

## The fragility of randomised controlled trials on port site hernias in laparoscopic cholecystectomy

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### Introduction

- Laparoscopic** offers several benefits over open **cholecystectomy**, e.g. reduced risk of incisional hernia
- Port site hernias** (PSH) are uncommon but potentially significant
- Evidence for PSH prevention methods is of **limited quality**
- We assessed the **robustness** of **randomised controlled trials** (RCTs) evaluating intra-operative technical factors influencing PSH development post-LC, using the **fragility index** or **reverse fragility index**

### Methods

- Systematic review per PRISMA
- PROSPERO registration (CRD42024504809)
- Search: Medline, Embase, CENTRAL

(cholecystectomy) AND (“incisional hernia” OR “port site hernia” OR “trocar site hernia” OR “postoperative hernia”)

- Formal narrative synthesis of data
- Risk-of-Bias 2 assessment
- FI or RFI calculation

**10 RCTs included**

Minimum number of patients that would need a different outcome to:

**Fragility index (FI) = lose statistical significance**

**Reverse fragility index (RFI) = gain statistical significance**

### Results

\*S = significant, NS = non-significant

	Author Year	Intervention	Control	PSH incidence (I)	PSH incidence (O)	S or NS study* FI or RFI
Port insertion	Channa 2009	Veress needle	Hasson technique	0/60 (0.0%)	0/60 (0.0%)	Non-sig 6
	Lee 2016	Intra-umbilical	Infra-umbilical	0/64 (0.0%)	0/66 (0.0%)	Non-sig 6
Port size	Toktas 2019	15mm epigastric (extraction)	10mm epigastric (extraction)	0/100 (0.0%)	0/100 (0.0%)	Non-sig 6
Port for extraction	Kaya 2017	Epigastric	Umbilical	1/60 (1.7%)	0/60 (0.0%)	Non-sig 5
	Li 2018	Epigastric	Umbilical	4/81 (4.9%)	12/82 (14.6%)	Significant 0
Port closure (umbilical)	Calik 2008	Berci's needle	Suture	0/50 (0.0%)	0/50 (0.0%)	Non-sig 6
	Armañanzas 2014	Intra-perit PP w-3 mesh	Non-absorb suture	2/45 (4.4%)	15/47 (31.9%)	Significant 5
	Colak 2022	Video-assisted	Standard	1/121 (0.8%)	8/119 (6.7%)	Significant 1
	Ferreres Serafini 2023	PDS + onlay synth mesh	PDS	(41.7%)	(28.5%)	Unable to calculate
	Ciscar 2024	PDS + onlay PP mesh	2/0 PDS	9/64 (14.1%)	9/52 (17.3%)	Non-sig 6

### Conclusions

- None of the RCTs were robust, regardless of significant or non-significant primary outcome
- Current evidence on PSH prevention in LC is **fragile** and **low-quality**
- Higher quality RCTs on PSH prevention in LC are needed to guide best practice