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Do drain tubes help reduce risks of post-operative complications in complex incisional hernia repair (as defined by a recent court ruling)?

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Title Page

Title - Do drain tubes help reduce risks of post-operative complications in complex incisional hernia repair (as defined by a recent court ruling)?

Running Title – Drain tubes in incisional hernia repair?

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Abstract

Background

A recent legal case described in the ANZ Journal of Surgery has sparked significant topical interest in drain tube use in incisional hernia repairs in Australia. This study reviews a single centre experience of drain tube use in incisional hernia repair.

Methods

Data from online clinical records was collected retrospectively from patients that underwent incisional hernia repair from the 1st January 2013 to the 31st December 2017. 'Complexity' factors of smoking, obesity and lower midline incision (as identified by the legal case) were also used to stratify groups.

Results

410 incisional hernia repair cases were identified during the 5-year period. Median length of stay of the non-drain placement group was significantly shorter than that of the drain placement group (2 vs 6 days, $p < 0.001$). 10.8% of patients with drain suffered from post-op wound infection compared to 3.6% in patients without a drain tube in-situ ($p = 0.005$). Seroma rates were no different with or without a drain (15.7% vs 16.9% $p = 0.78$). When stratified by 'complexity', there was a trend towards increased complications when drains were used.

Conclusion

Drain tubes were placed in only a small proportion of patients during incisional hernia repairs and were associated with a higher post-operative wound infection rate. When stratified by the

'complexity' factors outlined by the recent legal case, complications in more 'complex' patients may actually increase when a drain tube is used.

Keywords:

Incisional Hernia, Drain Tube, Wound Infection

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Introduction

Incisional hernia is one of the most common complications following abdominal operations with a reported incidence of 2% to 20%^{1,2}. Incisional hernia left untreated can become a cosmetic concern, impair quality of life, and in serious circumstances, it causes pain, incarceration or strangulation^{1,3}. The definitive treatment of incisional hernia is surgery, and many operative techniques are described^{2,4-6}. Following either laparoscopic or open approach, common post-operative complications include seromas and wound infections. Wound infections and seromas can lead to readmissions and involve long-term wound dressings or major complications including mesh infection⁷. Traditionally, drain tubes are often considered to prevent such complications⁸. However, benefits of drain tube placement are yet to be proven based on evidence with the scant available randomised trials demonstrating no difference^{9,10}. Other literature, based on other operations, retrospective or expert opinion, have inconsistent conclusions on drain tube effects claiming they either increases or decreases seroma formation^{11,12}, risks of infection^{13,14}, and pain¹⁵.

A recent legal case involving infected mesh following incisional hernia repair has sparked significant topical interest in drain tube use in Australia¹⁶. The court concluded, after hearing from 5 expert witnesses, that, the legal standard of care to be observed by the surgeon of ordinary skill and competence required the use of a negative pressure surgical drain in a complex case. The complexity to which the judge referred were obesity, a smoker and an incisional hernia from a lower abdominal wound. The combined use of these three items as complexity markers has not been established in the literature.

The term “complex hernia” is often used by surgeons to describe cases that are technically difficult to repair and time-consuming, however there is a lack of consensus to provide standard guidance for definition and treatment of complex incisional hernia¹⁷. In the last 20 years, the definition of complex abdominal hernias has changed significantly from simply depending on anatomical location in 1990s¹⁸, to involving size of hernial defect in 2000s¹⁹, and then to discussion on skin thickness involvement, factors influencing wound healing such as immunosuppression, steroid dependency, nutritional status, smoking and alcohol²⁰. Recent literature also studied classification based on patient age, recurrence, reducibility, loss of domain, wound contamination, past medical history including obesity, COPD and connective tissue disorder^{21,22}. An extensive systematic review was published for better understanding of definition and risk classifications of “complex abdominal hernias”¹⁷. This review described inclusion criteria in 4 categories: size and location, contamination and soft tissue condition, patient history, and other clinical scenarios (e.g. emergency operation with bowel resection, mesh removal, multiple defects). After identifying risk factors, it recommends further categorisation into 3 groups, i.e. minor, moderate and major complex hernias¹⁷. Despite this, complexity definitions have not yet become a part of regular clinical practice. However, it is not unusual for clinicians to defer hernia surgery for the treatment of modifiable risk factors such as obesity, with evidence suggesting decreased complications and recurrence rates after weight loss^{23,24}.

This study follows on from a national survey of surgeons confirming that drain tube use is not routine throughout Australia, with a variety of surgical practice²⁵. We hypothesise that surgical practice in incisional hernia repair at a single metropolitan centre is similarly varied, and also compare the relationship between drain tube use and complications, including seroma and wound infection, stratified by various complexity measures as defined by the recent court ruling. We aim to use our

data to bridge the gap in definition between the recently discussed legal case and the published medical literature, and determine whether the court ruling definitions have validity.

Methods

This retrospective audit was performed at a single centre, Northern Health, Melbourne, Australia. Incisional hernia repair is practiced by all 21 general surgeons at Northern Health, with no dedicated hernia service, no standardised protocol for managing patients, and a variety of meshes and drains available for use. The choice of type of repair, approach, and use of drain was made by individual surgeons. Surgeons were not screened or surveyed regarding regular practice including whether they were routine drain tube users.

Data from online clinical records was collected retrospectively from patients that underwent incisional hernia repair from the 1st January 2013 to the 31st December 2017. All elective and emergency cases of incisional hernia repair were included. Basic demographic data, pre-operative details, including smoking status, BMI, incisional hernia site, nature and size of hernia were collected. Operative details included approach of surgery, intra-operative finding of adhesion, length of operation. Post-operative details included drain output, length of drain in-situ, length of stay, post-operative wound infection, post-operative antibiotics, 30-day re-admission, re-admission length of stay and complications by Clavien-Dindo classification. The smoking status in this study was extracted from pre-operative health questionnaire, preadmission clinic documentation and the general practitioner referral letters. BMI was calculated based on operative anaesthetic entry of weight and height for each patient. Obesity is defined as a BMI value above 30 kg/m²²⁶. A 'lower abdominal wound' was defined as

patients with an incisional hernia located below and excluding the umbilicus (i.e. right iliac fossa, left iliac fossa, lower midline, and Pfannenstiel sites).

This study was approved by the local research and ethics committee (ALR 07.2018).

Analysis

Descriptive analysis was undertaken to provide a comparative profile of patients with and without drain tube and by the complexity of the incisional hernias. Results were presented as mean and standard deviation for normally distributed variables and medians and interquartile ranges (IQR) for those variables which were non-normally distributed. Categorical variables were presented as counts and frequencies or percentages. To test for statistically significant differences between groups, Student's t-test and the Mann–Whitney (rank-sum) test were utilized for continuous normal and non-normally distributed variables, respectively. For categorical variables, the chi-squared test was performed, with Fisher's exact tests used on occasions when frequencies were <5 for any combination. Stata version 15.1 (Stata Corp, College Station, Texas, USA) was used to conduct the statistical analysis, with all tests two-sided and a p-value of <0.05 considered to indicate statistical significance.

Results

410 incisional hernia repair cases were retrospectively identified during the 5-year period from the 1st January 2013 to the 31st December 2017. 166 patients (40.5%) were male, and 244 patients (59.5%)

were female (Table 1). Surgical drains were placed in 102 cases (24.9%). With regard to all the pre-operative risk factors considered in this study, no-drain tube placement is the favoured option in the past 5 years. By isolating each individual risk factor for complex hernia, 98 out of 136 smokers (72.1%, $p=0.31$), 169 out of 228 obese patients with BMI>30 (74.1%, $p=0.64$), 39 out of 58 patients with a lower abdominal sites (67.2%, $p=0.015$), 245 out of 317 patients with reducible hernia (77.3%, $p=0.13$), and 62 out of 92 patients with incarcerated hernia (67.4%, $p=0.13$) did not have a drain tube placed.

When the size of the incisional hernia (measured at the neck of the hernia defect) was below 5cm, there was a significantly larger number of patients managed without a drain compared with when the neck of the hernia measured between 5-10cm and above 10cm (86.1% vs 57.7% and 64.0% respectively, $p<0.001$) (Table 1).

Surgeons placed a drain tube more frequently in open mesh repair, especially during an open extra-peritoneal (onlay) approach for which a drain was used in 50.0% of cases ($p<0.001$). Placing a drain tube was also associated with an increased duration of surgery (80 min (IQR 50.0, 119.5) vs 120 min (IQR 80.0,160.0), $p<0.001$).

Post-operatively, patients with a drain had a first 24-hour drain output median of 65.0 mL (IQR 50.0, 100.0), and the last 24-hour drain output before removal was 30.0 mL (IQR 20.0, 62.0) (Table 1). The average length of drain in-situ was a median of 3 days (IQR 2, 6). Median length of stay of the no-drain placement group was significantly shorter compared to that of the drain placement group (2 days vs 6 days, $p<0.001$). 88.0% of patients without a drain tube did not receive any prophylactic or

therapeutic antibiotic treatment, whereas significantly more (50%) of patients with drain tubes received intravenous antibiotics post-operatively ($p < 0.001$).

There were no statistically significant differences in complications; 12.7% in drain group vs 9.1% in no-drain group with Clavien-Dindo grade 1 and 2, and 7.8% in drain group vs 4.5% in no-drain group with Clavien-Dindo grade 3 and 4 ($p = 0.27$) (Table 1). Additionally, there was no difference in clinically detectable seromas between drain and no-drain groups (Table 2).

By isolating each of the 3 “complex” risk factors individually, and regrouping patients meeting one or two, or all three risk factor criteria, the results revealed that there was an increase in the percentage of cases with drain tube placement as the complexity increased, although this apparent trend was not statistically significant ($p = 0.45$) (Table 3). The rate of post-operative wound infection rate was higher in the drain tube group compared to the no drain tube group (10.8% compared to 3.6%, $p = 0.005$) (Table 1), with Table 4 including a breakdown by complexity level. Only the ‘one’ complexity risk factor level retains statistical significance ($p = 0.006$) with a higher rate of post-op wound infection in the drain tube group (14.9%) compared to the no drain tube group (3.6%), although small sample sizes prevent a thorough inspection across each complexity level. A similar pattern appears when considering the association between drain tube use and Clavien-Dindo grade when considering each complexity level. The ‘one’ complexity group indicates a higher likelihood of a Clavien-Dindo complication, particularly in the Grade 1-2 group, but is not statistically significant ($p = 0.082$).

Discussion

Our retrospective study has confirmed a varied approach to incisional hernia repair, particularly in respect to the use of drain tubes. Our cohort includes laparoscopic repairs, different open approaches, and some newer techniques including retro-rectus repairs, consistent with the modern landscape of incisional hernia repairs⁴⁻⁶.

The court case in Australia which has sparked a renewed interest in the technique of incisional hernia repair highlights several issues. In Truskett's editorial, the issue of uninformed testimony and possible ramifications for expert witnesses is explored²⁷. In this study, we concentrate on two other issues: the use and outcomes following the use of a drain tube; and the definition and outcomes of 'complex' incisional hernia repair and relate both of these issues to a single institution practice.

In our patient cohort, drains were used in only a quarter of all incisional hernia repairs (24.9%), and a minority of all types of techniques except on-lay extraperitoneal mesh repairs where drains were used in 50% of cases, presumably in an attempt to reduce seromas and haematomas. Similar to scant published literature, our study showed no great difference in seroma, infectious and overall complication rates whether a drain was used or not^{9, 11, 28, 29}. The decision to place a drain tube is often borne out by training and a desire to prevent complications, with very little substantiated data to guide decision making. A Cochrane review was unable to come to a conclusion with only one randomised trial comparing two different types of drains¹⁰. Since then, a randomised controlled trial of only 42 patients found no difference in seroma rates⁹. Clearly, there is no current evidence to support drains to a point where they are mandatory in all cases.

The complexity of incisional hernias has been studied in some details and an in-depth review article has categorised complexity under the groupings of "size and location", "contamination/soft tissue

condition”, “patient history/risk factors”, and “clinical scenario”, with obesity, smoking and lower abdominal location not featuring highly¹⁷. On the contrary, mesh placement difficulty was considered the major impediment when considering location, and laterally located hernias including lumbar and subcostal locations were considered the more complex incisional hernias. Obesity and smoking were considered minor or moderate wound healing risk factors only¹⁷. When we adopted the Australian court decision of what defines a complex hernia and considered lower abdominal defects, obesity and smoking as “complexity” issues, we found no apparent trend in seroma, infection and complication rates with 1, 2 or all 3 factors. However, when dividing the groups into those who received drains or not, we found an increase in minor complications in those with a “complexity” factor, and an increase in major complications in those with 1 or 2 “complexity” factors. While our numbers are small, the retrospective data does not support the definition of complexity as defined by the Australian court¹⁶.

The major limitation of this study is that as a retrospective study it was impossible to determine the major factors behind a surgeon’s placement of a drain tube in individual cases. While we and others have shown no difference in outcomes, particularly seroma formation, with a drain tube, it is possible that surgeons intuitively recognise high risk cases and their use of drain tubes reduces the complication rate to that of the non-drained patients. If this were true, then this would support the use for selective drain tube use. However, the converse argument is that our data supports other similar data in that drain tubes may promote wound infections through colonisation of the drain³⁰. A well designed randomised controlled trial will be required to determine the true answer to this long-debated issue.

In conclusion, our study showed that drain tubes were placed in only a small proportion of patients irrespective of the smoking status, BMI or anatomical location of the incisional hernia, and were

associated with a similar post-operative outcome with the exception of hospital stay which was longer. Interestingly, there was a close relationship between the degree of 'complexity' of hernia repair and increased post-operative complications, particularly wound infections, when drain tubes were used. Generally, placing a drain tube had no effect on the post-operative seroma rate. Our study results significantly differ from the recommended (mandatory) approach as suggested by the Australian court but follow the best evidence available and are consistent with published data.

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Table 1 – Demographics of cases, possible predictive risk factors comparing drain versus no drain groups, and post-operative outcomes

	Number	No drain tube	With a drain tube	p-value
Total number	410	308 (75.1%)	102 (24.9%)	
Male	166	129 (77.7%)	37 (22.3%)	
Female	244	179 (73.4%)	65 (26.6%)	
Pre-operative factors				
Smoker	136	98 (72.1%)	38 (27.9%)	0.31
Obesity (BMI>30)	228	169 (74.1%)	59 (25.9%)	0.64
Lower abdominal sites (RIF, LIF, lower midline, Pfannenstiel)	58	39 (67.2%)	19 (32.8%)	0.015
<i>Nature</i>				0.13
Reducible	317	245 (77.3%)	72 (22.7%)	
Incarcerated	92	62 (67.4%)	30 (32.6%)	
<i>Size</i>				<0.001
0-5cm	231	199 (86.1%)	32 (13.9%)	
5-10cm	104	60 (57.7%)	44 (42.3%)	
>10cm	75	48 (64.0%)	27 (36.0%)	
Intra-operative factors				
<i>Approach of surgery</i>				<0.001
Laparoscopic intraperitoneal	140	136 (97.1%)	4 (2.9%)	
Open intra-peritoneal	12	8 (66.7%)	4 (33.3%)	
Open pre-peritoneal (Sublay)	75	47 (62.7%)	28 (37.3%)	
Open extra-peritoneal (Onlay)	122	61 (50.0%)	61 (50.0%)	
Suture repair	53	51 (96.2%)	2 (3.8%)	
Retro-rectal	8	5 (62.5%)	3 (37.5%)	
Adhesion	157	119 (75.8%)	38 (24.2%)	0.80
Length of surgery (mins), median (IQR)		80.0 (50.0, 119.5)	120 (80.0, 160.0)	<0.001
Post-operative outcomes				
First 24-hr drain output (mL), median (IQR)			65.0 (50.0, 100.0)	
Last 24-hour drain output before removal (mL), median (IQR)			30.0 (20.0, 62.0)	
Length of drain in-situ (days), median (IQR)			3.0 (2.0, 6.0)	
Length of stay, median (IQR)		2.0 (2.0, 4.0)	6.0 (4.0, 9.0)	<0.001
Post-op wound infection		11 (3.6%)	11 (10.8%)	0.005
<i>Post-op antibiotics</i>				<0.001
No antibiotics		271 (88.0%)	40 (39.2%)	
IV antibiotics		25 (8.1%)	51 (50.0%)	
Oral antibiotics only		11 (3.6%)	11 (10.8%)	
30-day unexpected readmissions		31 (10.1%)	12 (11.8%)	0.20
Readmission LoS, median (IQR)		3.0 (2.0 – 6.0)	7.5 (3.0 – 41.5)	0.043
Clavien-Dindo grade				0.27
No grade		263 (85.4%)	81 (79.4%)	

Grade 1 and 2	28 (9.1%)	13 (12.7 %)
Grade 3 and 4	14 (4.5%)	8 (7.8%)
Grade 5	3 (1.0%)	0

Table 2 – Post-operative seroma by comparing cases with versus without a drain

	Number	Without a drain	With a drain	p-value
Total number	404	302	102	
Seroma	67	51 (16.9%)	16 (15.7%)	0.78
No seroma	337	251 (83.1%)	86 (84.3%)	

Table 3 – Outcomes for “Complex” incisional hernias

Group / Variable	“Simple” incisional hernias	“Complex” incisional hernias, meeting 1 out of the 3 criteria	“Complex” incisional hernias, meeting 2 out of the 3 criteria	“Complex” incisional hernias, meeting all 3 criteria	P-value
Total	110	187	104	9	
With Drains	22 (20.0%)	47 (25.1%)	30 (28.8%)	3 (33.3%)	0.45
Without Drains	88 (80.0%)	140 (74.9%)	74 (71.2%)	6 (66.7%)	
Post-op wound infection <i>Clavien-Dindo grade</i>	4 (3.6%)	12 (6.5%)	5 (4.8%)	1 (11.1%)	0.63
Uncomplicated	96 (87.3%)	152 (81.3%)	88 (84.6%)	8 (88.9%)	0.16
Grade 1/2	6 (5.5%)	27 (14.4%)	8 (7.7%)	0	
Grade 3/4	6 (5.5%)	7 (3.7%)	8 (7.7%)	1 (11.1%)	
Grade 5 (death)	2 (1.8%)	1 (0.5%)	0	0	

“Complexity” criteria defined as 1. Smoker, 2. Obesity, 3. Lower abdominal wound (i.e. Lower midline, Pfannenstiel, RIF, LIF).

Table 4 - Clavien-Dindo grade by drain within each complexity level

Group / Variable		“Simple” incisional hernias	“Complex” incisional hernias, meeting 1 out of the 3 criteria	“Complex” incisional hernias, meeting 2 out of the 3 criteria	“Complex” incisional hernias, meeting all 3 criteria
Post-op wound infection	No drain	3 (3.4%)	5 (3.6%)	3 (4.1%)	0 (0%)
	Drain	1 (4.5%)	7 (14.9%)	2 (6.7%)	1 (33.3%)
	<i>p-value</i> †	0.596	0.006	0.625	0.333
Uncomplicated	No drain	75 (85.2%)	119 (85.0%)	63 (85.1%)	6 (100%)
	Drain	21 (95.5%)	33 (70.2%)	25 (83.3%)	2 (66.7%)
Grade 1/2	No drain	5 (5.7%)	16 (11.4%)	7 (9.5%)	0
	Drain	1 (4.5%)	11 (23.4%)	1 (3.3%)	0
Grade 3/4	No drain	6 (6.8%)	4 (2.9%)	4 (5.4%)	0
	Drain	0	3 (6.4%)	4 (13.3%)	1 (33.3%)
Grade 5 (death)	No drain	2 (2.3%)	1 (0.7%)	0	0
	Drain	0	0	0	0
	<i>p-value</i> †	0.765	0.082	0.262	0.333

† *p-value* for association between drain status and post-op wound infection or Clavien-Dindo grade within each complexity level

