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Original Research

Is antibiotic prophylaxis mandatory in laparoscopic incisional hernia repair? Data from the herniamed registry

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ABSTRACT

Background: Several meta-analyses showed that laparoscopic incisional hernia repair is associated with lower surgical site infection (SSI) rates compared to open repair. However, the efficiency of antibiotic prophylaxis (AP) in laparoscopic incisional hernia repair alone is unknown and needs evaluation. Due to increasing antimicrobial resistance, a major global health care problem, AP needs to be critically evaluated.

The aim of this study was to investigate the impact of AP on the rate of SSI and complication-related re-operations in patients undergoing laparoscopic incisional hernia repair.

Materials and methods: Prospectively documented data from the Herniamed Hernia Registry from 2009 to 2017 were retrospectively analysed. Multivariable analyses were used to study the influence of AP as well as further patient and surgery-related risk factors on SSI and complication-related reoperation rates. This was verified in a sensitivity analysis using propensity-score matching.

Results: In the analysed time period 13′513 patients undergoing elective laparoscopic incisional hernia repair were recorded, of which 14.4% (n = 1949) did not receive AP. The overall SSI rate showed no significant difference when directly comparing patients with (0.74%) and without AP (0.97%; p = 0.262). In the multivariable analysis the presence of patient related risk factors (p = 0.015) and defect size > 10 cm (p = 0.035) significantly increased the rates of SSI and complication-related reoperations. The propensity-score matching analysis verified that SSI rates are not significantly different between the two groups (p = 0.265).

Conclusions: In cases of laparoscopic incisional hernia repair in patients without risk factors and moderate hernia diameter (< 10 cm), routine administration of AP in laparoscopic incisional hernia repair does not seem to be justified.

1. Introduction

Systematic reviews and meta-analyses of laparoscopic versus open abdominal incisional hernia repair demonstrated significantly lower wound infection and wound complication rates for the endoscopic approach [1–5]. However, high-level evidence studies investigating the impact of antibiotic prophylaxis (AP) on the surgical site infection (SSI) rate following laparoscopic ventral hernia repair are sparse. Using multicentre, prospectively collected data of the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) in 21.463 cases with open and 5.303 cases with laparoscopic repair of ventral/incisional hernias the propensity score adjusted odds ratios were significantly different for reducible hernias in favour of the laparoscopic approach [6]. Specifically, the odds of an adverse event in open repair were 5.5 times greater for superficial surgical site infections (SSI) (OR 5.5, 95% CI 3.6–8.4; p < 0.01), 6.9 times greater for deep SSI (OR 6.9, 95% CI 3.0–15.6; p < 0.01), 4.5 times greater for wound disruption (OR 4.5, 95% CI 1.8–11.0; p < 0.01), and 1.9 times greater for organ/space SSI (OR 1.9, 95% CI 1.1–3.3; p = 0.02) [6]. Considering the highly significant reduction in the rate of SSI after incisional hernia repair by the use of the laparoscopic technique the question arises, whether an antibiotic prophylaxis (AP) regimen can

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further reduce wound complications. However, according to the guidelines a clear recommendation for or against the use of AP in laparoscopic incisional hernia repair cannot be given [7]. Specific studies to answer this scientific question are completely missing [7–9]. In patients with risk factors (diabetes, obesity, immunosuppression, chronic obstructive pulmonary disease, advanced age, corticoid therapy etc.) the current guidelines recommend AP in laparoscopic incisional hernia repair [7].

However, inappropriate administration of AP must be avoided, since the problem of antibiotic resistance is rapidly emerging worldwide [10]. Therefore, optimizing administration of antibiotics is a key element of the current World Health Organization (WHO) action plan on global antimicrobial resistance [11]. A recent registry-based analysis of laparo-endoscopic and open inguinal hernia repair has contributed to this important topic. The study revealed that AP does not add any beneficial effect in laparo-endoscopic inguinal hernia repair regarding the SSI rate. In contrast, AP significantly reduces the risk for SSI, and is still recommended in open inguinal hernia repair [12].

Based on the data of the Herniamed Registry [13] this analysis attempts to determine the rate of SSI following incisional hernia repair with and without AP. Additionally, the rates of complication-related reoperation depending on AP are compared. Furthermore, patient – and procedure – related risk factors influencing the outcome of SSI and complication-related reoperations were identified.

2. Methods

The Herniamed Registry is a multicentre, internet-based hernia registry [13] with 618 participating hospitals and surgeons in private practice (Herniamed Study Group) in Germany, Austria, and Switzerland (status: July 03, 2017) who have shared data on their patients undergoing routine hernia surgery. All patients signed an informed consent agreeing to participate. As part of the information provided to patients regarding participation in the Herniamed Quality Assurance Study and signing the informed consent declaration all patients were informed that the treating hospital or medical practice should be informed about any problem occurring after the operation and that the patient should have a clinical control if needed. All postoperative complications occurring up to 30 days after surgery were recorded. The work has been reported in line with the STROCSS criteria [14].

The present retrospective analysis compares the prospectively documented postoperative data collected for all patients who underwent laparoscopic incisional hernia repair between September 1, 2009 and July 03, 2017. Inclusion criteria were a minimum age of 16 years, elective setting of the operation and complete registry database entry. In total, 13,513 patients were enrolled (Fig. 1).

Data collected were gender, American Society of Anesthesiologists (ASA) status, age, body mass index (BMI), primary versus recurrent incisional hernia, defect size (W1/W2/W3) and hernia location based on the European Hernia Society (EHS) classification [15].

The following factors were assessed as possible risk-factors for the development of SSI: chronic obstructive pulmonary disease (COPD), diabetes mellitus, aortic aneurysm, immunosuppression, steroids, smoking, coagulation disorder, or antiplatelet or anticoagulant therapy. As in registries only routinely performed hernia repairs are documented, there is no agreement about a unified technique. According to the German, Austrian and Swiss Guidelines antibiotic prophylaxis was given routinely 30–60 min prior to skin incision.

Unadjusted analysis was carried out to analyse the influence of antibiotic prophylaxis on the outcome parameters. Chi-square test was used for categorical outcome variables and the robust *t*-test (Satterthwaite) was used for continuous outcome variables that followed the normal distribution.

A binary logistic regression model was used to study the influence of patient and surgery-related characteristics on increased SSI rates and complication-related reoperation rates, while odds ratios with 95% confidence interval based on the Wald test were given. For influence variables with more than two categories, all pairwise odds ratios were provided. For the continuous influence variable “age”, the 10-year odds ratio and for the influence variable “BMI”, a five-point odds ratio was given.

For sensitivity analysis, pairwise propensity-score (PS) matching analysis was performed to obtain homogeneous comparison groups because the groups with and without AP highly differed in size. Matched samples were then analysed via McNemar's test. PS matching was performed using Greedy algorithm and a caliper of 0.2 standard deviations. The variables used for matching were: sex (male/female), ASA status, age, BMI (kg/m^2), recurrence (yes/no), defect size (W1/W2/W3), presence of at least one risk factor (COPD, Diabetes, aortic aneurysm, immunosuppression, steroids, smoking, coagulation disorder, anticoagulants, antiplatelet therapy) and hernia location according to the European Hernia Society Guidelines [15]. The balance of the matched sample was checked using standardized differences (also given for the pre-matched sample) that should not exceed 10% (< 0.1) after creating matched pairs.

All analyses were performed with the software SAS 9.4 (SAS Institute Inc., Cary, NC, USA) and intentionally calculated to a full significance level of 5% that is, they were not corrected with to multiple tests, and each $p \leq 0.05$ represents a significant result.

3. Results

Between September 1, 2009 and July 3, 2017, n = 13,513 incisional hernia repairs were recorded in the Herniamed Registry in accordance with the inclusion criteria. Laparoscopic incisional hernia repair was performed with AP in 11,564 cases (85.6%) compared to 1949 cases (14.4%) without AP (Table 1).

3.1. Unadjusted analysis

Unadjusted analyses of the relationship between the group with AP and the group without AP showed that there were highly significant differences between both groups regarding patient- and procedure-related characteristics. Patients in the AP group were significantly older (61.5 ± 13.3 vs. 60.6 ± 13.9; $p < 0.009$) and had a lower BMI (30.4 ± 6.2 vs. 30.0 ± 6.0, $p < 0.011$). Additionally, these patients had significantly more risk factors (41.4% vs. 37.0%, $p < 0.001$), significantly higher ASA scores and significantly larger defects (Table 2).

For the incidence of SSI and complication–related reoperations no difference can be found between the group with and the group without AP (Table 3).

3.2. Multivariable analysis of SSI

The results of the multivariable analysis of SSI are summarized in Table 4 (model fit: $p = 0.011$). The risk for SSI significantly increases if one or more risk factors are present (OR = 1.663, 95% CI [1.103; 2.509]; $p = 0.015$) and in patients with larger defects ($p = 0.035$; i.e. W3 vs. W1: OR = 2.084, 95% CI [1.187; 3.656], $p = 0.010$). In the multivariable analysis AP alone shows no significant benefit in regards to reduction of the rate of SSI (OR = 0.674 [0.407; 1.116]; $p = 0.125$).

3.3. Multivariable analysis of complication-related reoperations

The results of the multivariable analysis of complication-related reoperations are summarized in Table 5 (model fit: $p < 0.001$). Larger defect size ($p < 0.001$; i.e. W3 vs. W1: OR = 2.087, 95% CI [1.439; 3.028], $p < 0.001$; W2 vs. W1: OR = 1.524, 95% CI [1.132; 2.051], $p = 0.005$), higher ASA-scores ($p = 0.004$; i.e. ASA III/IV vs. II: OR = 1.517, 95% CI [1.153; 1.996], $p = 0.003$; ASA III/IV vs. I: OR = 2.012, 95% CI [1.135; 3.565], $p = 0.017$), recurrence

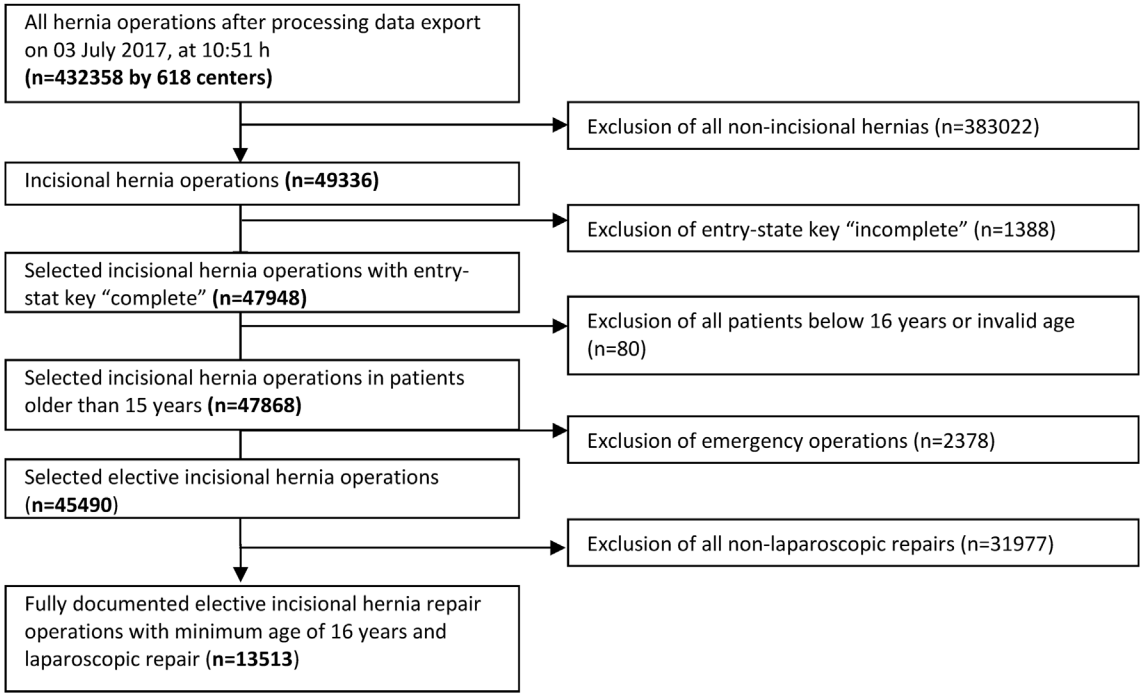

Fig. 1. Flowchart of patient inclusion.

Table 1
Frequency distribution of antibiotic prophylaxis.

	Antibiotic prophylaxis				Total	
	Yes		No			
	N	%	N	%	N	%
single shot	11,096	82.1			11,096	82.1
≤24 h	79	0.6	.	.	79	0.6
> 24–72 h	194	1.4	.	.	194	1.4
> 72 h	195	1.4	.	.	195	1.4
No antibiotic prophylaxis	.	.	1949	14.4	1949	14.4
Total	11,564	85.6	1949	14.4	13,513	100.0

(OR = 1.426, 95% CI [1.077; 1.886], p = 0.013), and presence of risk factors (OR = 1.340, 95% CI [1.035; 1.734], p = 0.026) significantly increase the risk of complication-related reoperations. In the multivariable analysis the use of AP alone did not significantly influence the reoperation rate due to complications (OR = 1.313, 95% CI [0.877; 1.965]; p = 0.186).

3.4. Propensity-score matched-pair analysis

Matching was successfully applied on 1940 patients without AP (99.5%). The group without AP had a mean age of 60.6 years (SD 13.9) whereas the group with AP had a mean age of 60.7 years (SD 13.8). Table 6 shows the standardized differences of the categorical matching variables before (original sample) and after matching (matched sample). All the matching variables show a standardized difference of less than 10% providing a good balance of these variables in the matched sample. The matched-pair analysis of the 1940 patient pairs showed no systematic deviation between the two groups for SSI rates: In 0.57%, SSI was developed in patients with AP but not in matched patients without AP, and vice versa in 0.93% SSI was only developed in patients without AP (OR = 0.611 [0.261; 1.366]; p = 0.265). Also for reoperations, no systematic discrepancy could be found: There were 2.1% reoperations only in patients with AP and on the other side 1.4% more reoperations in patients without AP (OR = 1.481 [0.887; 2.510]; p = 0.142), (Fig. 2).

4. Discussion

The present Herniamed Registry study investigated the influence exerted by AP on the occurrence of SSI and the rate of complication-relation reoperation following laparoscopic incisional hernia repair. Our analysis shows for the first time that routine use of an AP in patients with normal risk profile and hernias < 10 cm does not further reduce the incidence of SSI and the rate of complication-related reoperation after laparoscopic incisional hernia repair. In contrast, patients with risk factors such as diabetes, COPD, immunosuppression, smoking, steroid therapy and larger hernias (> 10 cm) have an increased risk for development of a SSI and complication-related reoperations.

This study contributes to the ongoing important discussion on the appropriate administration of antibiotics in medicine, since the problem of antimicrobial resistance threatens the sustainability of the public health response to many communicable diseases, threatening global health security. The impact of antimicrobial resistance goes beyond health and warrants a coherent, comprehensive and integrated approach at all levels of health care. Appropriate administration AP to reduce the risk of wound complication is one key factor to contribute to this problem in the field of surgery. Omitting AP in surgery must be justified by not increasing the risk for wound complications. Several risk factors for increased wound morbidity are identified, such as multiple comorbidities, advanced age, patient frailty, surgical complexity and prolonged operation time [16]. Although high-level data on this topic are missing, current guidelines for laparoscopic treatment of ventral hernias recommend AP administration in patients with risk factors [7]. Now our study adds higher-level evidence supporting this guideline recommendation in patients with risk factors and larger hernias. However, more importantly, our data also show that administration of AP in patients undergoing laparoscopic incisional hernia repair without risk factors and smaller hernias can be omitted, which may have significant impact on daily practice, fighting against the global antimicrobial resistance threat.

Our study also showed that larger hernia defects (> 10 cm) have a

Table 2
Unadjusted analysis for surgery-related parameters and risk factors.

			Antibiotic prophylaxis				p
			Yes		No		
			n	%	n	%	
Gender		Male	5741	49.65	936	48.02	0.186
		Female	5823	50.35	1013	51.98	
ASA		I	1180	10.20	297	15.24	< .001
		II	6638	57.40	1165	59.77	
		III/IV	3746	32.39	487	24.99	
Recurrence		Yes	2447	21.16	419	21.50	0.736
		No	9117	78.84	1530	78.50	
EHS-classification		Combined	1150	9.94	164	8.41	0.010
		Lateral	1824	15.77	275	14.11	
		Medial	8590	74.28	1510	77.48	
Defect size		W1 (< 4 cm)	4232	36.60	925	47.46	< .001
		W2 (> = 4–10 cm)	5746	49.69	847	43.46	
		W3 (> = 10 cm)	1586	13.71	177	9.08	
Risk factors	Overall	Yes	4782	41.35	722	37.04	< .001
		No	6782	58.65	1227	62.96	
	COPD	Yes	1243	10.75	155	7.95	< .001
		No	10,321	89.25	1794	92.05	
	Diabetes mellitus	Yes	1652	14.29	222	11.39	< .001
		No	9912	85.71	1727	88.61	
	Aortic aneurysm	Yes	160	1.38	20	1.03	0.203
		No	11,404	98.62	1929	98.97	
	Immunosuppression	Yes	192	1.66	11	0.56	< .001
		No	11,372	98.34	1938	99.44	
	Steroids	Yes	205	1.77	25	1.28	0.122
		No	11,359	98.23	1924	98.72	
	Smoking	Yes	1485	12.84	249	12.78	0.936
		No	10,079	87.16	1700	87.22	
	Coagulation disorder	Yes	212	1.83	34	1.74	0.786
		No	11,352	98.17	1915	98.26	
	Antithrombotic therapy	Yes	1278	11.05	197	10.11	0.216
		No	10,286	88.95	1752	89.89	
	Anticoagulant therapy	Yes	331	2.86	44	2.26	0.133
		No	11,233	97.14	1905	97.74	

ASA: American Society of Anesthesiologists; EHS: European Hernia Society.

negative impact on the rates of SSI and complication-related reoperations, which supports current guidelines, recommending the laparoscopic approach preferably for hernia defects < 10 cm [7]. This effect may be caused by a prolonged operation time or higher complexity of the procedure, which itself increase the risk of SSI [16]. Our findings are also supported by a study by Petro et al. which have found that larger and contaminated hernias significantly increase the risk for surgical site occurrences. Subsequently, they proposed a new ventral hernia grading system to estimate the risk of SSI [17].

Taking into account that this is a registry based study, the

Table 3
Unadjusted analysis for postoperative complications and complication-related reoperations.

				Antibiotic prophylaxis				p
				Yes		No		
				n	%	n	%	
Postoperative complications	Overall		Yes	513	4.44	62	3.18	0.011
			No	11,051	95.56	1887	96.82	
	Bowel injury		Yes	70	0.61	7	0.36	0.182
			No	11,494	99.39	1942	99.64	
	Ileus		Yes	78	0.67	8	0.41	0.175
			No	11,486	99.33	1941	99.59	
	Bleeding		Yes	109	0.94	15	0.77	0.459
			No	11,455	99.06	1934	99.23	
	Seroma		Yes	235	2.03	23	1.18	0.011
			No	11,329	97.97	1926	98.82	
	Surgical Site Infection (SSI)	Overall	Yes	85	0.74	19	0.97	0.262
			No	11,479	99.26	1930	99.03	
		Deep Infection	Yes	49	0.42	12	0.62	0.242
			No	11,515	99.58	1937	99.38	
		Wound healing disorder	Yes	45	0.39	11	0.56	0.265
			No	11,519	99.61	1938	99.44	
Complication-related Reoperation			Yes	238	2.06	28	1.44	0.068
			No	11,326	97.94	1921	98.56	

Table 4
Multivariable analysis on occurrence of surgical site infections (SSI).

Parameter	p-value	Category	Pairwise p-value	OR	[95% CI]	
Risk factors	0.015	Yes vs no	0.015	1.663	1.103	2.509
Defect size	0.035	W3 (≥10 cm) vs W2 (≥4–10 cm)	0.053	1.639	0.993	2.704
		W3 (≥10 cm) vs W1 (< 4 cm)	0.010	2.084	1.187	3.656
		W2 (≥4–10 cm) vs W1 (< 4 cm)	0.305	1.271	0.803	2.012
Antibiotic prophylaxis	0.125	Yes vs no	0.125	0.674	0.407	1.116
Recurrence	0.143	Yes vs no	0.143	1.390	0.895	2.157
ASA	0.301	III/IV vs II	0.128	1.403	0.907	2.171
		III/IV vs I	0.385	1.448	0.629	3.333
		II vs I	0.937	1.032	0.476	2.235
Gender	0.353	Male vs female	0.353	1.207	0.812	1.794
BMI [5-point OR]	0.750			1.027	0.870	1.212
Age [10-year OR]	0.779			1.024	0.867	1.210
EHS classification	0.880	Medial vs combined	0.773	1.103	0.565	2.155
		Medial vs lateral	0.713	0.905	0.532	1.540
		Combined vs lateral	0.624	0.820	0.372	1.810

limitations must be noted. Incorrect or missing data limit a registry [18]. Though, in the Herniamed Registry the following measurements are used to optimize data entry: signed contract with the responsible surgeon for data correctness and completeness, indication of missing data by the software, once again review of the perioperative outcome on 1-year follow up and control of the data entry by experts as part of the certification process of hernia centres. To address the problem of comparing two heterogeneous patient populations in a multivariable analysis, we performed a matched-pair propensity-score (PS) analysis. However, the timing of AP administration is unknown in our population, potentially diminishing the effectiveness of the AP [19,20]. No information is available regarding the approach to weight-based dosing of obese patients and the need for repeat doses during prolonged procedures [21].

In conclusion, our study results show that AP does not have any beneficial effect in laparoscopic incisional hernia repair and should be omitted in patient, where further risk factors are absent.

Disclosures

Ferdinand Köckerling-Grants to fund the Herniamed Registry from Johnson&Johnson, Norderstedt, Karl Storz, Tuttlingen, pfm medical, Cologne, Dahlhausen, Cologne, B Braun, Tuttlingen, MenkeMed, Munich and Bard, Karlsruhe.

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Table 6
Standardized differences of the categorical matching parameters before and after matching.

	Antibiotic prophylaxis				Standardized difference	
	Yes		No		Matched sample	Original sample
	n	%	n	%		
Male	960	49.48	932	48.04	0.029	0.032
ASA I	290	14.95	296	15.26	0.009	0.152
ASA II	1163	59.95	1158	59.69	0.005	0.048
ASA III-IV	487	25.10	486	25.05	0.001	0.164
EHS medial	1482	76.39	1501	77.37	0.023	0.075
EHS lateral	287	14.79	275	14.18	0.018	0.047
EHS combined	171	8.81	164	8.45	0.013	0.053
W1 (< 4 cm)	940	48.45	923	47.58	0.018	0.221
W2 (> = 4–10 cm)	812	41.86	842	43.40	0.031	0.125
W3 (> = 10 cm)	188	9.69	175	9.02	0.023	0.146
Recurrence	411	21.19	417	21.49	0.008	0.008
Risk factors	714	36.80	721	37.16	0.007	0.088

ASA: American Society of Anesthesiologists status; EHS: European Hernia Society.

Ethical approval

As Registries only document routine treatment of patients with their informed consent ethical approval is not necessary in our countries.

Table 5
Multivariable analysis of reoperation due to postoperative surgical complications.

Parameter	p-value	Category	Pairwise p-value	OR	[95% CI]	
Defect size	< .001	W3 (≥10 cm) vs W2 (≥4–10 cm)	0.056	1.369	0.993	1.889
		W3 (≥10 cm) vs W1 (< 4 cm)	< .001	2.087	1.439	3.028
		W2 (≥4–10 cm) vs W1 (< 4 cm)	0.005	1.524	1.132	2.051
ASA	0.004	III/IV vs II	0.003	1.517	1.153	1.996
		III/IV vs I	0.017	2.012	1.135	3.565
		II vs I	0.303	1.326	0.775	2.270
Recurrence	0.013	Yes vs no	0.013	1.426	1.077	1.886
Risk factor	0.026	Yes vs no	0.026	1.340	1.035	1.734
Antibiotic prophylaxis	0.186	Yes vs no	0.186	1.313	0.877	1.965
BMI [5-point OR]	0.420			0.957	0.859	1.065
Age [10-year OR]	0.688			1.022	0.919	1.136
EHS classification	0.694	Medial vs combined	0.764	0.940	0.630	1.404
		Medial vs lateral	0.402	0.868	0.623	1.209
		Combined vs lateral	0.742	0.923	0.573	1.487
Gender	0.708	male vs female	0.708	1.049	0.817	1.347

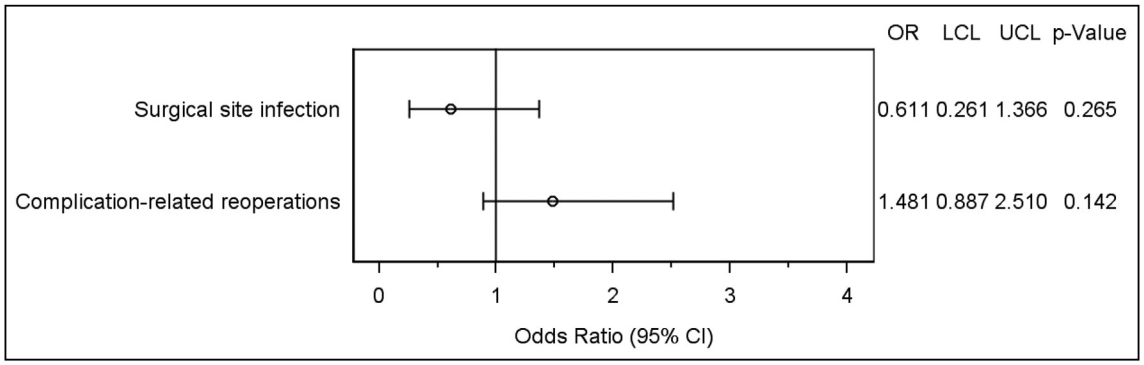

Fig. 2. Results of the matched-pair analysis.

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Author contribution

P. Kirchhoff: data collections, writing.
H. Hoffmann: writing.
F. Köckerling: study design, writing.
D. Adolf: data analysis.
R. Bittner: writing.
RF Staerkle: study design, writing.

Conflicts of interest

Ferdinand Köckerling-Grants to fund the Herniamed Registry from Johnson&Johnson, Norderstedt, Karl Storz, Tuttlingen, pfm medical, Cologne, Dahlhausen, Cologne, B Braun, Tuttlingen, MenkeMed, Munich and Bard, Karlsruhe.

Trial registry number

researchregistry4204.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ijsu.2018.08.012.

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