



Systematic Reviews and Meta-Analyses on Robotic Single Site Cholecystectomy: Can we Conclude that the Procedure is Safe?

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Abstract

Single-Site® technology for da Vinci® Surgical Systems has been used since 2010 for cholecystectomy. Recent systematic reviews and meta-analyses emphasize that this technique is safe, particularly regarding the risk of port-site hernia. However, several authors reported an increased risk of incisional hernia after Single-Site® technology cholecystectomy. This can be explained by incision size but also by specific factors. Indeed, articles included for systematic reviews and meta-analyses had short follow-up and were not focused on long-term complications. Outcomes of meta-analyses should be carefully interpreted and port site-hernia looked forward in any new trials on this topic.

Keywords: Single site; Da Vinci; cholecystectomy; Incisional hernia; Port site hernia

Introduction

Meta-analyses of randomized clinical trials represent the highest level of evidence to direct clinical decisions making. However, clinical studies are conducted with primary and secondary objectives that are sometimes different from outcomes measured by meta-analyses. This explains why the quality of meta-analyses is influenced by several factors, such as outright errors, confidence interval wideness and the absence of important variables, answering to research question, from included studies. Moreover, some time-related outcomes can be detected in retrospective and cohort studies, whereas randomized controlled trials fail to identify them because of their design.

Single-Site® technology for the da Vinci® Surgical Systems is an interesting add-on to models Si, X and Xi, which can facilitate single site surgery. Initial reports on this technique in the fields of general surgery and gynecology, and further clinical trials, claim that the procedure is feasible and safe [1]. However, concerns were raised initially regarding its costs, notably for procedures such as cholecystectomy [2]. However, short-term outcomes for cholecystectomy with Single-Site® technology, including biliary leak, appeared to be similar to standard laparoscopy in recent meta-analyses (odds ratio for biliary leak 0.38, 95% CI 0.07-2, p=0.26; standard laparoscopy versus Single-Site® technology) and the rate of this complication remained very low (<1%) [3,4].

Port Site Hernia after Robotic Single Site Surgery

Recent systematic reviews and meta-analyses focusing on safety (Table 1) argued that Single-Site® technology for cholecystectomy induced similar risk of port site hernia than standard laparoscopy or laparoscopic single site cholecystectomy [3,5]. Other systematic reviews and meta-analyses did not assess this important clinical outcome, but also concluded that Single-Site® technology is safe [4,6].

We note that many trials included in the meta-analyses published on this topic have very short follow-ups, whereas incisional hernia constitutes a long-term complication than can occur several years after surgery [7]. Moreover, the reported prevalence of this complication is influenced by the diagnostic method, and as much as 23% of incisional hernias are missed after plain clinical examination [8]. The incidence of incisional hernia is even higher in obese patients, who represent a significant part of the population who undergoes cholecystectomy.

At the University Hospitals of Geneva (Switzerland), we have been using Single-Site® technology for cholecystectomy since its pre-launch in 2010. In a pilot cross-sectional study, we performed ultrasound in 48 patients operated with Single-Site® technology and reported an overall incidence of incisional hernia of 16.7% (95% CI 7.5-30.2) after a median follow-up of 39 months [9]. However,

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Table 1: Published systematic reviews and meta-analyses regarding da Vinci Single-Site® technology cholecystectomy.

Authors	Year	Article type	Groups	Maximal follow-up (months)	Rate of port site hernias after R-LESS	Conclusion about port site hernia for R-LESS
Migliore et al. [3]	2018	Systematic review and meta-analysis	NA	15	5.20%	Increased incidence of port site hernia, but similar to LESS.
Sun et al. [4]	2018	Systematic review and meta-analysis	R-LESS vs LESS	NR	NR	NR
Huang et al. [5]	2017	Systematic review and meta-analysis	R-LESS or R vs SL	NR	NA	The results did not suggest an increased rate of incisional hernia rates
Morelli et al. [6]	2016	Systematic review	R-LESS	NR	NR	NR

LESS: Laparoscopic Single Site Surgery; R-LESS: Robotic LESS; Robotic SL: Standard Laparoscopy; NR: Not Reported; NA: Not Applicable

we did not propose repair for all cases and adopted a “watch and see” strategy for selected patients. Further, in a case-matched retrospective study of our entire cohort, we described an incidence of port-site hernia repair of 7% vs. 0% in the standard laparoscopy group after a median follow-up of 59 months [10]. These results were similar to other retrospective studies [11,12]. However, to date, no randomized controlled trial has assessed the long-term incidence of incisional hernia after procedures using the Single-Site® technology. Therefore, we believe that most of the meta-analyses published on the subject are unable to precisely assess the occurrence of incisional hernia because of the designs of the studies they have included.

Torsion on Fascia and Surgical Site Infection

A recent meta-analysis of randomized controlled trials including 2471 patients reported that umbilicus single incision non-robotic laparoscopic surgery was associated with a higher risk of port-site hernia (odds ratio 2.37, 95% CI 1.25-4.50, $p=0.008$) when compared to standard laparoscopic cholecystectomy [13,14]. As the robotic and standard techniques for single site access share similar access and incision size, it is highly unlikely that da Vinci with that Single-Site® technology induces less port-site hernia when compared to the standard technique. Physiopathology of port-site incisional hernia is not fully understood, but we consider that at least two specific factors might contribute to the observed increased rate of incisional hernia after single site robotic cholecystectomy:

First, the initial Single-Site® technology was designed to quickly answer to surgeons' demand and to settle a new market [15]. Indeed, the technology required to establish all the potential of single site surgery will require years of research and development. Advantages or solved problem of the classic da Vinci® Surgical System are lost with this platform, such as the range of motion, the stability, the external conflicts with the assistant and the docking. In addition to the above, with the Single-Site® technology, it is difficult to properly set the remote center of the port. As a result, the fulcrum of the instruments and trocars will be at the wrong level and induce tension on the abdominal wall. Thus, we observed excessive torsion on fascia with the Single-Site® technology, which may induce fascia ischemia. However, the causality between this observation and port-site hernia remains to be established. Since April 2018, the da Vinci® SP surgical system was approved by the Food and Drug Administration, initially for urological procedures. This device is a complete robotic system designed exclusively for single incision procedure. As the SP system has only a single cannula, it might be easier to dock and to install. However, it will still be challenging to precisely install the remote center particularly. Moreover, this new system still uses a 2.5 cm access port [16]. Second, Lim et al. [17] recently reported an increased rate of surgical site infection after robotic single site surgery. As surgical site infection strongly contributes to the occurrence of incisional hernia, that finding might also explain the increased rate of incisional

hernia after robotic single site surgery [17,18].

Conclusion

Safety assessment of new surgical procedures should not only consider short-term outcomes but also look for potential long-term complications. When several studies with short follow-ups report low incidence of incisional hernia after robotic single site cholecystectomy, meta-analyses pooling the results of these studies cannot reach different conclusions and contribute to spread the low incidence reported by included studies, therefore influencing medical opinion. Port site-hernia should be looked forward in any new trials regarding any procedure that might induce the development of an incisional hernia, including robotic single site surgery, but also be carefully interpreted by meta-analyses. To detect incisional hernia, trials with a length of follow-up of at least 3 years would be required [7].

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