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REVIEW

Single-incision laparoscopic surgery through the umbilicus is associated with a higher incidence of trocar-site hernia than conventional laparoscopy: a meta-analysis of randomized controlled trials

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Abstract
Background Single-incision laparoscopic surgery has been developed with the objective to reduce surgical trauma, decrease associated surgical stress and to improve cosmetic outcome. However, concerns have been raised regarding the risk of trocar-site hernia following this approach. Previous meta-analyses have suggested a trend toward higher hernia rates, but have failed to demonstrate a significant difference between single-incision and conventional laparoscopic surgery.
Method Medline, AMED, CINAHL and CENTRAL were searched up to May 2014. Randomized controlled trials comparing single-incision and conventional laparoscopic surgery were considered for inclusion. Studies with patients aged less than 18 years and those reporting on robotic surgery were disregarded. Pooled odds ratios with 95 % confidence intervals were calculated to measure the comparative risk of trocar-site hernia following single-incision and conventional laparoscopic surgery.
Results Nineteen randomized trials encompassing 1705 patients were included. Trocar-site hernia occurred in 2.2 % of patients in the single-incision group and in 0.7 % of patients in the conventional laparoscopic surgery group (odds ratio 2.26, 95 % confidence interval 1.00–5.08, $p = 0.05$). Sensitivity analysis of quality randomized trials validated the outcome estimates of the primary analysis. There was no heterogeneity among studies ($I^2 = 0$ %) and no evidence of publication bias.
Conclusion Single-incision laparoscopic surgery involving entry into the peritoneal cavity through the umbilicus is associated with a slightly higher risk of trocar-site hernia than conventional laparoscopy. Its effect on long-term morbidity and quality of life is a matter for further investigation.

Keywords Single-incision · Single-site · Laparoscopy · Incisional · Trocar-site · Hernia

Members of the Bonham Group are listed in "Appendix 1".

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Introduction

Single-incision laparoscopic surgery constitutes a relatively novel concept of minimally invasive surgery, aiming at further reducing the abdominal scar of the traditional laparoscopic technique. It was first reported in 1997 by Navarra et al. [1, 2], but it has not gained wide popularity until the late 2000s' [2], when ad hoc trocar systems and instrumentation were launched by the medical industry. A number of reviews have supported the safety profile of single-incision laparoscopic cholecystectomy in the elective

setting [3–14]; however, others have commented on the lack of adequate power in the published literature [15–17].

The European Hernia Society Guidelines Development Group for Guidelines on the closure of abdominal wall incisions has concluded that there is a lack of sufficient evidence on the comparative risk for the development of trocar-site hernia after single-incision laparoscopic surgery and conventional laparoscopic surgery [18]. Observational studies have reported a higher incidence of trocar-site hernia in the midline, at the umbilicus, and when larger size trocars are used [19–21]. Published reviews report exclusively on laparoscopic cholecystectomy and none have included trocar-site hernia as a primary outcome measure. Pooled analyses have found no difference in the relative risk of incisional hernia between single-incision laparoscopic surgery and conventional laparoscopic procedures. Milas et al. have identified a difference in favor of conventional laparoscopic cholecystectomy after employing a random-effects model for sparse dichotomous data [17].

This systematic review and meta-analysis aimed at estimating the comparative risk of trocar-site hernia after single-incision and conventional laparoscopic surgery, upon recruiting evidence on the widest spectrum of laparoscopic procedures performed using the single-incision approach.

Methods

The study protocol was registered under the number CRD42014009533 at the International prospective register of systematic reviews, developed and maintained by the Centre for Reviews and Dissemination of the University of York, United Kingdom [22]. The review conformed to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement standards [23].

Eligibility criteria and study selection

The protocol was established prior to initiation of the study, to determine the criteria for inclusion, the methods of analysis and the investigated outcomes. Randomized controlled trials (RCTs) comparing single-incision and conventional laparoscopic surgery, providing trocar-site hernia rates for both treatment arms and reporting on the site of insertion of the trocars, were considered for inclusion. Studies enrolling patient populations of age less than 18 years, those reporting on robotic surgery and those not satisfying all inclusion criteria, were disregarded.

Search strategy

The electronic databases of the National Library of Medicine (Medline; provider Pubmed, from 1997 to February 2014), the Allied and Complementary Medicine (AMED, provider Athens, from inception to February 2014), the Cumulative Index to Nursing and Allied Health Literature (CINAHL, provider Athens, from inception to February 2014) and the Cochrane Central Register of Controlled Trials (CENTRAL, provider Wiley Online Library, from inception to February 2014) were searched, to identify relevant articles. No language restrictions were applied. The Medical Subject Headings (MeSH terms) 'hernia' and 'laparoscopy', and the terms 'incisional hernia', 'trocar-site hernia', 'trocar site hernia', 'port-site hernia', 'port site hernia', 'single-incision', 'single incision', 'single-port', 'single port', 'single-access', 'single access', 'one-access', 'one access', 'one-port', 'one port', 'single-site', 'single site', 'laparoscopy' and 'laparoscopic' were used ("Appendix 2"). The last search was run on February 2014 and an update search of the PubMed interface was performed in May 2014. A second-level manual search included the bibliography of published systematic reviews [3–16] and the reference lists of the selected studies. Eligibility assessment was performed independently in an unblinded standardized manner by two reviewers. Disagreements were resolved by consensus.

Data collection

An electronic data extraction sheet was developed and refined accordingly. One review author extracted the data from included studies and a second author checked the extracted data. The latter included name of the primary author, year of publication, country (or countries) of participating institution(s), number of participating centers, patient recruitment period, inclusion and exclusion criteria, number of patients assigned to randomization, number of patients allocated to either group, number of patients having completed the follow-up, duration of follow-up, type of follow-up assessment, intention-to-treat or as treated analysis, type of trocar and the incidence of trocar-site hernia in the study and the control groups.

Methods of analysis

A fixed-effects model was initially applied to synthesize the data. If significant heterogeneity among the included studies was identified, random-effects analysis was planned. Pooled odds ratios with 95 % confidence intervals were calculated to measure the effect of each type of procedure on the risk for trocar-site hernia. Heterogeneity was assessed using the I^2 statistic, a method expressing the percentage of variation across studies. I^2 values between 0 and 25 % suggest low level, values above 25 % suggest moderate level, and values above 75 % suggest high level of heterogeneity. Publication bias was assessed visually

evaluating the symmetry of funnel plots. Statistical analysis was performed using RevMan (Review Manager 5.2, The Nordic Cochrane Centre, Copenhagen, Denmark).

Methodological assessment

To assess risk of bias of randomized trials, the selected records were screened by two independent reviewers using the Scottish Intercollegiate Guidelines Network (SIGN) tool [24]. Studies were considered eligible for secondary analysis on the basis of minimal bias (high quality or acceptable). Methodological quality of quality randomized trials was evaluated using the Cochrane's Collaboration Tool [25]. This tool considers the sequence generation, allocation concealment, blinding of participants, personnel, and outcome assessors, inadequately reported or missing outcome data, selective outcome reporting, and other potential threats to validity. Disagreements between the reviewers were resolved by consensus.

Results

Literature search results and selection of studies

The search of the electronic databases retrieved 491 results after exclusion of duplicate records. Forty-seven articles were selected for full-text review and 19 randomized trials fulfilled the inclusion criteria [26–44]. Details on the search history are presented in the flow chart of Fig. 1. A list of the records excluded during the reviewing process is available upon request.

Quality screening and methodology assessment

Following assessment using the SIGN tool for controlled trials, five articles were considered to be of high quality [26–30], nine articles of acceptable quality [31–39] and five articles of poor quality [40–44]. Nineteen reports were included in the primary meta-analysis [26–44]. Fourteen articles of high or acceptable quality were further assessed using the Cochrane's Collaboration Tool and were the subject of a secondary analysis [26–39]. Methodological quality of eligible studies can be assessed in Fig. 2. Complete assessment data are available upon request.

Study characteristics

The 19 included studies were published between 2011 and 2014. Twelve studies were written in the English language and two in Spanish. A total of 1705 patients were included, randomized to single-incision ($n = 851$) or conventional laparoscopic surgery ($n = 849$). Seven trials were multicentric [27, 29, 33, 42–44]. Seventeen articles reported on cholecystectomy [26, 27, 29, 31–44] and two on appendectomy [29–31]. Multiport systems were utilized in 13 studies [28–32, 35, 37–44] and multiple conventional ports in three studies [26, 27, 36]. Duration of follow-up ranged between 1 month and 1 year. Follow-up outcome assessment was inconsistently reported among studies (Table 1). Trocar-site hernia rates ranged between 0 and 10.0 % in the single-incision group and between 0 and 3.3 % in the conventional laparoscopic surgery group.

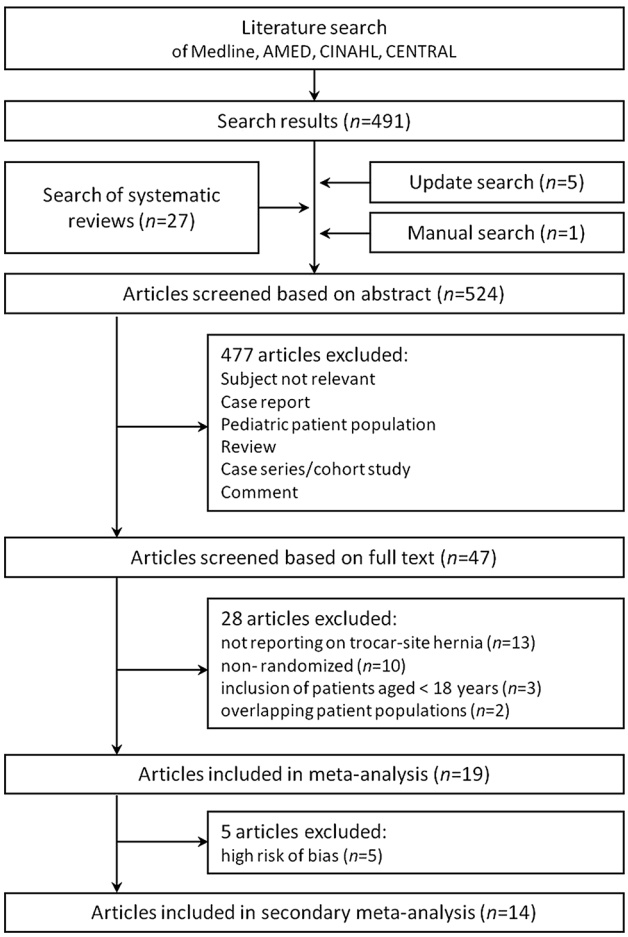

Fig. 1 Flow chart of search history

Synthesis of data

Trocar-site hernia occurred in 2.2 % of patients in the single-incision group and in 0.7 % of patients in the conventional laparoscopic surgery group (odds ratio 2.26, 95 % confidence interval 1.00–5.08, $p = 0.05$). Heterogeneity among studies was not evident ($I^2 = 0$ %) and visual assessment of the funnel plot was not suggestive of publication bias (Figs. 3, 4; Table 2).

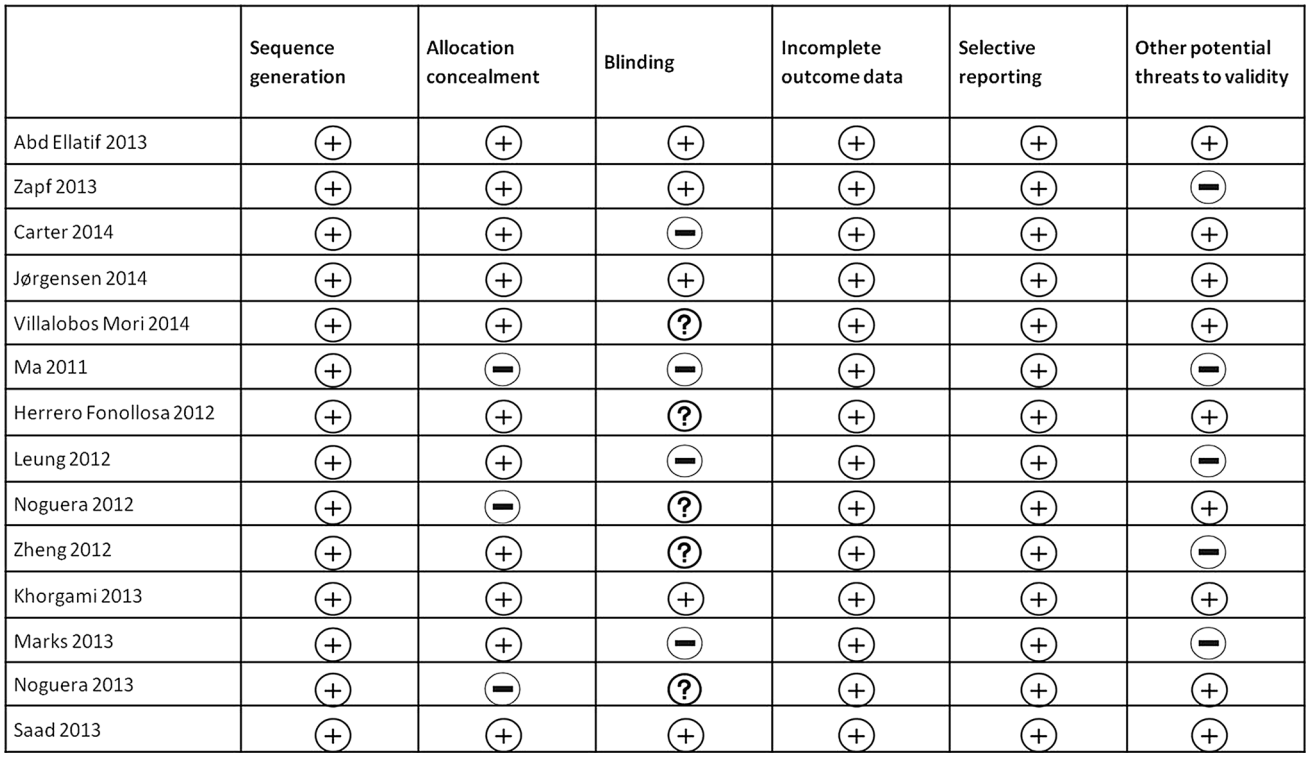

Fig. 2 Methodology assessment of included trials. '+' refers to absence of bias; '−'refers to presence of bias; '?' refers to absence of information to make a judgment regarding the presence of bias

Secondary analysis of quality RCTs

Sensitivity analysis of 14 quality trials demonstrated a pooled odds ratio of 2.88 (95 % confidence interval 1.09–7.61, $p = 0.03$) (Fig. 5). There was no heterogeneity among studies and no evidence of publication bias.

Discussion

Key results

Our meta-analysis suggested a slightly higher incidence of incisional hernias after single-incision involving entry into the peritoneal cavity through the umbilicus compared to conventional laparoscopic surgery. This difference was more pronounced in sensitivity analysis of RCTs of high or acceptable quality.

Limitations

A shortcoming of this analysis lies on the lack of risk–benefit assessment and cost analysis. Our study protocol did not include relevant data because (1) a focused clinical question was considered a quality factor and (2) other reports have thoroughly addressed these issues [14, 16, 33, 45]. Furthermore, details on fascia closure were not reported by several studies. However, it seems unlikely that closure of single-incision sites was omitted in contrast to conventional trocar sites, which would have biased the treatment effect. The use of different suture materials may also have an effect on the risk for recurrence; however, such an association could not be evaluated due to the lack of relevant data.

Another limitation is introduced by the fact that only seven studies provided information on follow-up assessment [26–29, 32, 36, 37] and three studies applied physical examination and/or computed tomography imaging [26, 27, 37], which might have contributed to an amount of heterogeneity across reports. Furthermore, trocar-site hernia was considered a primary outcome measure in two studies only [34, 38], which limits the reporting quality in the remaining body of evidence. Additionally, a single RCT carrying 13 and 20 % relative weight in the primary and sensitivity analysis, respectively, reported on a 10 % incisional hernia rate in the single-incision group [37].

Interpretation

Novel evidence in the field of single-incision laparoscopic surgery is being added since the dissemination of this concept. Previous meta-analyses have failed to demonstrate

Table 1 Study characteristics

References	Year	Country	No. of centers	Recruitment period	Type of surgery	Type of trocar	Duration of follow-up	Type of follow-up
Abd Ellatif [26]	2013	Egypt	1	2008–2012	Cholecystectomy	2 ports	6 months	Physical
Zapf [27]	2013	USA	3	2009–2012	Cholecystectomy	3 ports	Mean, 16.4 ± 12.1 SILS, mean, 16.2 ± 10.5 CLS	Physical
Carter [28]	2014	USA	1	2010–2012	Appendectomy	SILS port	6 months	Survey
Jørgensen [29]	2014	Denmark	3	2010–2011	Cholecystectomy	SILS port	1 year	Telephone interview
Villalobos Mori [30]	2014	Spain	1	2011–2012	Appendectomy	SILS port	NR	NR
Ma [31]	2011	USA	1	2009–2010	Cholecystectomy	Triport	NR	NR
Herrero Fonollosa [32]	2012	Spain	1	2009–2011	Cholecystectomy	SILS port	6 months	Telephone interview
Leung [33]	2012	USA	3	NR	Cholecystectomy	NR	24 months	NR
Noguera [34]	2012	Spain	1	2009–2010	Cholecystectomy	NR	1 year	NR
Zheng [35]	2012	China	1	2008–2010	Cholecystectomy	Triport	Median, 9.4 (4–24) SILS, median, 11.6 (8–24) CLS	NR
Khorgami [36]	2013	Iran	1	2011	Cholecystectomy	3 ports	12 months	Telephone interview
Marks [37]	2013	USA/UK	10	NR	Cholecystectomy	SILS port	12 months	Physical/CT
Noguera [38]	2013	Spain	1	2011	Cholecystectomy	SILS port	1 year	NR
Saad [39]	2013	Germany	1	2010–20s11	Cholecystectomy	SILS port	6 months	Telephone interview
Bucher [40]	2011	Switzerland	1	2009–2010	Cholecystectomy	Triport	1 month	Physical
Sinan [41]	2012	Turkey	1	2010–2011	Cholecystectomy	SILS port	Median 29.9 (15.7–63.3) SILS, median 22.7 (8.0–56.4) CLS	NR
Solomon [42]	2012	USA	NR	2009–2010	Cholecystectomy	SILS port	30 days	Physical
Vilallonga [43]	2012	Spain/ Turkey	2	2009–2010	Cholecystectomy	SILS port and Triport	Mean, 7.3 months	Physical
Madureira [44]	2013	Brazil	2	2011	Cholecystectomy	Various multiports	Mean, 5.9 months	NR

NR not reported, *SILS* single-incision laparoscopic surgery, *CLS* conventional laparoscopic surgery, *CT* computed tomography

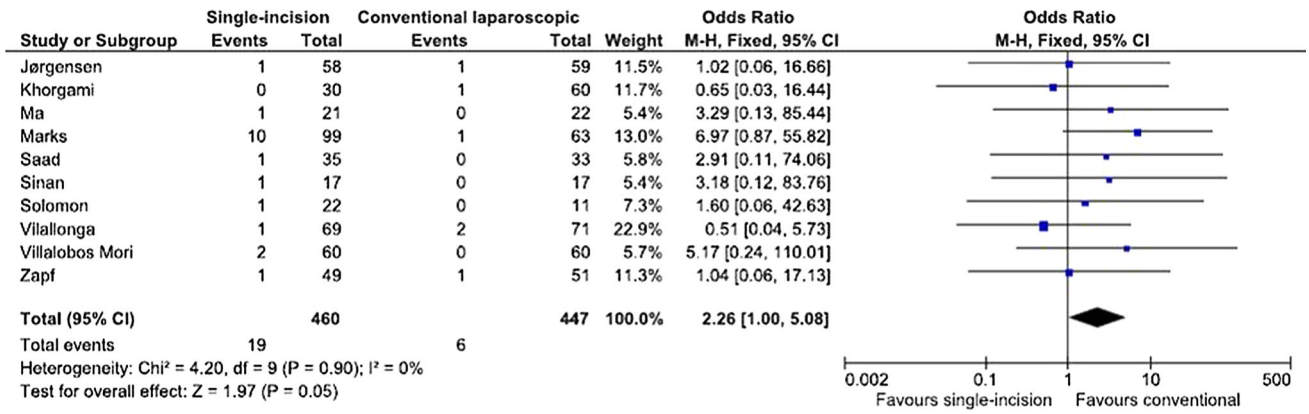

Fig. 3 Forest plot of primary analysis of the risk of trocar-site hernia. Nine of 19 studies reported on zero events and 10 were included in the meta-analysis model

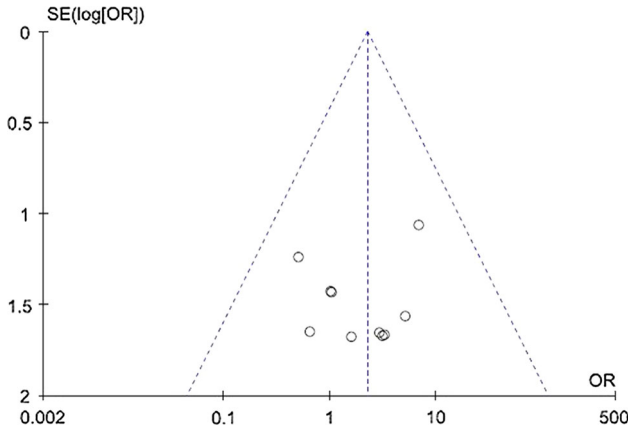

Fig. 4 Funnel plot of the risk of trocar-site hernia

Table 2 Outcome data

References	No. of patients		Trocar-site hernia (%)	
	SILS	CLS	SILS	CLS
Abd Ellatif [26]	125	125	0 (0)	0 (0)
Zapf [27]	49	51	1 (2.0)	1 (2.0)
Carter [28]	31	36	0 (0)	0 (0)
Jørgensen [29]	58	59	1 (1.7)	1 (1.7)
Villalobos Mori [30]	60	60	2 (3.3)	0 (3.3)
Ma [31]	21	22	1 (4.8)	0 (0)
Herrero Fonollosa [32]	26	24	0 (0)	0 (0)
Leung [33]	36	43	0 (0)	0 (0)
Noguera [34]	20	20	0 (0)	0 (0)
Zheng [35]	30	30	0 (0)	0 (0)
Khorgami [36]	30	60	0 (0)	1 (1.7)
Marks [37]	99	63	10 (10)	1 (1.6)
Noguera [38]	20	20	0 (0)	0 (0)
Saad [39]	35	33	1 (2.9)	0 (0)
Bucher [40]	75	75	0 (0)	0 (0)
Sinan [41]	17	17	1 (5.9)	0 (0)
Solomon [42]	22	11	1 (4.6)	0 (0)
Vilallonga [43]	69	71	1 (1.5)	2 (2.8)
Madureira [44]	28	29	0 (0)	0 (0)

SILS single-incision laparoscopic surgery, *CLS* conventional laparoscopic surgery

significant differences in terms of wound-related complications between single-incision and conventional laparoscopic surgery [4, 11, 16]. This may be a result of (1) the lack of sufficient high-quality evidence, (2) the fact that trocar-site hernia was not considered as the primary outcome measure, (3) the fact that systematic reviews have focused solely on cholecystectomy and (4) the fact that long-term follow-up was not available. This systematic review collected data of publications from a wide spectrum of databases and did not exclude reports on the basis of examined procedures, provided that the single incision was performed at the umbilicus. As such, latest evidence with the longest available follow-up and the widest possible representation of procedures was considered. Nevertheless, the spectrum of single-incision operations covered by current evidence allows for assessment of umbilical incisions only. The outcome estimates of this analysis cannot be extrapolated in single-incision surgery through a lateral muscle-splitting incision, in operations such as colectomy or ventral hernia repair, and in operations where the posterior layer of the abdominal wall is not incised.

The results of this review have to be interpreted in the context of available evidence in the field of single-incision laparoscopic surgery. Studies which referred to surgeons' expertise report limited experience with the single-incision laparoscopic technique. However, while the learning curve for single-incision cholecystectomy may be as low as 25 cases in terms of operating time [46], the risk for wound complications may not decrease until after some 500 cases [47].

Meta-analysis of the data was suggestive of a higher incidence of trocar-site hernia after single-incision laparoscopic surgery. The lack of heterogeneity amplifies the significance of the intervention effect, whereas publication bias was not evident. The report with the strongest effect reported on an incisional hernia rate of 10.0 % for single-incision surgery and 1.6 % for conventional laparoscopic surgery [37]. However, this study was industry sponsored and participating surgeons had a limited experience with the technique. The authors based their follow-up assessment on physical examination and performed a computed tomography in case of unclear diagnosis. This was the study with the largest patient population, thus contributing a relative weight of 20.1 % of the combined data. Upon exclusion of this report in sensitivity analysis, the increased incidence of higher hernia rates in single-incision surgery was not maintained (fixed odds ratio 1.85, 95 % confidence interval 0.58–5.86, $p = 0.30$, $I^2 = 0$ %).

The strengths of this systematic review and meta-analysis lie on an extensive literature search of various databases, the outcome-focused criteria for inclusion and exclusion and the sensitivity assessment of quality trials. Studies reporting on or including pediatric patients were disregarded, because trocar-site hernia in younger ages might present with a higher prevalence [48–50], which might had affected the pooled outcome estimates. Single-incision robotic surgery was considered an exclusion criterion, because manipulation forces at the trocar site might differ between robotic and laparoscopic surgery [51], whereas excessive instrument manipulation has been suggested to result in higher incisional hernia rates [52–57].

Methodological and reporting quality was assessed using two screening tools, namely the SIGN checklist and the

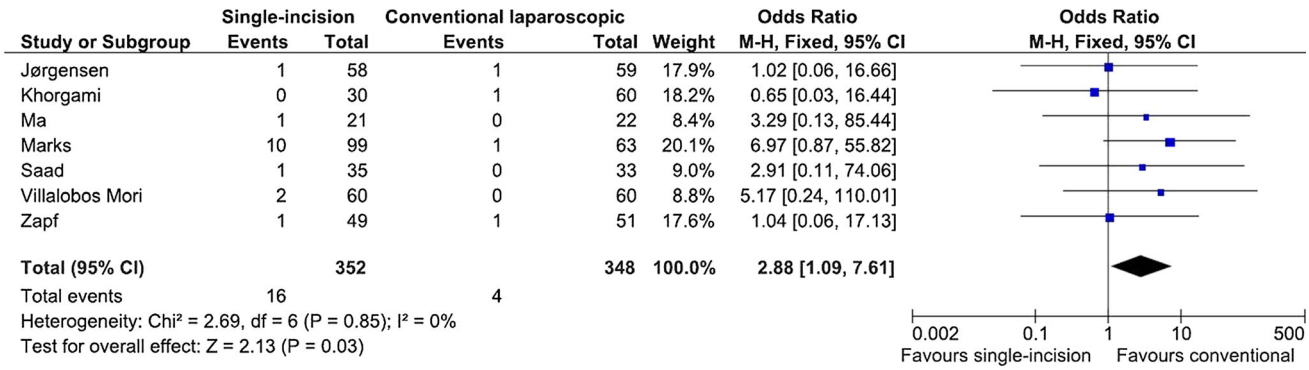

Fig. 5 Forest plot of secondary analysis (RCTs with high or acceptable quality) of the risk for trocar-site hernia. Seven studies reported on zero events and seven were included in the meta-analysis model

Cochrane Collaboration tool, to ensure reliability of results and minimize publication bias. A total of five reports were thus disregarded in the secondary analysis on the basis of inadequate quality. The included reports were further assessed using the Cochrane's Collaboration tool and were considered to be of adequate methodological quality. Nevertheless, it is unclear whether long-term outcomes were assessed by blinded investigators, although blinding of participants and assessors has been applied by several protocols for the short-term outcome assessment. Furthermore, conflicts of interest were either present or not declared in four publications [27, 31, 33, 37].

Due to the aforementioned limitations and specific characteristics of available RCTs, pooled outcome estimates cannot be considered as definite. Future clinical research on single-incision laparoscopic surgery should encompass incision-related complications and provide adequate follow-up data upon uniform and reliable clinical assessment of the risk for trocar-site hernia.

In the light of current evidence, it is necessary to alert the surgical community regarding the potential higher risk of incisional hernia associated with single-incision laparoscopic surgery involving entry into the peritoneal cavity through an umbilical incision. Meticulous closure of the fascia should be exercised, whereas enlargement of the skin incision might be necessary for this purpose. As this concept may be more relevant to patients with specific interest to optimal cosmetic outcome, incisional hernia might significantly affect long-term quality of life and morbidity.

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Conflict of interest SAA declares no conflict of interest. SMC declares no conflict of interest. GAA declares no conflicts of interest. FAA declares no conflict of interest. FB declares conflict of interest not directly related to the submitted work. FEM declares conflict of interest not directly related to the submitted work. ACB declares conflict of interest not directly related to the submitted work. KB declares no conflict of interest. MLC declares conflict of interest not directly related to the submitted work. DC declares conflict of interest not directly related to the submitted work. EBD declares conflict of interest not directly related to the submitted work. BEE declares no conflict of interest. RHF declares conflict of interest not directly related to the submitted work. JFG declares conflict of interest not directly related to the submitted work. NAH declares no conflict of interest. MM declares conflict of interest not directly related to the submitted work. DLS declares conflict of interest not directly related to the submitted work. MPS declares no conflict of interest. LV declares no conflict of interest.

Appendix 1

"The Bonham Group" is the European Hernia Society Guidelines Development Group for Guidelines on the closure of abdominal wall incisions:

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Appendix 2: Search strategy

1. Hernia
2. Incisional hernia
3. Trocar-site hernia

4. Trocar site hernia
5. Port-site hernia
6. Port site hernia
7. Single-incision
8. Single incision
9. Single-port
10. Single port
11. Single-access
12. Single access
13. One-access
14. One access
15. One-port
16. One port
17. Single-site
18. Single site
19. Laparoscopy
20. Laparoscopic
21. 1 OR 2 OR 3 OR 4 OR 5 OR 6
22. 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18
23. 19 OR 20

Search terms combination: 21 AND 22 AND 23

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