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Prospective Cohort Study to Assess the Risk of Seroma Following Giant Midline Incisional Hernia Repair with and Without Subcutaneous Medical Talc Application

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Abstract

Background: Seroma formation is a recognized complication following Abdominal Wall Reconstruction (AWR) for Giant Midline Incision Hernia (GMIH). The effectiveness of Subcutaneous Medical Talc (SMT) application to prevent seroma formation in these patients has been reported with variable success rates. We aim to investigate whether SMT application reduces the risk of seroma in this group of patients.

Methods: A retrospective analysis of prospectively collected data identified 40 patients who underwent AWR for GMIH in a UK District General Hospital between September 2007 and March 2016. The first 20-patients underwent AWR without talc and the subsequent 20-patients underwent AWR with SMT application. Patients' demographics, clinical parameters and postoperative outcomes were analysed.

Results: Similar number of patients in the talc group (5, 25%) and no-talc group (6, 30%) suffered from postoperative seroma ($\chi^2(1)$ =0.13, p=0.72). However, the length of hospital-stay was significantly (p=0.008) longer in the talc group (mean =7 days, SD=2.7) than no-talc group (mean =5 days, SD=1.9). There were significant differences in the patients' characteristics between the two groups including: Gender; BMI; duration of symptoms; mesh size used for the repair; and duration of surgery. However, there was no significant increase of the likelihood of seroma in a logistic regression analysis of any of these factors.

Conclusion: This study did not show a significant reduction in the incidence of postoperative seroma, in patients, who underwent AWR for GMIH with or without SMT application. Randomized control, powered study is required to conclude the role of SMT application for seroma prevention in this patient population.

Keywords: Giant Medline Incisional Hernia; Subcutaneous Medical Talc; Seroma formation; Seromadesis

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Introduction

Incisional hernia is a common surgical occurrence following a midline laparotomy with yearly figures reported as high as 11% to 20% [1,2]. Open or laparoscopic repairs are performed in symptomatic patients based on the size and grade of the hernia [3]. Seroma is a pocket of clear serous fluid that accumulates in the surgical plane, often in the space between the mesh and the overlying skin [4]. Although radiological finding of seroma is reported in up to a 100% of the cases after hernia repair, clinically symptomatic seroma is reported in 5.4% and 12.5% of patients following laparoscopic and open incisional hernia repair respectively [5-7]. In particular, Giant Midline Incisional Hernia (GMIH) repair may have increased risk of seroma and related wound complications because it involves the formation of large free skin flaps, component separation, fascial apposition and mesh placement [8]. Thus, the extensive tissue dissection causing disruption of the tissues' microvasculature and lymphatic drainage is believed to lead to seroma formation [9]. Fortunately, majority of cases with clinically symptomatic postoperative seroma are managed conservatively and resolve after a month or two following surgeries, however, some suffer from persistent symptoms that require further surgical interventions [10]. Radiologically guided drainage is usually a sufficient intervention, although a small minority of patients may develop significant

wound complication, sepsis, hernial recurrence, or may require further major surgery.

Strategies to reduce the incidence of postoperative seroma have been a surgical challenge [9,11]. Subcutaneous Medical Talc (SMT) application, hydrated magnesium silicate, exerts an inflammatory reaction and promotes adherence of cavity surfaces, thus, potentially obliterates 'dead spaces' and limits fluid accumulation [12]. SMT application has been most effective in creating pleurodesis in thoracic surgery [13,14] and there is some positive evidence of its use in reducing seroma formation in musculocutaneous flap dissection [5], breast surgery [6], inguinal hernia repairs [7] and incisional hernia repairs [9]. Whilst there have been conflicting reports of the role of talc in open incisional hernia repairs, there is no published data of its impact on seroma for patients undergoing AWR with sublay mesh and Component Separation Technique (CST).

This study aims to investigate whether SMT application in patients undergoing AWR for GMIH with rectus mesh placement following CST improves the incidence of symptomatic seroma accumulation.

Patients and Method

This is a retrospective analysis of a prospectively collected data of 40 consecutive patients who underwent abdominal reconstruction for GMIH from September 2007 to March 2016 in a UK District General Hospital. A total number of 20-patients underwent AWR without talc (no-talc) and another 20-patients underwent AWR with SMT application (talc). All procedures performed in this study were in accordance with the ethical standards of East Kent Hospitals University NHS Foundation Trust. The project was deemed to be a service evaluation conducted by the direct care team and ethics approved was not required. Strict adherence to the trust research governance guidelines was followed throughout the study period. Inclusion criteria were as follows: Patients with Ventral Hernia Working Group [15] (VHWG) grade I and II; hernial defect ≥ 15 cm in either craniocaudal or transverse length; age older than 18 and younger than 80 years old; American Society of Anesthesiologists (ASA) physical status I to III; and able to complete a written consent form. Patients who suffer from lateral abdominal hernia; are classified as VHWG grades III and IV; or those who required concomitant surgical intervention were excluded.

Computerized tomography (CT) of the abdomen and pelvis was performed in all patients. This was specifically interpreted with the objectives to: Delineate the area of the fascial defect; define the contents of the sac; identify any loss of domain, assess the abdominal musculature; and detect any occult hernias. None of the patients received Botox injections preoperatively. We have described our technique and outcome for AWR previously [16,17]. The repair technique was standardized in all patients undergoing laparotomy with or without adhesiolysis, retro-rectus mesh placement, Components Separation Technique (CST) and anterior sheath closure [16,17]. Surgical diathermy was used for the dissection of the subcutaneous tissue down to the fascia and for hemostasis. Composite mesh (Ethicon, Somerville, NJ, USA) was sutured in the retro-rectus space in all the patients. All of the patients underwent anterior component separation bilaterally. Furthermore, all patients had four vacuum-assisted suction drains placed in the subcutaneous plane.

For patients who underwent SMT application we uniformly sprinkled 8 g to 12 g of medical talc in the subcutaneous space on the anterior rectus sheath and external oblique muscle. The subcutaneous tissue and skin were subsequently closed. All the surgical AWRs were performed by a senior experienced surgeon (SB). All patients were given an induction dose of antibiotics (Co-Amoxiclav 1.2 g intravenously or Cefuroxime 1.5 g intravenously) in accordance with the hospital policy. Deep vein thrombosis prophylaxis of 40 mg subcutaneous Clexane (Low Molecular Weight Heparin) was commenced 6 h after completion of the procedure. This was continued until the patient's full mobility was restored. Vacuum-assisted drains were removed when the drainage was <50 ml within 24 h or between 7 to 10 days postoperatively. Early post-operative complications were recorded using Clavien-Dindo classification [18].

Outpatient clinic follow-up was arranged at 8 weeks and 6 months of the postoperative period. Thereafter, a yearly telephone-based review was conducted for 5 years to ensure that any clinical symptomatic recurrence is identified and treated. Telephone interviews used a structured questionnaire (Carolina Comfort Score) that assessed quality of life, pain and sensation of bulging. Patients were reviewed in person if there were any concerns identified during their telephone review. Seroma that was evident on clinical examination was recorded and persistent symptomatic seromas were drained radiologically. Superficial wound infection was defined as erythema of the abdominal wound requiring the administration of oral antibiotics.

Statistical analysis

Data were analyzed using GraphPad Prism (GraphPad Prism version 8.2.0 for MAC OS X, GraphPad Software, San Diego California USA) and "Statistical Package for the Social Sciences" (IBM SPSS Statistics for Macintosh, version 25.0, Armonk, NY: IBM Corp.). For inference statistics, paired t-test was used to analyses continuous data and Chi-square test was used to analyze categorical data. Univariate as well as multivariate regression analyses were performed. Logistic regression was used to determine the Odds Ratio (OR). The level of statistical significance was set at 5% ($p \leq 0.05$) for all test procedures. Post-hoc power analysis for sample size calculation was performed using the web-based calculator (©2019 – ClinCalc LLC. www.clincal.com).

Results

Patients' characteristics

Table 1 summarizes the main findings of this study including patients' characteristics. There were differences in the gender distribution between the groups. Significantly, more females (85%) and less males (15%) were included in the talc group in comparison to no-talc group (50%) (Fisher's exact p=0.009). There was similar patients with VHWG grades I and II in both groups. Furthermore, the duration of symptoms was significantly (p=0.002) higher in the talc group (median =138 months, range: 12-150) in comparison to no-talc (median =26 months, range: 12-18).

Operative variables

In terms of operative variables, the size of mesh used to repair the defect and the duration of surgery were significantly different. The mesh size in the talc group (mean =538 cm^2, SD=82) was significantly (p=0.008) smaller than no-talc group (mean =652 cm^2, SD=163). The duration of surgery in the talc group (mean =273 minutes, SD=73) was significantly (p=0.03) longer than no-talc group (mean =225 minutes, SD=65). All other operative variables were similar (Table 1).

Table 1: Patients characteristics.

	No talc (*n*=20)	Talc (*n*=20)	p value
Age: mean (SD)	61 (11)	60 (12)	0.7
Gender*			
Male	10 (50%)	3 (15%)	0.04
Female	10 (50%)	17 (85%)	
BMI (SD)**	31 (5)	36 (6)	0.009
ASA score			
I	2 (10%)	2 (10%)	0.58
II	13 (65%)	10 (50%)	
III	5 (25%)	8 (40%)	
VHWG			
I	8 (40%)	10 (50%)	0.75
II	12 (60%)	10 (50%)	
Duration of symptoms in months: Median (range)	26 (12 to 38)	138 (12 to 150)	0.002
Recurrent hernia repair			
Yes	17 (85%)	13 (65%)	0.27
No	3 (15%)	7 (35%)	
Defect size in cm² (SD)	306 (113)	301 (109)	0.89
Size of the mesh used in cm² (SD)	652 (163)	538 (82)	0.008
Anterior rectus sheath closure			
Complete	17 (85%)	18 (90%)	0.99
Incomplete	3 (15%)	2 (10%)	
Duration of surgery in minutes (SD)	225 (65)	273 (73)	0.03
Length of hospital stay in days (SD)	5 (1.9)	7 (2.7)	0.008
Seroma			
Yes	6 (30%)	5 (25%)	0.72
No	14 (70%)	15 (75%)	

ASA: American Society of Anesthesiologists physical status classification; BMI: Body Mass Index; SD: Standard Deviation; VHWG: Ventral Hernia Working Group; *p value<0.05; **p value<0.01

Postoperative outcome

A total number of 5 (25%) and 6 (30%) patients in the talc and no-talc groups respectively suffered from postoperative seroma. However, this difference in ratio was not statistically significant ($\chi^2(1)$ =0.13, p=0.72) (Figure 1A). Postoperative complications reported according to Clavien-Dindo classification were reported as: Grade I in 13 (65%) and 12 (60%) patients in the talc and no-talc groups respectively; Grade II in 4 (20%) of the patients in both groups; and Grade IIIa in 3 (15%) and 4 (20%) patients in the talc and no-talc groups respectively. These differences were statistically insignificant ($\chi^2(2)$ =0.18, p=0.91). Furthermore, the length of hospital stay in the talc group was significantly (p=0.008) higher (mean =7 days, SD=2.7) than no-talc group (mean =5 days, SD=1.9) (Figure 1B).

Control of confounding effect

To adjust for the differences in the independent variables against our primary outcome (the development of seroma), binary logistic regression analysis was performed. Table 2 shows the output including OR with 95% CI, LR and significance. None of the variables examined demonstrated statistically significant OR (or) LR for the development of postoperative seroma.

Table 2: Univariate logistic regression analysis of the likelihood of seroma development.

	OR (95% CI)	LR (df)	p value
Age	1.03 (0.96 to 1.09)	χ^2 (1)=46.4	0.43
Gender	2.75 (0.45 to 15.14)	χ^2 (1)=45.5	0.24
BMI	1.06 (0.94 to 1.19)	χ^2 (1)=43.6	0.38
ASA score			
I	2 (0.21 to 18.69)	χ^2 (1)=45.1	0.54
II	0.47 (0.10 to 2.17)	χ^2 (1)=45.1	0.33
Duration of symptoms	1.01 (0.99 to 1.04)	χ^2 (1)=42.5	0.26
Hernia defect size in cm²	0.99 (0.98 to 1.00)	χ^2 (1)=45.9	0.3
Mesh size in cm²	0.99 (0.99 to 1.00)	χ^2 (1)=46.1	0.37
Closure of anterior rectus sheath	1.93 (0.28 to 13.44)	χ^2 (1)=46.6	0.51
Duration of surgery in minutes	1.00 (0.99 to 1.01)	χ^2 (1)=47.0	0.91
Recurrent repair	1.7 (0.30 to 9.72)	χ^2 (1)=46.7	0.54

ASA: American Society of Anesthesiologists physical status classification; BMI: Body Mass Index; χ^2: Chi Square; LR: Likelihood Ratio; OR: Odds Ratio; SD: Standard Deviation; *p<0.05; **p<0.01

Length of hospital stay correlation

Length of hospital Stay (LoS) was significantly positively correlated with age (r=0.32; 95% CI 0.01-0.57; p=0.04); duration of surgery (r=0.45; 95% CI 0.16-0.67; p=0.004); and ASA score (r=0.37; 95% CI 0.06-0.60; p=0.02) (Figure 2). There was no significant correlation between LoS and gender (r= -0.18; 95% CI -0.47-0.13; p=0.25); BMI (r=0.31; 95% CI -0.01-0.57; p=0.06); duration of symptoms (r=0.29; 95% CI -0.03-0.56; p=0.08), hernial defect size (r=0.30; 95% CI -0.01-0.57; p=0.06), mesh size (r= -0.06; 95% CI -0.37-0.25; p=0.68), closure of anterior rectus sheath (r=0.16; 95% CI -0.16-0.45; p=0.31), or recurrent repair (r=0.05; 95% CI -0.26-0.36; p=0.75).

Post-hoc sample size calculation

With seroma being the primary outcome, we performed a post-hoc sample size calculation. A total of 1,098 patients, 549 in each group is required to achieve 80% power, 20% beta and 5% alpha. The current sample size of 20 patient in each group provides a post-hoc power of 5.4% considering an alpha value of 5%.

Discussion

Seroma formation following GMIH has been associated with postoperative abdominal discomfort; wound dehiscence; infection leading to cellulitis and abscess formation; delay in wound healing; and mesh infection [2,11]. Various operative techniques have been attempted to reduce the incidence of seroma formation that includes use of negative vacuum drains, SMT application, fibrin sealant, and quilting sutures [19]. The most common prophylactic procedure has been the placement of subcutaneous drains in order to prevent fluid accumulation in the early postoperative period, however, so far this has had a limited success [20]. SMT application has been confirmed to be safe in patients and in particular has been beneficial for chronic pneumothorax to achieving pleurodesis [13]. Similar to thoracic surgery, the use of SMT to prevent seroma formation following mastectomy has shown significant benefit to patients [9]. Thus far, the use of SMT application following AWR has demonstrated conflicting results. This study aims to investigate whether SMT application reduces the risk of postoperative seroma following AWR.

We have not found significant difference in the rate of seroma complication following AWR with or without SMT. Previous

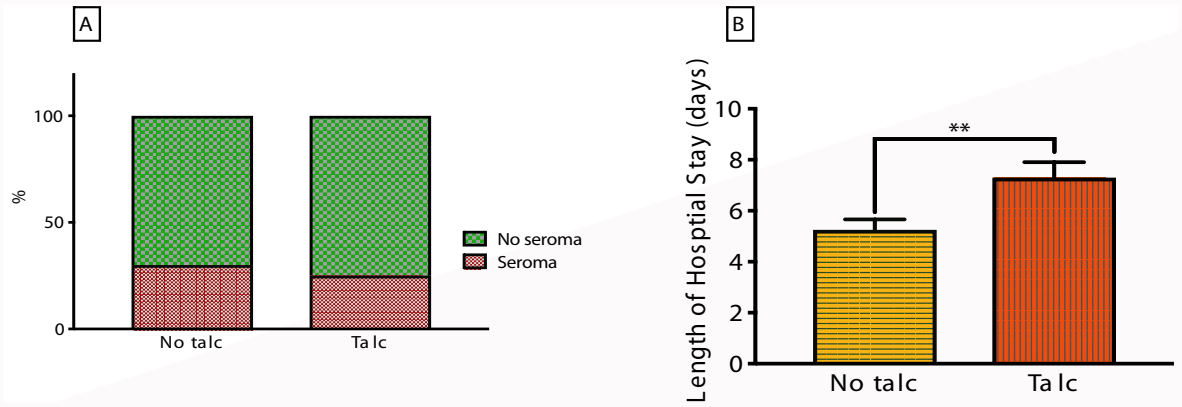

Figure 1: The development of seroma (A) is similar between the patients who were treated with talc and those who were treated without talc. Length of hospital stay (B) was significantly longer in patients treated with talc. **: p<0.01.

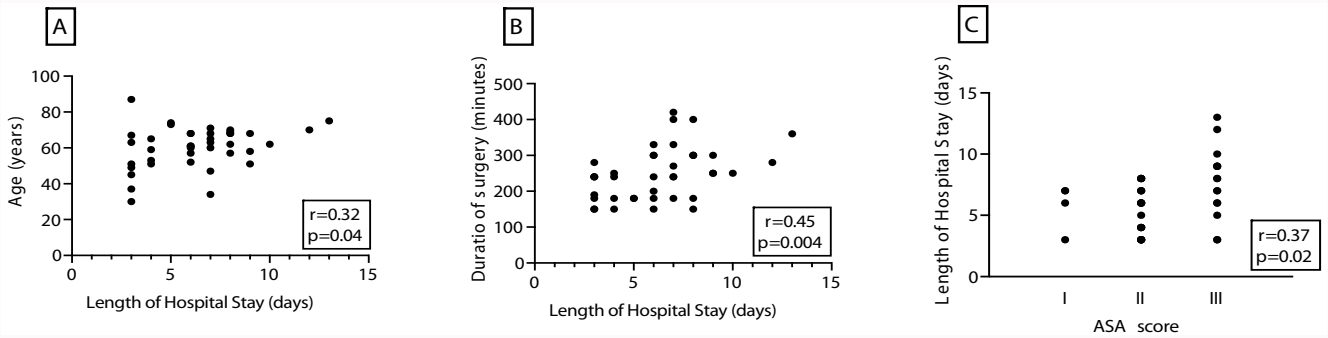

Figure 2: Length of stay correlation with age (A), duration of surgery (B) and ASA score (C).

studies assessing SMT application following preperitoneal mesh placement for open large ventral hernia repairs, have shown a reduction in seroma formation, whilst others have highlighted an increased incidence of subsequent wound complications [9,21,22]. However, results were disappointing after onlay mesh placement for AWR [23]. Direct contact between the mesh surface and talc particles may have prevented quick fibrinous fixation of the mesh and effective penetration of blood vessels through the mesh pores leading to increased seroma formation [23]. In comparison, our technique employs the application of talc powder in the subcutaneous space above the anterior abdominal sheath and separated from the mesh, which is placed in the recto-rectus plane [16]. Similarly, the application of fibrin sealant in the subcutaneous space to prevent seroma remains inconclusive [22,24]. Furthermore, the use of quilting sutures, which aim to suture the skin flaps to the underlying tissue to reduce the dead space and prevent seroma formation has been demonstrated benefit in abdominoplasty surgery, however, its role in AWR is unclear [25,26]. In this study we obliterated the dead space by the insertion of two vacuum drain and have not used quilting sutures for their implication in significantly prolonging operative time.

Other significant findings in this study include longer LoS in patients who underwent AWR with SMT application in comparison to patients without talc. This is likely to be related to a significantly higher BMI, and longer duration of surgery in the patients who had SMT application. As speculated, there was significant positive correlation between LoS and patients' age, duration of surgery and ASA score. These factors may be relevant to service provision and prediction of LoS in patients who are undergoing AWR.

This study is the first to report on the outcome of patients who underwent AWR for GMIH with the use of talc and is strengthened by the following factors: 1) well established surgical technique, whereby the mesh is placed in the retro-rectus plane and separated from the talc; 2) the operating surgeon is the same for all the patients which minimized the surgeon's technical variability; 3) the selection bias is minimized by performing the technique in two subsequent period of time: The first 20 patients had surgery without SMT application and the subsequent 20 patients had surgery with SMT application; 4) data collection and analysis was performed by members of the clinical research team who had no direct involvement in the patients' operative and perioperative care, which reduces interpretation bias; 5) analysis methods have adjusted for confounding factors and confirmed that although there were statistically different variables between the two groups, there was no significant association between those variables and the primary outcome; and 6) our study provides a power size calculation for future work to conclude whether SMT prevents seroma in AWR.

We do recognize that large sample size of 549 patients randomized in each group may not be practical or feasible and therefore extensive analysis of prospectively collected data on this group of patients may provide further understanding of the role of talc use in patients undergoing AWR for GMIH. Gather data on this topic through national database and large sample size observational studies maybe a more practical approach in this group of patients.

Despite the strengths that this study entertains, it is not without limitations. The lack of randomization, small sample size and inherent biases in an un-randomized, un-blinded study may have impact on

the results.

In conclusion, although this study did not show a significant reduction in the incidence of seroma by MST application in patients who are undergoing AWR for GMIH, the application of talc remains to be of uncertain benefit. Therefore, until further evidence concludes the role of this treatment modality, we do not advocate its routine use.

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