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Effect of Negative Pressure Wound Therapy on Wound Complications Post-Pancreatectomy

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Abstract

Surgical site infection (SSI) and incisional hernia are common complications after major pancreatectomy. We investigated the effects of negative pressure wound therapy (NPWT) on short- and long-term wound outcomes in patients undergoing pancreatectomy. A randomized controlled trial comparing the effect of NPWT with standard surgical dressing (SSD) on wounds was performed in 265 patients undergoing open gastrointestinal resections from 2012 to 2016. We performed a subset analysis of 73 patients who underwent pancreatectomy. Wound complications in the first 30 days and incisional hernia rates were assessed. There were 33 (45%) female patients in the study and the average BMI was 27.6. The pancreaticoduodectomy rate was 68 per cent, whereas 27 per cent of patients underwent distal or subtotal pancreatectomy, and 4 per cent total pancreatectomy. Incisional hernia rates were 32 per cent and 14 per cent between the SSD and NPWT groups, respectively ($P = 0.067$). In the SSD (n = 37) and NPWT (n = 36) cohorts, the superficial SSI, deep SSI, seroma, and dehiscence rates were 16 per cent and 14 per cent ($P > 0.99$), 5 per cent and 8 per cent ($P = 0.67$), 16 per cent and 11 per cent ($P = 0.74$), and 5 per cent and 3 per cent ($P \geq 0.99$), respectively. After adjusting for pancreatic fistula and delayed gastric emptying, no statistically significant differences in the primary outcomes were observed. These findings were true irrespective of the type of resection performed. Short- and long-term wound complications were not improved with NPWT. We observed a trend toward decreased incisional hernia rates in patients treated with NPWT. Owing to the multifactorial nature of wound complications, it is yet to be determined which cohorts of pancreatectomy patients will benefit from NPWT.

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Michael Kuncewitch compiled data and wrote the manuscript. Aaron Blackham helped design the prospective randomized trial and acquired data. Rebecca Dodson performed data acquisition and critical review of manuscript. Clancy Clark helped design the trail, acquired data, and provided critical review. Gregory Russel assisted in trial design and data interpretation. Edward Levine contributed to trial design, data acquisition, and critical review. Perry Shen designed the trial, acquired data, and wrote the manuscript.

SURGEONS WHO TREAT disorders of the pancreas are accustomed to giving considerable attention to the incidence, management, and potential prevention of complications after pancreatectomy. Pancreatic fistula is typically the most studied of these complications and perhaps the one most discussed with patients while obtaining informed consent. It may therefore be easy to overlook the notion that wound complications following pancreatectomy happen with similar or even greater frequency. Several recent studies put the incidence of surgical site infection (SSI) after major pancreatectomy between 10 and 35 per cent.[1–4] With an average cost of approximately US $11,000 per SSI after pancreatectomy and an additional 6.5 days hospital stay, this represents a great cost burden to health-care systems.[3] SSI represents a major health burden to patients as well when considering that SSI after major surgery has been associated with a doubling in the risk of postoperative mortality as well as increased likelihood of hospital readmission and need for ICU care.[5]

Incisional hernia is another potentially adverse out-come that can cause significant morbidity for patients undergoing major pancreatectomy. One recent study found that incisional hernia may incur in up to 50 per cent of patients undergoing open pancreatectomy.[6] This can be potentially detrimental to a patient's quality of life after an operation already known to carry considerable morbidity risks. Furthermore, many major pancreatectomies are performed for tumors that may portend a greatly shortened life expectancy, thereby ruling certain patients out for potentially complex ventral hernia repair that might otherwise improve their quality of life.

Last, it should be noted that there is a strong association between SSI and subsequent incisional hernia after laparotomy, so efforts aimed at curbing SSI could reasonably be considered to be preventative toward incisional hernia as well.[7] One such method that has been considered as a potentially prophylactic measure toward these ends is negative pressure wound therapy (NPWT). We previously reported the results of a Phase II randomized controlled trial using NPWT in an attempt to decrease SSI in patients undergoing laparotomy for various abdominal malignancies.[8] We herein report the results on short- and long-term wound out-comes on a subset of these patients undergoing major pancreatectomy (pancreaticoduodenectomy (PD), total pancreatectomy, or distal/subtotal pancreatectomy) randomized to prophylactic application of NPWT *versus* standard surgical dressing (SSD) at the time of primary wound closure.

Materials and Methods

This study was approved by the Protocol Review Committee of the Wake Forest Baptist Comprehensive Cancer Center and the Wake Forest University Institutional Review Board. As previously reported, we performed a prospective Phase II randomized controlled trial assessing the differences in SSI rates for patients undergoing open oncologic gastrointestinal resections from 2012 to 2016, whose wounds were dressed with either a SSD or NPWT at the time of primary closure.[8] Eligible participants were those patients aged 18 years or older who were able to understand and sign written informed consent and who underwent a pancreatectomy *via* a midline laparotomy incision with a class II (clean-contaminated) case. Those patients undergoing a laparoscopic-assisted procedure were included as long as an incision of no less than 7.5 cm was required for either a hand port or specimen extraction.

Surgical drains were permitted in the study as long as the drain exited the abdominal wall at a site remote from the primary incision. Exclusion criteria included any wound that was not class II, purely laparoscopic cases, patient history of allergic reaction to adhesives, and steroid or immunosuppressive use within three months of the planned operation.

For the present study, we performed a subset of analysis of 73 of the original 265 patients who underwent a major pancreatectomy to see whether there was any difference in the rates of SSI at 30 days from operation for this particular cohort. The technique for application of the NPWT has been previously described.[9] To determine whether an SSI occurred, study members performed wound checks that included a daily assessment of the incision and abdominal wall during the patient's postoperative hospital stay as well as any readmissions or outpatient clinic visits until 30 days after surgery. Team members were instructed to assess wounds by using an incision assessment form that documented wound status according to SSD soilage level or NPWT drainage quantity, cellulitis, seroma, hematoma, dehiscence, or organ/space SSI. Patients were considered to develop an SSI if they met the criteria for either a superficial or deep SSI as defined by the Centers for Disease Control.[10] Both the SSD and NPWT were discontinued on postoperative day 4 as part of the study protocol. If any wound in either study arm was found to be productive of either pancreatic or enteric effluent before this, the dressing was to be discontinued and replaced with a wet-to-dry dressing.

To ascertain the medium- to long-term effects of NPWT on laparotomy incisions after major pancreatectomy, we also analyzed as a primary outcome the incidence of incisional hernia in the SSD and NPWT groups. Patients were assessed at postoperative clinic visits for clinical evidence of incisional hernia as determined by a fascial defect appreciated on physical examination of the abdomen. Wound assessments were documented in the patient record at the initial postoperative visit, as well as at 6- and 12-month follow-up intervals. Assessments continued at yearly intervals thereafter or until the patient was lost to follow-up or died.

Secondary outcomes that were measured included the incidence of pancreatic fistula and delayed gastric emptying (DGE) because these factors were considered to have the potential to independently contribute to wound healing problems, thereby confounding the contribution of NPWT to the study. For purposes of this study, pancreatic fistula was defined as a surgical drain amylase level greater than three times the upper limit of normal for serum amylase after postoperative day 3.[11] Delayed gastric emptying was defined according to the 2007 International Study Group of Pancreas Surgery guidelines.[12]

Statistical Analysis

Descriptive statistics, including means and standard deviations for continuous measures and frequencies and percentages for categorical variables, were calculated for all study measures. To test for differences in demographic measures between study assignments, independent *t* tests were used for continuous measures and Fisher's exact tests were used for categorical data. To assess the strength of the relationship with hernia and SSI, single and multiple variate logistic regression models were created, with the independent study variables as predictors. SAS (version 9.4, Cary, NC) was used for all analyses.

Results

From 2012 to 2016, there were 73 patients undergoing major pancreatectomy out of 265 patients who were analyzed in the original study examining rates of SSI in patients receiving NPWT after open oncologic abdominal resections. Patients were followed for a median duration of 11 (range, 1–48) months before death or loss to follow-up. The average age of patients treated in both groups was 65 years (age range, 35–85 years), with 45 per cent of the patients being women. Both the SSI and NPWT groups were demographically similar in terms of race, BMI, performance status, medical comorbidities, tobacco use, previous abdominal surgery, and whether or not study participants received neoadjuvant chemotherapy or radiation (Table 1). Most resections in the study were performed for pancreatic adenocarcinoma (51%). In both the SSD and NPWT groups, respectively, the most common type of resection was PD (65% vs 72%), with the remaining patients undergoing similar rates of distal, subtotal, and total pancreatectomy between the groups. There were also no statistically different differences in the use of laparoscopy, operative time, or estimated blood loss in those patients whose wounds were dressed with SSD or NPWT. There was a trend toward more frequent need for blood transfusion in the SSD group compared with the NPWT group (eight patients vs two patients), but this also did not reach statistical significance ($P = 0.085$; Table 2).

The rates of any degree of SSI were equal (22%; $P > 0.99$) in both the SSD and NPWT groups. This was borne out with similar rates in the SSD and NPWT cohorts, respectively, for superficial SSI (16% *vs* 14%; $P > 0.99$), deep SSI (5% *vs* 8%; $P = 0.67$), seroma formation (16% *vs* 11%; $P = 0.74$), and wound dehiscence rates (5% *vs* 3%; $P = 0.99$; Fig. 1). A similar number of patients required that their wounds be opened for any reason in the SSD and NPWT groups (35% *vs* 25%, respectively; $P = 0.45$) and no statistically significant difference was appreciated in the need for readmission within 30 days of operation owing to a wound complication (15% vs 7%; $P = 0.26$; Fig. 2).

The rates of incisional hernia as determined by postoperative clinical examination in the SSD and NPWT groups were 32 per cent and 14 per cent, respectively ($P = 0.067$; Fig. 2). Resection-specific incisional hernia rates for those patients undergoing PD, distal/subtotal pancreatectomy, and total pancreatectomy were 25 per cent, 17 per cent, and 50 per cent, respectively (Fig. 3). NPWT was not found to be preventative toward incisional hernia in any of these groups (all $P > 0.33$). Of the 17 total patients who developed an incisional hernia between the two treatment arms, 4/17 (24%) subsequently underwent an incisional hernia repair.

In those patients with laparotomy incisions dressed with SSD or NPWT, respectively, the incidence of postoperative pancreatic fistula (22% *vs* 31%, $P = 0.43$) and DGE (11% *vs* 8%, $P > 0.99$) was not statistically different (Fig. 2). Neither univariate nor multivariate analysis identified any demographic or operative factors associated with a difference in incisional hernia rates in either treatment arm (Table 3).

Discussion

SSI is a major driver of patient morbidity and hospital cost. As a result, investigators in various surgical fields have turned their gaze to the NPWT in the hopes of finding a better way to manage elective wounds and reduce this burden.[13–15] For the patient with pancreatic malignancy, however, the potential benefits of avoiding an SSI could also include prolonged survival, as SSI after pancreatectomy has been demonstrated to lead to a delay in receiving adjuvant treatment.[16]

The purported benefits of NPWT in improving wound healing include the abilities to remove excess fluid from the wound microenvironment, to reduce shear stresses and tissue hypoxia on the wound edges, and to stimulate the release of vascular endothelial growth factor in the wound milieu.[17,18] In theory, the application of NPWT to an elective midline laparotomy wound might then decrease the incidence of superficial SSI at the very least. It stands to reason that a corollary to such a benefit would be an associated decrease in postoperative incisional hernia. In practice, however, this line of reasoning has not yet been successfully proven. We recently published the results of a Phase II randomized controlled trial in patients undergoing laparotomy incisions for gastrointestinal malignancies that showed no statistically significant difference in the rates of either superficial or deep SSI for patients whose wounds were treated with either SSD or NPWT at the time of primary closure.[8] The design of that trial, however, was limited to a 30-day follow-up and intended only to assess the short-term effects of NPWT on laparotomy for oncologic resection. This study includes a median patient follow-up of 11 months, during which we were able to perform interval clinical examinations to assess patients for the presence of an incisional hernia.

Pancreatectomy is often performed in patients with pancreas adenocarcinoma, an entity that can carry a poor prognosis. For this reason, the importance of emphasizing a patient's quality of life after resection is magnified, a sentiment that is gaining considerable traction in the world of medicine.[19] Identifying any potential benefit of NPWT in preventing incisional hernia could greatly benefit the pancreatectomy patient as patients with incisional hernia can experience a detrimental impact on their quality of life.[20] Moreover, many patients with pancreatic pathologies might not be good surgical candidates for ventral hernia repair after their major pancreatectomy. This is suggested by the fact that in our study, only 4 of 17 patients who had a postoperative hernia appreciated on physical examination underwent subsequent surgical repair of that hernia. Although we did observe a trend toward improvement in incisional hernia rates after major pancreatectomy with NPWT, this was not statistically significant.

However, the 14 per cent rate of incisional hernia using NPWT compared with 32 per cent without should not be ignored and may simply be a result of the pancreas subset of the initial study being underpowered. There are several factors that may explain a correlation between NPWT and a decreased hernia rate. One potential mechanism of action of NPWT is to provide a localized abdominal binder-like effect on the fascia and soft tissues of the abdominal wall, thereby counteracting the sheering forces and lateral tensile forces placed on the wound post-operatively.[21] Another possible explanation for the association between NPWT and decreased hernia rate is its effect on local interstitial fluid accumulation.

Although we did not observe a statistically significant difference in the rate of seroma formation with the use of NPWT, it is still likely that NPWT reduces local tissue edema, which should lead to an increase in local tissue perfusion.[22]

In addition, it has been demonstrated that treating a wound with subatmospheric pressures of 125 mmHg can result in up to a 4-fold increase in perfusion of the tissues at the edges of the wound.[23] Finally, the use of NPWT has been demonstrated to apply a constant, equally distributed mechanical stress to the tissues at the edge of the porous foam used in NPWT.[24] Unlike lateral tensile forces or shearing forces from abdominal wall movement that may distract the fascia as it attempts to heal, these local mechanical forces may act increase angiogenesis and upregulate genes leading to increased fibroblast activity and collagen turnover.[25, 26] Together, all of these factors may lead to an optimization of fascial healing with a subsequent decrease in the likelihood of an incisional hernia.

One potential reason why we did not observe a statistically significant difference in incisional hernia after pancreatectomy with NPWT may be the duration of therapy itself. The optimal duration of NPWT when applied to a primary abdominal incision has not yet been determined. We chose four days of therapy based on the extensive experience of the plastic surgeons at our institution, but that may not be the optimal length of time when considering healing of the abdominal fascia. It is then possible that a longer period of NPWT may be most beneficial, with patient length of stay acting to limit duration on practicality and cost bases. In any case, perhaps other ongoing trials evaluating NPWT for primary transabdominal incisions can guide us toward the optimal duration of therapy.

Our assessment of the rates of incisional hernia was also limited by the fact that this study only sought to establish the presence or absence of a clinically appreciable incisional hernia. We did not measure the size of the hernia or the impact on a patient's performance status or quality of life. We did not assess the hernias for symptomatology or whether the patient desired surgical repair. Another limitation of the study is the median follow-up of 11 months. Although most incisional hernias will present within the first postoperative year, a significant proportion of incisional hernias can be first diagnosed at two to five years from the index operation.[27] For this reason, it is possible the incidence of incisional hernia in either or both of our treatment groups would change at longer follow-up. This limited follow-up may support the notion that, although prevention of incisional hernia in this study could not be demonstrated, the trend toward statistical significance might merit further study.

Conclusion

The use of NPWT in midline laparotomy incisions for patients undergoing major pancreatectomy did not demonstrate a difference in the rates of SSI or incisional hernia. Based on the results of this study, NPWT cannot be recommended to prevent short- or long-term wound complications in patients undergoing major pancreatectomy.

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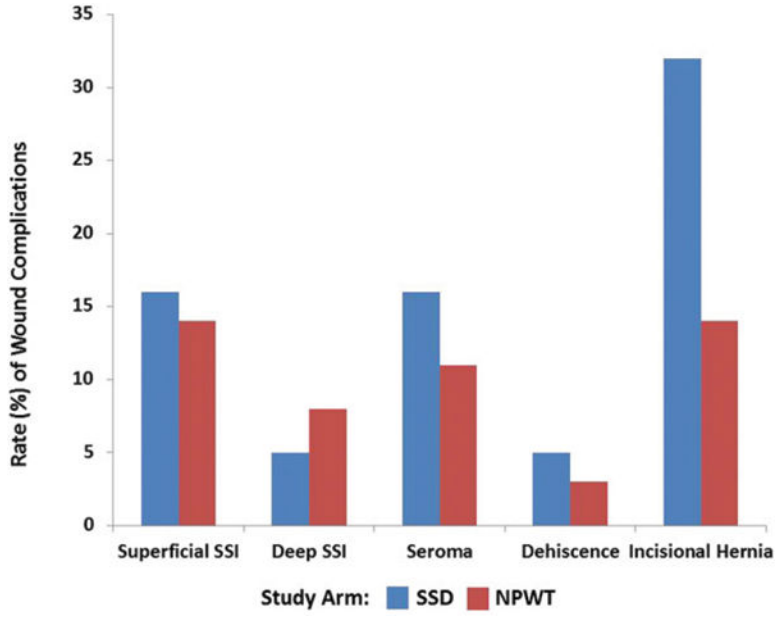

Fig. 1.
Incidence rates of wound complications by study arm. All $P > 0.05$.

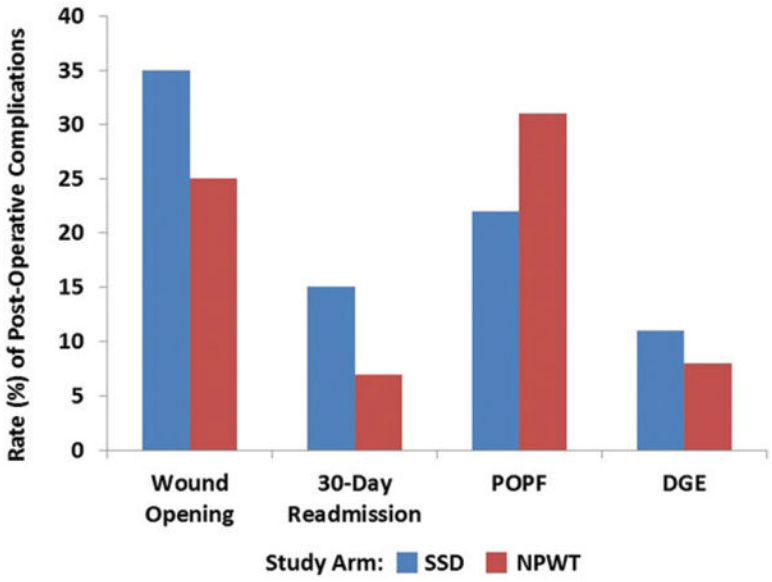

Fig. 2.

Rate of postoperative complications by study arm. POPF, postoperative pancreatic fistula. All $P > 0.05$.

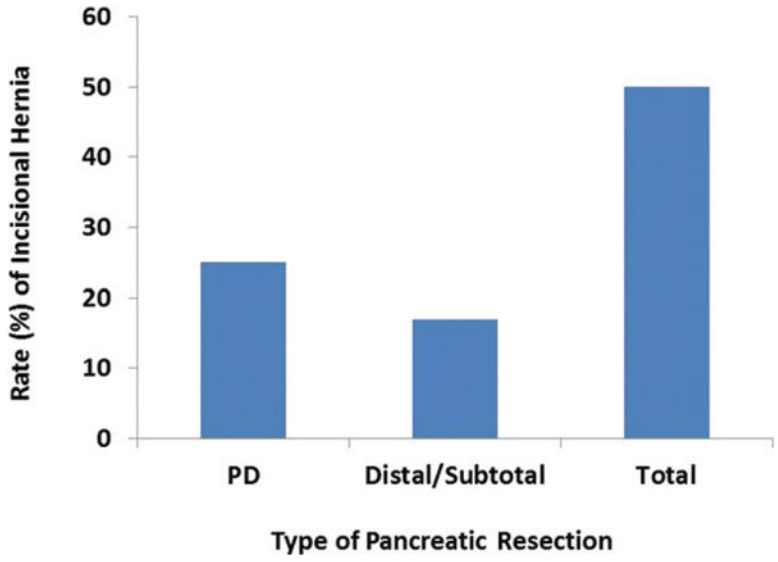

Fig. 3.
Overall rate of incisional hernia by resection type.

Table 1.

Baseline Patient Demographics

Variable	SSD		NPWT		
	Median (Range)	**n (%)**	**Median (Range)**	**n (%)**	***P* Value**
		37			36
Age	65 (35, 81)	17 (46)	65.5 (43, 85)	13 (36)	0.65
Gender (female)					
Race					
Black		2 (5)		2 (6)	>0.99
White		31 (84)		31 (86)	
Others		3 (8)		2 (6)	
Unknown		1 (3)		1 (3)	
Eastern Cooperative Oncology Group					
0		16 (44)		20 (61)	0.41
1		16 (44)		11 (33)	
2		4 (11)		2 (6)	
BMI	27.2 (15.2, 46)		28.1 (19.8, 45)		0.68
Diabetes		15 (41)		13 (36)	0.81
COPD		3 (8)		5 (14)	0.48
Renal failure		0		1 (3)	>0.99
HTN		25 (68)		23 (64)	0.81
CV disease		8 (22)		7 (19)	>0.99
Smoking					
Current		5 (14)		4 (11)	
Prior		10 (28)		19 (54)	0.074
Never		21 (58)		12 (34)	
Ever		15 (42)		23 (66)	0.058
Previous abdominal surgery					
Yes		16 (43)		16 (44)	>0.99
Preoperative chemotherapy					
Yes		5 (14)		6 (17)	0.75

Variable	SSD		NPWT		P Value
	Median (Range)	n (%)	Median (Range)	n (%)	
Preoperative radiation					
Yes		2 (5)		4 (11)	0.43
Preoperative albumin	3.6 (2.6, 4.7)		3.8 (27, 4.9)		0.27

HTN, hypertension; CV, cardiovascular.

TABLE 2.

Operative Characteristics

Variable	SSD		NPWT		*P* Value
	Median (Range)	n (%)	Median (Range)	n (%)	
American Society of Anesthesiologists class					
I		0		0	0.15
II		4 (11)		3 (8)	
III		29 (78)		33 (92)	
IV		4 (11)		0	
Type of resection					
Whipple		24 (65)		26 (72)	0.92
Subtotal		5 (14)		4 (11)	
Distal		6 (16)		5 (14)	
Total		2 (5)		1 (3)	
Laparoscopic-assisted cases		0		1 (3)	0.49
Operating room time (hours)	7.5 (2, 12.5)		7.8 (1.8, 19.5)		0.98
Estimated blood loss	500 (60, 2500)		600 (150, 2000)		0.2
Transfusions		8/37 (22)		2/36 (6)	0.085
Median units transfused	1.5 (1, 2)		4.5 (3, 6)		NA

TABLE 3.

Univariate and Multivariate Analysis for Incisional Hernia

Univariate Factors for Hernia				
Variable	**n**	**OR**	**95 Per Cent CI**	***P* Value**
Arm of study	73	0.34	(0.10, 1.08)	0.067
Age	73	0.85	(0.67, 1.07)	0.17
Gender (female)	73	0.73	(0.24, 2.24)	0.58
Race	71	0.39	(0.05, 3.39)	0.39
Eastern Cooperative Oncology Group	69	0.89	(0.38, 2.10)	0.79
BMI	73	0.96	(0.88, 1.06)	0.41
Diabetes	73	1.17	(0.39, 3.53)	0.78
COPD	73		Not enough events to model	
Renal failure	72		Not enough events to model	
HTN	73	0.68	(0.22, 2.07)	0.49
CV disease	73	0.79	(0.20, 3.18)	0.74
Previous abdominal surgery	73	0.87	(0.29, 2.61)	0.8
Smoking	71	0.97	(0.33, 2.89)	0.96
Preoperative chemotherapy	73	1.26	(0.29, 5.41)	0.76
Preoperative radiation	73	1.73	(0.29, 10.4)	0.55
Preoperative albumin	69	1.05	(0.94, 1.17)	0.42
American Society of Anesthesiologists class	73	1.44	(0.34, 6.07)	0.62
Operating room time (hours)	73	1.07	(0.89, 1.30)	0.47
Estimated blood loss	72	0.99	(0.89, 1.10)	0.87
Units of blood transferred	73	1.01	(0.56, 1.84)	0.97
Multivariate Factors for Hernia				
Arm of study	73	0.35	(0.11, 1.15)	0.083
Age	73	0.86	(0.67, 1.10)	0.22