision of informed consent.
Exclusion criteria
Ventral hernia smaller than 3 cm.
Hernias with loss of domain.
Patient not recommended for general anesthesia.
ASA III not compensated, or ASA IV.
Trophic skin defects.
Coagulopathies.
Background of multiple abdominal surgery or abdominal sepsis.

ASA American society of anesthesiologists

Group 1

Group 1 comprised patients with ventral hernia submitted to laparoscopic repair of ventral hernia with PTFE-e dual-mesh plus prosthesis with holes (W. L. Gore & Associates, Flagstaff, AZ, USA) and fixed with 5 mm ProTack tackers (Covidien, Mansfield, MA, USA) using the double crown technique described by Morales-Conde et al. [7]. After surgery, a compressing bandage was applied, being removed on day 7 after surgery.

Group 2

Group 2 comprised patients with ventral hernia submitted to laparoscopic repair of ventral hernia according to the technique described above. Once the pneumoperitoneum was evacuated, between 1 and 5 ml of Tissucol Duo was injected percutaneously in the space between the prosthesis and the hernia sac. The amount of fibrin sealant applied was 1 ml for every 16 cm^2 of prosthesis. A compression bandage was then applied, which was removed on day 7 after surgery.

After surgery, the patients were checked at day 7, month 1, and month 3 by clinical and radiological exploration and abdominal computed tomographic (CT) scan; the patient's subjective sensation of normalization and pain in the abdominal wall were also assessed. During the clinical exploration, the following parameters were analyzed: palpable seroma in clinical exploration; superficial infection (cellulitis) and deep infection; normalization of the abdominal wall by means of the patient's subjective sensation in comparison to the shape of their abdominal wall before surgery; and pain measured by a 1–10 visual analogue scale (VAS). Radiological exploration consisted of performing an abdominal CT scan with oral contrast and without intravenous contrast. The radiologist did not know the group to which each patient belonged.

The CT scan was limited to the area where the prosthesis was located in order to minimize the radiation. Once the CT scan was carried out, the following parameters were analyzed: existence of preprosthetic seroma; volume of preprosthetic seroma; hernia recurrence; and signs of prosthesis infection. The seroma was then classified according to Morales-Conde [8]. On this basis, we analyzed whether there were differences in the type of seroma between the two groups because types I and II are considered a simple incident after surgery and groups II and IV are considered a complication.

Statistical analysis

In order to compare the qualitative variables depending on the two groups of the study, Pearson's Chi square test or Fisher's exact test were used when the expected frequency was smaller than 5 on a 2 × 2 contingency table.

The analysis of the quantitative variables in line with the group under study was carried out by Student's *t* test for independent samples under the case of normality, or by the Mann–Whitney *U* test when they failed to follow a normal distribution.

The statistical significance was established at $p < 0.05$ and power of the study was 80 %.

Results

A total of 50 patients were submitted to laparoscopic repair of ventral hernia following the double crown technique and were included in the study between 2006 and 2009 in the University Hospital Virgen del Rocío. The first 25 patients were included in group 1 and the second 25 patients in group 2 (treated with fibrin sealant).

The demographic characteristics of the patients in both groups are described in Table 2, and no significant differences are found between them.

The analysis of the postoperative pain by VAS at 7 days, 1 month, and 3 months after operation showed no significant differences between both groups (Table 3).

The average hospital stay was 2.52 days in group 1 and 2.36 days in group 2 ($p = 0.428$), with no significant differences between the groups. The average stay in the 50 patients was 2.4 days (range, 2–4 days). The mortality in the series was 0 %. There were no recurrences or infections of the seroma or of the mesh in the 50 patients in the 3 months of follow-up, nor was there any reintervention or rehospitalization in this period of time.

The incidence of seroma and the percentage of patients achieving complete normalization of the abdominal wall in the follow-up is described in Table 4; significant differences were observed in favor of group 2 at both 7 days and 1 month after surgery. No significant differences were found after 3 months.

The volume of the seroma in both groups is reflected in Fig. 1. Statistically significant differences were observed at 1 week ($p = 0.002$) and 1 month after surgery ($p = 0.001$), but not after month 3 ($p = 0.178$).

Table 2 Demographic characteristics of 50 patients

Characteristic	Group 1 ($n = 25$)	Group 2 ($n = 25$)	p[a]
Gender			0.556
Female	15 (60 %)	17 (68 %)	
Male	10 (40 %)	8 (32 %)	
Age (years)	59.72 (10.37)	60.16 (12.03)	0.89
BMI	34.12 (5.325)	34.28 (9.09)	0.94
ASA			0.676
I	2 (8 %)	1 (4 %)	
II	13 (52 %)	12 (48 %)	
III	10 (40 %)	12 (48 %)	
Primary hernia	3 (12 %)	3 (12 %)	1
Incisional hernia	22 (88 %)	22 (88 %)	
Mesh size (cm^2)	252 (114)	244 (123)	0.817

BMI body mass index, *ASA* American society of anesthesiologists, datas without percentage sign are number of patients

Data of mesh size item corresponds to mean. Standard deviation is shown in parentheses

[a] No p values were statistically significant

Table 3 Postoperative pain according to VAS

Time	Mean of VAS		p[a]
	Group 1	Group 2	
Day 7	2.36 (SD 1.469)	2.68 (SD 2.116)	0.537
Month 1	0.64 (SD 1.036)	1.32 (SD 1.574)	0.077
Month 3	0.20 (SD 0.577)	0.56 (SD 1.158)	0.170

VAS visual analog scale, *SD* standard deviation

[a] No p values were statistically significant

Table 4 Incidence of preprosthetic seroma and percentage of complete normalization of abdominal wall

Characteristic	Group 1 (%)	Group 2 (%)	p
Seroma incidence			
Day 7	92	64	0.017
Month 1	72	28	0.002
Month 3	24	12	0.269 (NS)
Abdominal wall normalization			
Day 7	24	52	0.041
Month 1	64	88	0.047
Month 3	92	96	0.221 (NS)

NS not significant

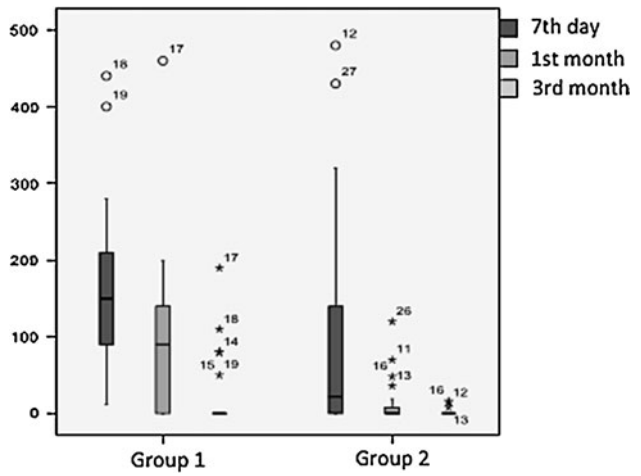

Fig. 1 Volume of seroma in both groups

Table 5 Seromas developed by patients

Seroma	Group 1 (%)	Group 2 (%)
Seroma class[a]		
0a	15.2	44.6
0b	12.8	15.4
I	44	20
IIa	12	4
IIb	4	0
IIIc	12	8
IIId	0	8
IV	0	0
Type of seroma[b]		
Absence of clinical seroma	28	60
Incident	60	24
Complication	12	16

Following the classification of Morales-Conde [8]

[a] $p = 0.089$ (not significant)

[b] $p = 0.032$

Finally, on the basis of the classification published by Morales-Conde [8], a significant difference was observed with regard to the existence of patients without clinical seroma in favor of group 2, with differences found between the groups with respect to the seromas considered to be complications. These were all included in group III, never in group IV—in other words, those referring to major complications related to the seroma (Table 5).

Discussion

Seroma of the hernia sac after laparoscopic repair of ventral hernia is a frequent entity in the immediate postoperative period of this procedure when it is studied radiologically, as was described by Susmallian et al. [3] in 100 % of patients, and as our study confirms: it was present in 92 % of the patients in our control group at day 7 after the operation. There had previously been no consensus when describing seroma, as there are many references in the literature. The present distinction between incidence and resulting complication in a recent article from our group is of great value [8]. The large variability in the incidence of seroma described by the different groups is precisely due to this lack of consensus in its definition. Parker et al. [9] define seroma as serous fluid that requires an evacuating puncture and rate its incidence at 0.5 %. Other studies [10, 11] describe an incidence of seroma that persists beyond 2 months after the operation, presenting an incidence of 2.6 and 3.7 %, respectively. Chowbey et al. [12] provide a seroma incidence of 33 % based on the simple presence in palpation under clinical exploration.

For this reason, in order to be able to assess the effectiveness of any manoeuvre or treatment to reduce the incidence of seroma, it is important to speak the same language—that is, to base the results on the same classification [8]. The treatments proposed to date to reduce the incidence of seroma, such as placing suction drains or performing evacuating punctures, have been shown to be ineffective because they fail to avoid its appearance and enhance its potential contamination. One of the great hopes of some groups has been the reduction of the dead space in the sac before the mesh is placed, by closing the defect with an intracorporeal or transparietal suture [4, 5], with or without sac fulguration, although this manoeuvre has been criticized by some authors because it might break with the principle of tension-free hernia repair. Therefore, we think it is necessary to seek new therapeutic strategies that do not require modifications in the original surgical technique.

Thanks to the application of fibrin sealant, we managed to reduce the incidence of seroma by 28 % (92 % in group 1, 64 % in group 2) by day 7 after the operation and by 46 % (72 % in group 1, 28 % in group 2) by the first month. In both periods of time, the difference was statistically significant. However, in the third month, the obtained difference of 12 % (24 % in group 1, 12 % in group 2) failed to achieve statistical significance. This last difference demonstrated by our study coincides with the findings of Susmallian et al. [3], who studied the volume of the seroma in the 3-month postoperative period and observed that although the seroma achieves its maximum volume by day 7 after surgery, after this, a process of seroma reabsorption occurs. In the series of 20 patients in this study, at month 3 after surgery in 80 % of the cases, there was complete reabsorption of the seroma, which coincides with our control group, where the absence of the seroma in the group who did not receive fibrin adhesive was 76 % after 3 months.

It is therefore possible to confirm the data in the literature in which it is observed that the seroma is a concern to the surgeon and the patient in the first 3 months after operation, and usually requires no puncture, as it disappears spontaneously in most cases. The fact that seroma disappears spontaneously has not been a reason for surgeons not to struggle to avoid it because the laparoscopic approach of ventral hernias was described as a result of its potential relationship with pain, infection and recurrences because its weight can release fixation devices. It is also a reason for concern for patients, as they may notice a "tumor" in the abdominal wall similar to what they had before surgery.

For these reasons, the analysis of the efficacy of the fibrin sealant in reducing the volume of the seroma becomes important, as it would allow the clinical repercussion of the seroma to be reduced in these first 3 months while simultaneously reducing patient concerns. We have observed that the largest volume of the seroma is seen in both groups, just as in Susmallian et al. [3], by day 7 after operation, but in 82 % of cases, a complete reabsorption has occurred by month 3 after surgery. The results show that fibrin sealant reduced the volume at 7 days and 1 month after the operation with a statistically significant difference ($p = 0.002$ and 0.001, respectively). This reduction in the volume translated into a smaller clinical repercussion of the seroma, given that in group 2 the percentage of patients without clinical seroma was 60 %, whereas in group 1 it was 18 % ($p = 0.032$).

Another aspect of the study to be considered is that with the application of fibrin sealant, we indirectly managed to reduce the patient's concern after surgery for the "tumor" caused by the seroma. The influence of the heterologous fibrin adhesive on the aesthetic result of the procedure was assessed in our study by the complete normalization of the abdominal wall perceived by the patient. We have not found authors who have studied the influence of seroma on the aesthetic result of the procedure, despite patients frequently mistaking the seroma for a persistence or recurrence of the hernia, which could reduce their degree of satisfaction. The percentage of patients achieving complete normalization of the abdominal wall was higher in the group treated with fibrin sealant by days 7 and 30 after surgery, a statistically significant difference.

It must be stressed that there were no differences in the hospital stay and postoperative pain between both groups, so the fibrin sealant does not have a negative effect on the patients. Postoperative pain analyzed by the VAS in our 50 patients at 1 week, 1 month, and 3 months after surgery is similar to the results published by Wassenaar et al. [13], who studied similar periods of time (weeks 2 and 6, and month 3).

One of the limitations of our study might be the nonrandomization of the patients. However, as there were no differences in the demographic characteristics of the patients in both groups, we consider that the validity of our study was not affected by this.

We might conclude that the percutaneous application of a heterologous fibrin sealant in the preprosthetic space after laparoscopic repair of ventral hernia reduces the incidence and volume of seroma at 1 week and 1 month after surgery in a statistically significant way. The treated patients experience a larger percentage of abdominal wall normalization at 1 week and 1 month after intervention, as well as a smaller clinical repercussion of the seroma.

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