Centre universitaire de santé McGill

McGill University Health Centre

L'Unité d'évaluation des technologies et des modes d'intervention en santé (UETMIS) du Centre Universitaire de Santé McGill (CUSM)

Health Technology Assessment Unit (TAU) of the MUHC

July 24, 2025

Low-pressure Insufflation Devices for Laparoscopic Surgeries

Health Technology Assessment Report

Report no. 102

Report prepared for the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC)

by

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Reviewed by the Policy Committee of the TAU on July 24, 2025

Mission Statement

The MUHC Health Technology Assessment Unit (TAU) advises hospital administrators and clinical teams in difficult resource allocation decisions. Using an approach based on independent, critical evaluations of the available scientific evidence and a transparent, fair decision-making process, novel and existing medical equipment, drugs and procedures used by healthcare professionals are prioritized on a continuous basis ensuring the best care for life with the best use of resources.

TAU Policy Committee

Declaration of Conflicts of Interest

Members of TAU's research staff and policy committee declare no conflicts of interest.

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- Steeve Gaudreault, Nurse Advisor for specialized products for the operating room, interventional plateau, and sterilization in the Nursing Directorate, McGill University Health Centre (MUHC)
- André Guigui, Deputy to the Director of Finance at the MUHC

REPORT REQUESTOR

There is local interest at the McGill University Health Centre (MUHC) in evaluating the clinical benefits of using low pneumoperitoneum pressure during laparoscopic surgery. The current equipment can generate intra-abdominal pressures between 10 and 20 mmHg. Steeve Gaudreault requested the Technology Assessment Unit (TAU) to conduct this evaluation to support decision-making regarding a potential upgrade to devices that enable pressure settings lower than 10 mmHg.

TYPES OF RECOMMENDATIONS ISSUED BY THE TAU COMMITTEE

Type of recommendation	Explanation
Approved	• Evidence for relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, is sufficiently strong to justify a recommendation that the technology be accepted, used and funded through the institutional operating budget
Approved for evaluation	• There is a reasonable *probability* that relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, are favorable but the evidence is not yet sufficiently strong to support a recommendation for permanent and routine approval. • The evidence is sufficiently strong to recommend a *temporary* approval in a restricted population for the purposes of evaluation, funded through the institutional operating budget.
Not approved	• There is insufficient evidence for the relevant decision criteria, including efficacy, safety, and cost; • The costs of any use of the technology (e.g. for research purposes) should not normally be covered by the institutional budget.

DISCLAIMER

The Technology Assessment Unit ("TAU") of the McGill University Health Centre ("MUHC") was created in order to prepare accurate and trustworthy evidence to inform decision-making and when necessary to make policy recommendations based on this evidence. The objective of the TAU is to advise the hospitals in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments and a transparent, fair decision-making process. Consistent with its role within a university health centre, it publishes its research when appropriate, and contributes to the training of personnel in the field of health technology assessment.

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LIST OF ABBREVIATIONS

CI	Confidence interval
I^2 statistic	The percentage of variation across studies in a meta-analysis that is due to heterogeneity rather than chance
IAP	Intra-abdominal pressure
INAHTA	International network of agencies for health technology assessment
LOS	Length of stay
MUHC	McGill University Health Center
NICE	National Institute for Health and Care Excellence
OR	Odds ratio
RCT	Randomized clinical trial
RR	Risk ratio
TAU	MUHC Technology Assessment Unit

PLAIN LANGUAGE SUMMARY

Can the use of lower intra-abdominal pressure during laparoscopic surgery improve outcomes without increasing risks?

KEY MESSAGES

- Using low-pressure (<10 mmHg) during laparoscopic surgery appears to be safe and might help reduce post-operative pain and shorten hospital stays.
- The hospital could save money over time by adopting machines that support both low and standard pressures.
- Most of the evidence is considered low certainty, meaning the results are not fully reliable and may change with future research.

What is low pressure laparoscopic surgery?

Laparoscopic surgery is a type of surgery done through small cuts using a camera and thin instruments. To make enough space for the surgeon to see and move the tools, the abdomen is gently filled with gas (usually carbon dioxide). This is called abdominal insufflation or pneumoperitoneum; it is usually done at pressures of 10-20 mmHg**.** Filling the abdomen with gas can stretch the muscles inside and irritate the body, sometimes leading to pain after surgery—especially in the shoulders. This happens because the gas can press on the diaphragm (the muscle that helps you breathe) and affect nearby nerves.

What did we want to find out?

We wanted to know if using lower pressure (<10 mmHg) during laparoscopic surgery is better for patients than using standard pressure (≥10 mmHg). Specifically, we looked at whether low pressure reduces pain, complications, or hospital stay, and whether it is worth the cost for the McGill University Health Centre (MUHC) to invest in machines that can use low pressure.

What did we do?

We reviewed the results of a recent large meta-analysis that combined data from 85 randomized clinical trials. We focused on outcomes like post-surgery pain, opioid use, nausea, complications, and hospital stay. We also estimated the cost impact of switching to low-pressure machines for gallbladder surgeries at the MUHC.

What did we find?

- **Pain relief and recovery**: Low-pressure surgery may reduce shoulder pain in the first 24 hours after surgery. It also probably reduces the length of hospital stay by 8 hours. However, the effect on opioid use was small and likely not clinically meaningful. The impact on nausea and vomiting is unclear.
- **Surgical safety**: Low pressure does not appear to significantly affect blood loss or duration of surgery. However, surgeons may be more likely to switch back to higher pressure mid-surgery. The impact on surgical complications is still uncertain.
- **Costs**: For gallbladder (cholecystectomy) surgeries, using low-pressure laparoscopy could save the MUHC about $18,600 per year, mainly by reducing hospital stays.

How reliable is the evidence?

Most of the evidence is rated as low to moderate in certainty. This means we cannot be fully confident in the results, and future studies might change the conclusions. Some differences, like pain reduction and shorter stays, appear consistent, but safety data remains uncertain.

Bottom line

Using low-pressure gas in laparoscopic surgery may offer modest benefits for patients and small cost savings for hospitals. The new machines being considered can use both low and standard pressure, giving surgeons flexibility. Despite low certainty, low-pressure insufflation appears to be a safe and reasonable option worth considering by hospitals as they update their equipment.

EN BREF

L’utilisation d’une pression intra-abdominale plus faible pendant la chirurgie laparoscopique peut-elle améliorer les résultats sans augmenter les risques ?

MESSAGES CLÉS

- L'utilisation d'une basse pression (< 10 mmHg) pendant la chirurgie laparoscopique semble sûre et pourrait contribuer à réduire la douleur postopératoire et la durée d'hospitalisation.
- L'hôpital pourrait réaliser des économies à long terme en adoptant des machines prenant en charge à la fois les pressions basses et standard.
- La plupart des données probantes sont considérées comme peu fiables, ce qui signifie que les résultats ne sont pas totalement fiables et pourraient évoluer avec les recherches futures.

Qu’est-ce que la chirurgie laparoscopique à basse pression ?

La chirurgie laparoscopique est une intervention pratiquée par petites incisions à l'aide d'une caméra et d'instruments fins. Afin de libérer suffisamment d'espace pour que le chirurgien puisse voir et manipuler les instruments, l'abdomen est doucement rempli de gaz (généralement du dioxyde de carbone). C'est ce qu'on appelle l'insufflation abdominale ou pneumopéritoine ; elle est généralement réalisée à des pressions de 10 à 20 mmHg.

Remplir l'abdomen de gaz peut étirer les muscles internes et irriter le corps, provoquant parfois des douleurs postopératoires, notamment au niveau des épaules. Cela se produit car le gaz peut comprimer le diaphragme (le muscle qui vous aide à respirer) et affecter les nerfs voisins.

Que voulions-nous découvrir ?

Nous voulions savoir si l'utilisation d'une pression plus faible (< 10 mmHg) lors d'une chirurgie laparoscopique était plus bénéfique pour les patients que la pression standard (≥ 10 mmHg). Plus précisément, nous avons examiné si une basse pression réduisait la douleur, les complications ou la durée d'hospitalisation, et si l'investissement dans des appareils capables d'utiliser une basse pression était rentable pour le Centre universitaire de santé McGill (CUSM).

Qu'avons-nous fait ?

Nous avons examiné les résultats d'une récente méta-analyse de grande envergure combinant les données de 85 essais cliniques randomisés. Nous nous sommes concentrés sur des critères tels que la douleur postopératoire, la consommation d'opioïdes, les nausées, les complications et la durée d'hospitalisation. Nous avons également estimé l'impact financier du passage aux appareils à basse pression pour les chirurgies de la vésicule biliaire au CUSM.

Qu'avons-nous trouvé ?

- **Soulagement de la douleur et récupération** : La chirurgie à basse pression peut réduire la douleur à l'épaule dans les 24 heures suivant l'intervention. Elle réduit également probablement la durée d'hospitalisation de 8 heures. Cependant, l'effet sur la consommation d'opioïdes était faible et probablement non cliniquement significatif. L'impact sur les nausées et les vomissements n'est pas clair.
- **Sécurité chirurgicale** : La basse pression ne semble pas avoir d'effet significatif sur la perte sanguine ou la durée de l'intervention. Cependant, les chirurgiens pourraient être plus susceptibles de revenir à une pression plus élevée en cours d'intervention. L'impact sur les complications chirurgicales est encore incertain.
- **Coûts** : Pour les chirurgies de la vésicule biliaire (cholécystectomie), le recours à la laparoscopie à basse pression pourrait permettre au CUSM d'économiser environ 18 600 $ par an, principalement en réduisant la durée d'hospitalisation.

Quelle est la fiabilité des données probantes ?

La plupart des données probantes sont jugées d'un niveau de certitude faible à modéré. Cela signifie que nous ne pouvons pas être totalement sûrs des résultats, et que de futures études pourraient modifier les conclusions. Certaines différences, comme la réduction de la douleur et la durée plus courte des séjours, semblent cohérentes, mais les données de sécurité restent incertaines.

En résumé

L'utilisation de gaz basse pression en chirurgie laparoscopique pourrait offrir des avantages modestes aux patients et de légères économies aux hôpitaux. Les nouvelles machines envisagées peuvent utiliser à la fois une pression basse et une pression standard, offrant ainsi une certaine flexibilité aux chirurgiens. Malgré le manque de certitude, l'insufflation basse pression semble être une option sûre et raisonnable, à considérer par les hôpitaux lors de la modernisation de leurs équipements.

EXECUTIVE SUMMARY

BACKGROUND

- Laparoscopic surgery requires abdominal insufflation (pneumoperitoneum), a process to create adequate working space for surgical instruments by inflating the abdominal cavity with gas, typically carbon dioxide. This can cause postoperative pain due to diaphragmatic stretching, chemical irritation from carbonic acid, and sympathetic nervous system activation, potentially leading to shoulder tip pain and other discomfort.
- A systematic review of 85 randomized controlled trials has shown that low-pressure pneumoperitoneum (<10 mmHg) could reduce postoperative pain without compromising surgical duration or hospital stay compared to standard or high-pressure approaches (≥10 mmHg). This suggests a favourable risk-benefit profile for low-pressure techniques.
- The current fleet of insufflation devices at the McGill University Health Centre (MUHC), which operate at 10-20 mmHg, needs to be replaced and therefore, there is interest in assessing the clinical benefits of low-pressure (<10 mmHg) pneumoperitoneum in laparoscopic surgery. Steeve Gaudreault, Nurse Advisor for Specialized Operating Room Products, has requested that the Technology Assessment Unit (TAU) evaluate devices capable of delivering pressures below 10 mmHg to inform potential equipment upgrades.

POLICY QUESTION

Should the MUHC procure insufflation machines capable of delivering both low (<10 mmHg) and standard/high (≥10 mmHg) intra-abdominal pressures for laparoscopic surgeries?

EVALUATION QUESTIONS (Objectives of this report)

The objectives of this report were:

1. To evaluate the clinical outcomes of laparoscopic surgery performed with intra-abdominal pressure (IAP) <10 mmHg compared to ≥10 mmHg.
2. To assess the budget impact of using low-pressure (<10 mmHg) insufflation devices vs. the current practice for laparoscopic cholecystectomy procedures at the MUHC.

METHODS

Literature Review

We conducted a search on PubMed, Medline and Embase to identify studies that met our criteria, defined below.

- Population: Patients who underwent any minimally invasive surgery using laparoscopic instruments and devices
- Intervention: Insufflation device that can create a pneumoperitoneum using low-pressure (<10 mmHg)
- Control: Any device that can create a pneumoperitoneum using pressure ≥10 mmHg
- Outcomes
    - Clinical benefit: Post-operative (shoulder) pain; opioid use; post-operative nausea and vomiting; length of stay (LOS); duration of surgery
    - Safety: Intraoperative complications; perioperative complications; conversion to a higher pressure; blood loss

Budget Impact Analysis

We estimated the additional cost per patient of using low-pressure (<10 mmHg) insufflation for laparoscopic cholecystectomies at our hospital. We obtained volumes, average LOS, and average costs of laparoscopic cholecystectomies from the Finance Department of the MUHC, and device costs from Steeve Gaudreault, Nurse Advisor for Specialized Operating Room Products.

RESULTS

Clinical Impact

One systematic review, by Reijnders-Boerboom et al., met our inclusion criteria and included 85 RCTs published as of November 2021. While this study showed low concerns in the domains of eligibility criteria, study selection, data collection, and appraisal, the findings should be interpreted with caution. The synthesis had high concerns due to the inclusion of RCTs using per-protocol analyses and those with co-interventions (e.g., neuromuscular blockade), making it difficult to isolate the effects of low versus standard IAP. Additionally, the risk of bias was assessed at the study level rather than by individual outcomes.

We further identified eight RCTs published after 2021. However, three had a moderate risk of bias and three had a high risk of bias due to lack of concealment information and/or unequal deviations from the intended intervention. Therefore, we chose not to include them to update Reijnders-Boerboom's meta-analysis.

Below, we summarize the meta-analysis by Reijnders-Boerboom et al. for all outcomes except LOS, where we conducted our own meta-analysis because we were interested in LOS by surgery type. We also included a narrative review of hospital readmission from one RCT, as this outcome was not reviewed by Reijnders-Boerboom.

Summary of meta-analysis by Reijnders-Boerboom et al.

Clinical Benefit:

Post-operative shoulder pain

- 12-24 hours: The meta-analysis (8 RCTs; 180 events in 794 participants) reported a relative risk (RR) of 0.64 (95% CI 0.44, 0.94) for shoulder pain with low pressure (<10 mmHg) compared to higher pressure (≥10 mmHg) (low certainty evidence). This suggests that low pressure **may reduce** post-operative shoulder pain at 12-24 hours.
- 24-72 hours: Pooled results from 6 RCTs (110 events, 662 participants) showed a relative risk of 0.61 (95% CI 0.33, 1.13) (low certainty evidence). The low certainty evidence (imprecision and indirectness of evidence) indicates that the effect of low-pressure laparoscopy on post-operative shoulder pain at 24-72 hours is **uncertain**.

Post-operative opioid use

- 12-24 hours: The meta-analysis of 7 RCTs (704 participants) reported a mean reduction in post-operative opioid use of 1.73 mg of morphine equivalents at 12-24 hours for <10 mmHg compared to ≥10 mmHg IAP (mean difference (MD) -1.73, 95% CI -2.36 to -1.10 mg) (moderate certainty of evidence). While this suggests low-pressure laparoscopy probably reduces opioid use at 12–24 hours, the magnitude of this reduction is **not considered clinically meaningful**.
- 24-72 hours: Based on 2 RCTs (241 participants), the mean difference in opioid use was -0.45 mg (95% CI -2.05 to 1.15) (moderate certainty evidence). This indicates that low-pressure laparoscopy **probably has little or no effect** on post-operative opioid use at 24–72 hours.

Post-operative nausea and vomiting

- 12-24 hours: A meta-analysis of 2 RCTs (34 events, 238 participants) reported a relative risk of 0.61 (95% CI 0.18 to 2.13) for post-operative nausea and vomiting with low-pressure laparoscopy compared to higher pressure (low certainty evidence).

  The low certainty of the evidence (impacted by low quality studies, imprecision, and indirectness) suggests that the effect of low-pressure laparoscopy on nausea and vomiting at 12–24 hours **is uncertain**.

- 24-72 hours: Results from 2 RCTs (19 events, 429 participants) showed a relative risk of 0.46 (95% CI 0.19 to 1.14) (low certainty evidence). This indicates that the effect of low-pressure laparoscopy on nausea and vomiting at 24–72 hours **remains uncertain** due to the low certainty of the evidence (low quality studies, imprecision, and indirectness).

Length of stay

- All surgeries: A meta-analysis of 21 RCTs (2,508 participants) found that low-pressure laparoscopy was associated with a mean reduction in hospital stay of 0.33 days (95%

CI -0.55 to -0.11) (moderate certainty evidence). This suggests that low-pressure laparoscopy **probably reduces** hospital length of stay by approximately 8 hours

- Cholecystectomy laparoscopy: Our pooled analysis of 9 RCTs (955 participants) reported a reduction in mean length of stay of 0.31 days (95% CI -0.51 to -0.11) with low-pressure laparoscopy compared to higher pressure (moderate certainty evidence). This suggests that low-pressure laparoscopy **probably reduces** hospital stay following cholecystectomy.

Duration of surgery:

- A meta-analysis of 54 RCTs (5,047 participants) reported a mean difference in surgical duration of 1.75 minutes (95% CI -0.15 to 3.64) for low-pressure compared to higher pressure laparoscopy (low certainty evidence). This suggests that low-pressure laparoscopy **does not appear to have a clinically meaningful effect** on surgery duration

Safety:

- **Conversion to a higher pressure**: Results from 16 RCTs (119 events, 1,411 participants) showed a relative risk of 4.71 (95% CI 2.88 to 7.69) for conversion to higher pressure with low-pressure laparoscopy (low certainty of evidence). This suggests that low-pressure laparoscopy **may increase** the likelihood of conversion to a higher intra-abdominal pressure.
- **Blood loss:** A meta-analysis of 8 RCTs (861 participants) reported a mean difference in blood loss of 16.30 mL (95% CI -9.40 to 41.99) for low-pressure compared to higher pressure laparoscopy (low certainty evidence). This indicates that low-pressure laparoscopy **does not appear to have a clinically meaningful effect** on blood loss
- **Intraoperative complications**: Based on 16 RCTs (91 events, 1,661 participants), the relative risk of intraoperative complications was 1.15 (95% CI 0.77 to 1.73) (low certainty evidence). The low certainty evidence (imprecision, indirectness and inconsistency) suggests that the effect of low-pressure laparoscopy on intraoperative complications **remains uncertain.**
- **Serious perioperative complications**: A meta-analysis of 12 RCTs (50 events, 1,507 participants) found a relative risk of 1.25 (95% CI 0.71 to 2.20) for serious perioperative complications (Clavien-Dindo grade 3–4) (low certainty evidence). The low certainty evidence (imprecision and indirectness) indicates that the effect of low-pressure laparoscopy on serious perioperative complications **is uncertain**.

Budget Impact

Based on an estimated additional cost of low pressure devices of $100/patient, an average length of stay of 2.9 days for cholecystectomy patients at the MUHC and assuming a reduction in LOS of 0.31 days (95% CI: -0.51 to -0.11), obtained from our

meta-analysis, we estimated that using low pressure insufflation would result in a cost savings of $43 per patient or $18,663 (ranging from cost savings of $58,897 to a cost increase of $21,571) for 437 cholecystectomy patients annually.

CONCLUSIONS

- The best available evidence, derived from a recent, large meta-analysis, indicates that:
    - For **Clinical benefit**: Low-pressure pneumoperitoneum (IAP <10 mmHg) may modestly reduce post-operative pain within the first 24 hours, and probably reduces length of stay by approximately 8 hours. It has no clinically meaningful impact on opioid use or surgical duration.
    - For **Safety** impact: Low-pressure pneumoperitoneum may increase the likelihood of conversion to higher intra-abdominal pressure during surgery. It does not appear to meaningfully impact blood loss. The effects on intraoperative and serious perioperative complications remain uncertain due to imprecision in the estimates and low certainty of the evidence.
- In terms of budget impact for laparoscopic cholecystectomies at the MUHC, adopting low-pressure insufflation could yield modest annual cost savings (~$18,600) from projected reduced length of hospital stays.

RECOMMENDATION

- The TAU Policy Committee, comprising stakeholders from across the McGill University Health Centre, reviewed the evidence and issued the following recommendation for the adoption of insufflation devices that allow both low- and standard/high-pressure settings: Approved
- This recommendation was reached based on the following:
    - The best available evidence, although generally of low-certainty, suggests that low-pressure pneumoperitoneum (<10 mmHg) may offer patient benefits, including reduced pain and shorter hospital stays, without increasing safety risks.
    - The impact on hospital budget is minimal, with potential for long-term cost savings.
    - The new insufflation devices under consideration can accommodate both low and standard/high intra-abdominal pressures, therefore leaving the choice of pressure level to the discretion of the surgical team.
    - Recognition that conversion to higher pressure may decrease with increased surgeon experience.
- The Committee emphasized the importance of collecting local data to guide future use and identify the surgical populations most likely to benefit.

SOMMAIRE

Dispositifs d'insufflation basse pression pour chirurgies laparoscopiques

CONTEXTE

- La chirurgie laparoscopique nécessite une insufflation abdominale (pneumopéritoine), un procédé visant à créer un espace de travail adéquat pour les instruments chirurgicaux en gonflant la cavité abdominale avec un gaz, généralement du dioxyde de carbone. Cela peut entraîner des douleurs postopératoires dues à l'étirement du diaphragme, à l'irritation chimique due à l'acide carbonique et à l'activation du système nerveux sympathique, pouvant entraîner des douleurs à la pointe de l'épaule et d'autres inconforts.
- Une revue systématique de 85 essais contrôlés randomisés a montré que le pneumopéritoine à basse pression (< 10 mmHg) pouvait réduire la douleur postopératoire sans compromettre la durée de l'intervention ni la durée d'hospitalisation, comparativement aux approches standard ou à haute pression (≥ 10 mmHg). Cela suggère un profil risque-bénéfice favorable pour les techniques à basse pression.
- Le parc actuel de dispositifs d'insufflation du Centre universitaire de santé McGill (CUSM), qui fonctionnent à 10-20 mmHg, doit être remplacé ; par conséquent, il est intéressant d'évaluer les avantages cliniques du pneumopéritoine à basse pression (< 10 mmHg) en chirurgie laparoscopique. Steeve Gaudreault, infirmier-conseil pour les produits spécialisés en salle d'opération, a demandé à l'Unité d'évaluation des technologies (UETMIS) d'évaluer les appareils capables de délivrer des pressions inférieures à 10 mmHg afin d'éclairer les mises à niveau potentielles de l'équipement.

QUESTION STRATÉGIQUE

Le CUSM devrait-il se doter d'insufflateurs capables de délivrer des pressions intra-abdominales basses (< 10 mmHg) et standard/élevées (≥ 10 mmHg) pour les chirurgies laparoscopiques ?

QUESTIONS D'ÉVALUATION (Objectifs de ce rapport)

Les objectifs de ce rapport étaient :

1. Évaluer les résultats cliniques des chirurgies laparoscopiques réalisées avec une pression intra-abdominale (PIA) < 10 mmHg par rapport à ≥ 10 mmHg.

2. Évaluer l'impact budgétaire de l'utilisation de dispositifs d'insufflation à basse pression (< 10 mmHg) par rapport à la pratique actuelle pour les cholécystectomies

MÉTHODES

Revue de la littérature

Nous avons effectué une recherche sur PubMed, Medline et Embase afin d'identifier les études répondant à nos critères, définis ci-dessous.

- Population : Patients ayant subi une chirurgie mini-invasive utilisant des instruments et dispositifs laparoscopiques
- Intervention : Dispositif d'insufflation permettant de créer un pneumopéritoine à basse pression (< 10 mmHg)
- Comparateur : Tout dispositif permettant de créer un pneumopéritoine à une pression ≥ 10 mmHg
- Résultats :
    - Bénéfice clinique : Douleurs postopératoires (à l'épaule) ; consommation d'opioïdes ; nausées et vomissements postopératoires ; durée d'hospitalisation ; durée de l'intervention
    - Sécurité : Complications peropératoires ; complications périopératoires ; conversion à une pression plus élevée ; pertes sanguines

Analyse d'impact budgétaire

Nous avons estimé le surcoût par patient lié à l'insufflation à basse pression (< 10 mmHg) pour les cholécystectomies laparoscopiques dans notre hôpital. Nous avons obtenu les volumes, la durée moyenne d'hospitalisation et les coûts moyens des cholécystectomies laparoscopiques auprès du service des finances du CUSM, ainsi que les coûts des appareils auprès de Steeve Gaudreault, infirmier-conseil pour les produits spécialisés en salle d'opération.

RÉSULTATS

Impact clinique

Une revue systématique, réalisée par Reijnders-Boerboom et al., répondait à nos critères d'inclusion et incluait 85 ECR publiés en novembre 2021. Bien que cette étude ait suscité peu de questions concernant les critères d'éligibilité, la sélection des études, la collecte des données et l'évaluation, ses résultats doivent être interprétés avec prudence. La qualité de la synthèse était incertaine en raison de l'inclusion d'ECR utilisant des analyses per protocole et d'ECR avec co-interventions (par exemple, un blocage neuromusculaire), ce qui rendait difficile l'isolement des effets d'une PAI faible

par rapport à une PAI standard. De plus, le risque de biais a été évalué au niveau de l'étude plutôt que par les résultats individuels.

Nous avons également identifié huit ECR publiés après 2021. Cependant, trois présentaient un risque de biais modéré et trois un risque élevé en raison d'un manque d'informations sur le masquage de l'allocation et/ou des déviations inégales par rapport à l'intervention prévue. Par conséquent, nous avons choisi de ne pas les inclure afin de mettre à jour la méta-analyse de Reijnders-Boerboom. Ci-dessous, nous résumons la méta-analyse de Reijnders-Boerboom et al. pour tous les critères d'évaluation, à l'exception de la durée du séjour (DS), pour laquelle nous avons mené notre propre méta-analyse, car nous étions intéressés par la durée du séjour par type d'intervention chirurgicale. Nous avons également inclus une revue narrative des réadmissions à l'hôpital d'un ECR, ce critère n'ayant pas été examiné par Reijnders-Boerboom.

Résumé de la méta-analyse de Reijnders-Boerboom et al.

Bénéfice clinique :

Douleur postopératoire à l'épaule

- 12 à 24 heures : La méta-analyse (8 ECR ; 180 événements chez 794 participants) a rapporté un risque relatif (RR) de 0,64 (IC à 95 % : 0,44 à 0,94) pour la douleur à l'épaule à basse pression (< 10 mmHg) par rapport à une pression plus élevée (≥ 10 mmHg) (données probantes de faible certitude). Cela suggère qu'une basse pression **pourrait réduire** la douleur postopératoire à l'épaule à 12 à 24 heures.
- 24 à 72 heures : Les résultats regroupés de 6 ECR (110 événements, 662 participants) ont montré un risque relatif de 0,61 (IC à 95 % : 0,33 à 1,13) (faible certitude des données probantes). Ce faible niveau de certitude (imprécision et caractère indirect des données probantes) indique que l'effet de la laparoscopie à basse pression sur la douleur postopératoire de l'épaule à 24 à 72 heures est **incertain**.

Consommation d'opioïdes postopératoire

- 12 à 24 heures : La méta-analyse de 7 ECR (704 participants) a rapporté une réduction moyenne de la consommation d'opioïdes postopératoire de 1,73 mg d'équivalent morphine à 12 à 24 heures pour une pression intra-abdominale < 10 mmHg par rapport à une pression ≥ 10 mmHg (différence moyenne (DM) : -1,73 ; IC à 95 % : -2,36 à -1,10 mg) (certitude modérée des données probantes). Bien que cela suggère que la laparoscopie à basse pression réduit probablement la consommation d'opioïdes à 12-24 heures, l'ampleur de cette réduction **n'est pas considérée comme cliniquement significative**.
- 24-72 heures : D'après deux ECR (241 participants), la différence moyenne de consommation d'opioïdes était de -0,45 mg (IC à 95 % : -2,05 à 1,15) (preuve de

certitude modérée). Cela indique que la laparoscopie à basse pression a **probablement peu ou pas d'effet** sur la consommation d'opioïdes postopératoire à 24-72 heures.

Nausées et vomissements postopératoires

- 12-24 heures : Une méta-analyse de deux ECR (34 événements, 238 participants) a rapporté un risque relatif de nausées et vomissements postopératoires de 0,61 (IC à 95 % : 0,18 à 2,13) avec la laparoscopie à basse pression par rapport à une pression plus élevée (preuve de faible certitude). La faible certitude des données probantes (affectée par des études de faible qualité, leur imprécision et leur caractère indirect) suggère que l'effet de la laparoscopie à basse pression sur les nausées et vomissements à 12-24 heures est **incertain**.
- 24-72 heures : Les résultats de 2 ECR (19 événements, 429 participants) ont montré un risque relatif de 0,46 (IC à 95 % : 0,19 à 1,14) (données probantes de faible certitude). Cela indique que l'effet de la laparoscopie à basse pression sur les nausées et vomissements à 24-72 heures reste **incertain** en raison de la faible certitude des données probantes (études de faible qualité, imprécision et caractère indirect).

Durée du séjour

- Toutes interventions : Une méta-analyse de 21 ECR (2 508 participants) a révélé que la laparoscopie à basse pression était associée à une réduction de la durée moyenne de séjour de 0,33 jour (IC à 95 % : -0,55 à -0,11) (données probantes de certitude modérée). Cela suggère que la laparoscopie à basse pression **réduit probablement** la durée d'hospitalisation d'environ 8 heures.
- Laparoscopie pour cholécystectomie : Notre méta-analyse de 9 ECR (955 participants) a rapporté une réduction de la durée moyenne de séjour de 0,31 jour (IC à 95 % : -0,51 à -0,11) avec la laparoscopie à basse pression par rapport à la laparoscopie à haute pression (niveau de preuve modéré). Cela suggère que la laparoscopie à basse pression **réduit probablement** la durée d'hospitalisation après une cholécystectomie.

Durée de l'intervention :

- Une méta-analyse de 54 ECR (5 047 participants) a rapporté une différence moyenne de durée chirurgicale de 1,75 minute (IC à 95 % : -0,15 à 3,64) entre la laparoscopie à basse pression et la laparoscopie à haute pression (niveau de preuve faible). Ceci suggère que la laparoscopie à basse pression ne semble pas avoir d'effet cliniquement significatif sur la durée de l'intervention.

Sécurité :

- **Conversion à une pression plus élevée** : Les résultats de 16 ECR (119 événements, 1 411 participants) ont montré un risque relatif de 4,71 % (IC à 95 % : 2,88 à 7,69) de conversion à une pression plus élevée avec la laparoscopie à basse pression (faible niveau de preuve). Cela suggère que la laparoscopie à basse pression **pourrait** augmenter la probabilité de conversion à une pression intra-abdominale plus élevée.
- **Perte sanguine** : Une méta-analyse de 8 ECR (861 participants) a rapporté une différence moyenne de perte sanguine de 16,30 ml (IC à 95 % : -9,40 à 41,99) pour la laparoscopie à basse pression par rapport à la laparoscopie à haute pression (faible niveau de preuve). Cela indique que la laparoscopie à basse pression **ne semble pas avoir d'effet cliniquement significatif** sur les pertes sanguines.
- **Complications peropératoires** : D'après 16 ECR (91 événements, 1 661 participants), le risque relatif de complications peropératoires était de 1,15 (IC à 95 % : 0,77 à 1,73) (données probantes de faible certitude). Ces données probantes de faible certitude (imprécision, caractère indirect et incohérence) suggèrent que l'effet de la laparoscopie à basse pression sur les complications peropératoires reste **incertain**.
- **Complications périopératoires graves** : Une méta-analyse de 12 ECR (50 événements, 1 507 participants) a révélé un risque relatif de 1,25 (IC à 95 % : 0,71 à 2,20) de complications périopératoires graves (grade 3-4 selon l'échelle de Clavien-Dindo) (données probantes de faible certitude). Les données probantes de faible certitude (imprécision et caractère indirect) indiquent que l'effet de la laparoscopie à basse pression sur les complications périopératoires graves est **incertain**.

Impact budgétaire

Sur la base d'un coût supplémentaire estimé des dispositifs à basse pression de 100 $/patient, d'une durée moyenne de séjour de 2,9 jours pour les patients ayant subi une cholécystectomie au CUSM et en supposant une réduction de la durée du séjour de 0,31 jour (IC à 95 % : -0,51 à -0,11), obtenue à partir de notre méta-analyse, nous avons estimé que le recours à l'insufflation à basse pression entraînerait des économies de 43 $ par patient, soit 18 663 $ (allant de 58 897 $ à une augmentation de 21 571 $) pour 437 patients subissant une cholécystectomie chaque année.

CONCLUSIONS

- Les meilleures données probantes disponibles, issues d'une méta-analyse récente et de grande envergure, indiquent que :
    - **Pour le bénéfice clinique** : le pneumopéritoine à basse pression (PIA < 10 mmHg) peut réduire légèrement la douleur postopératoire dans les 24 heures et peut probablement réduire la durée de séjour d'environ

8 heures. Il n'a aucun impact cliniquement significatif sur la consommation d'opioïdes ni sur la durée de l'intervention.

- **Pour l'impact sur la sécurité** : le pneumopéritoine à basse pression peut augmenter la probabilité d'une augmentation de la pression intra-abdominale pendant l'intervention. Il ne semble pas avoir d'impact significatif sur la perte sanguine. Les effets sur les complications peropératoires et périopératoires graves demeurent incertains en raison de l'imprécision des estimations et du faible niveau de certitude des données probantes.

- Concernant l'impact budgétaire des cholécystectomies laparoscopiques au CUSM, l'adoption de l'insufflation à basse pression pourrait générer de modestes économies annuelles (environ 18 600 $) grâce à la réduction prévue de la durée moyenne de séjour.

RECOMMANDATIONS

- Le comité consultatif de l'Unité d'évaluation des technologies de la santé (TAU), composé d'intervenants de l'ensemble du Centre universitaire de santé McGill, a examiné les données probantes et a émis la recommandation suivante concernant l'adoption de dispositifs d'insufflation permettant des réglages de pression basse et standard/élevée : Approuvé

- Cette recommandation a été formulée sur la base des éléments suivants :
  - Les meilleures données probantes disponibles, bien que généralement de faible certitude, suggèrent que le pneumopéritoine à basse pression (< 10 mmHg) peut offrir des avantages aux patients, notamment une réduction de la douleur et une hospitalisation plus courte, sans augmenter les risques pour la sécurité.
  - L'impact sur le budget de l'hôpital est minime, avec un potentiel d'économies à long terme.
  - Les nouveaux dispositifs d'insufflation envisagés peuvent supporter des pressions intra-abdominales basses et standard/élevées, laissant ainsi le choix du niveau de pression à la discrétion de l'équipe chirurgicale.
  - Reconnaissant que le passage à une pression plus élevée peut diminuer avec l'expérience du chirurgien.

- Le Comité a souligné l'importance de recueillir des données locales pour orienter l'utilisation future et pour identifier les populations chirurgicales les plus susceptibles d'en bénéficier.

Low-Pressure Insufflation Devices for Laparoscopic Surgeries

1. BACKGROUND

1.1 Pneumoperitoneum in Laparoscopic Surgeries

Laparoscopic procedures involve small incisions made at a distance from the actual surgical site. Hence, the available surgical field (i.e. working space) is quite limited. To ensure proper visibility and allow sufficient room for instrument manipulation during surgery, the surgeons need to elevate the abdominal wall. This can be achieved either mechanically, using abdominal wall elevators, or by creating a pneumoperitoneum (i.e. forming a space in the abdomen by placing any gas into the peritoneal cavity). Pneumoperitoneum is typically established by insufflating carbon dioxide into the abdominal cavity with the help of pressure-regulated automatic insufflators.(1)

Bhupen et al.(2) summarized some theories about the cause of pain after pneumoperitoneum.

- Diaphragm Stretching: When carbon dioxide gas is pumped into the abdomen, the intra-abdominal pressure (IAP) increases. This can stretch and slightly tear the diaphragm muscles, which may irritate the phrenic nerve. This irritation can cause pain in the right shoulder, known as shoulder tip pain, since both areas are linked by the same nerve pathway (C4 dermatome).
- Chemical Effect of the Gas: Carbon dioxide is an acidic gas. It forms carbonic acid when it mixes with the fluid in the abdominal cavity. This acid can irritate the lining of the abdomen (peritoneum), possibly affecting the phrenic nerve and causing shoulder pain.
- Activation of the Nervous System: Hypercarbia, because of the buildup of carbon dioxide in the body, can trigger the sympathetic nervous system and cause inflammation. This may lead to the release of certain chemicals and reduce blood flow to the abdominal tissues, which could also contribute to the pain.

1.2 Low versus High Intra-abdominal Pressure

Since the late 1990s, the use of low intra-abdominal pressure (IAP <10 mmHg) in laparoscopic surgery has been explored primarily to reduce postoperative pain and minimize physiological disturbances associated with hypercarbia. Early randomized controlled trials (RCTs) by Wallace et al. (1997) and Sarli et al. (2000) demonstrated that low-pressure pneumoperitoneum (7-9 mm Hg) significantly reduced post-operative pain

following laparoscopic cholecystectomy compared to standard pressure (13-15 mm Hg). Operative time and the length of hospital stay were comparable in both groups.

1.3 Surgery Outcomes

The Standardized Endpoints in Perioperative Medicine – Core Outcome Measures for Perioperative and Anesthetic Care (StEPCOMPAC) consensus group divided the clinical and patient-centred core outcomes into six domains. They are mortality/survival; perioperative complications (measured with Clavien Dindo index [CDI]); resource use (i.e. hospital stay (length of stay [LOS]), hospital readmission); short-term recovery after surgery (post-operative pain, post-operative nausea and vomiting (PONV); longer-term recovery after surgery; and overall success/failure of surgery (3). Other commonly collected safety, surgical procedural feasibility and success outcomes include intraoperative complications, quality of the surgical field, conversion to laparotomy or a higher pressure, duration of surgery, and blood loss (4).

A systematic review and meta-analysis by the Reijnders-Boerboom et al. (4) evaluated 85 randomized clinical trials (RCTS) comparing the clinical outcomes between low pressure (<10 mmHg) and standard or high pressure (≥10 mmHg). They concluded that low-pressure laparoscopy is safe (i.e. it does not increase the rate of intraoperative complications), reduces the risk of mild post operative complications, offers better short-term recovery after surgery (i.e. reduces early pain scores, PONV), and has the potential to reduce resource use (i.e. shorter LOS).

1.4 Context of the current report

There is local interest at the McGill University Health Centre (MUHC) in assessing the clinical benefits of utilizing low pneumoperitoneum pressure during laparoscopic surgery. The current equipment in use can generate intra-abdominal pressures ranging from 10 to 20 mmHg. Steeve Gaudreault, Nurse Advisor for Specialized Operating Room Products, has requested that the Technology Assessment Unit (TAU) evaluate devices that allow pressure settings below 10 mmHg to inform decisions regarding potential equipment upgrades.

In the past five years, new RCTS have been published. Therefore, we decided to review more recently published clinical trials.

2. POLICY AND EVALUATION QUESTIONS

2.1 Policy Question

Should the MUHC procure machines that enable both low IAP (<10 mmHg) and standard or high IAP (≥10 mmHg) for the laparoscopic surgeries?

2.2 Evaluation Questions (Objectives of this report)

The objectives of this report were:

1. To evaluate the clinical outcomes of laparoscopy with IAP <10 mmHg compared to ≥10 mmHg.
2. To evaluate the budget impact of performing laparoscopy with IAP <10 mmHg compared to ≥10 mmHg at the MUHC

3. METHODS

3.1 Literature Search

We conducted a scoping review by searching the PubMed, Medline and Embase using the following search terms: "laparoscop*" AND ("low pressure" OR "low pneumoperitoneum pressure" OR "low intra-abdominal pressure"). The systematic review and meta-analysis by the Reijnders-Boerboom et al was published in April 2023, but their search was completed in November 2021. Therefore, we searched for RCTs published from 2021 and our last search was done on May 7, 2025. We limited the search to clinical trials in humans and adults. We also manually searched relevant studies from the references.

We also searched for published report and guidelines on the international network of agencies for health technology assessment (INAHTA) and the National Institute for Health and Care Excellence (NICE) of the UK databases.

3.2 PICO components

Our inclusion criteria for the population, intervention and outcomes targeted are shown in Table 1 below.

Table 1. Population, intervention, control and outcomes

	Inclusion Criteria
Population	Patients who underwent any minimally invasive surgery using laparoscopic instruments and devices
Intervention	Any device that can create a low-pressure (<10 mmHg)
Comparator	Any device that uses pressure ≥10 mmHg
Outcomes	• Safety, surgical procedural feasibility and success outcomes: intraoperative complications, conversion to a higher pressure, duration of surgery, and blood loss • Perioperative complications (measured with CDI above class I) • Short-term recovery outcomes: post-operative (shoulder) pain, opioid use, post-operative nausea and vomiting) • Resource use: LOS, hospital readmission

3.3 Data extraction

For the recent RCTs

Study selection and data extraction were done independently by ES and TO and any discrepancies were resolved by consensus. The following variables were collected:

- Study characteristics: first author, year of publication, country
- Surgery types (cholecystectomy, prostatectomy, hysterectomy etc.)
- IAP pressure
- Total number of patients per pressure group
- List of the reported outcomes

For the SR-MA by Reijnders-Boerboom

For each outcome, we extracted

- Number of the included studies
- Total number of subjects of the included studies
- Total number of events for dichotomous outcomes (i.e. presence of intra-operative complications, post-operative complications with Clavien-Dindo grade 3-4, post-operative nausea or vomiting, post-operative shoulder tip pain, and conversion to higher IAP)
- Effect estimates (the relative risk for dichotomous outcomes and the mean difference for continuous outcomes) and their 95% confidence intervals.
- Total number of the included RCTs considered to have a poor quality

3.4 Assessment of Bias and Certainty of Evidence

3.4.1 Risk of bias

Two reviewers independently assessed the risk of bias (RoB).

- For recent RCTs, we used the Cochrane Risk of Bias Tool for Randomized Trials (RoB 2.0) (5). RoB was done for each outcome result of each study. RoB 2.0 tool covers five domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported result. Each domain was graded as high, moderate (some concerns or unclear) or low risk of bias. A study is considered as having a low overall risk of bias when all domains have a low risk. We considered a high overall risk of bias when at least one domain had a high risk of bias for RCTs or a serious/critical risk of bias for observational studies. Other situations will be considered as moderate risk of bias.
- For the systematic review by Reijnders-Boerboom, we used ROBIS tool to assess the risk of bias (6). ROBIS is completed in three phases: (1) assess relevance (optional), (2) identify concerns with the review process and (3) judge risk of bias. Phase 2 covers four domains through which bias may be introduced into a systematic review: study eligibility criteria; identification and selection of studies; data collection and study appraisal; and synthesis and findings.

3.4.2 Certainty of the evidence

We rated the overall certainty of evidence as high, moderate or low for each outcome using an in-house decision tree, which was based on Grading of Recommendations Assessment, Development and Evaluation (GRADE) quality assessment (7). Our tool has six domains: the first was the overall risk of bias of the included studies (i.e. considered high risk if one-third or more of the included RCTs was considered to have a poor quality by Reijnders, which was defined as having three or more bias items scored ‘unclear bias’ or ‘high risk’ on RoB 1.0 tool (8)). Other domains included imprecision (i.e. wide confidence intervals, low number of events (<300 for categorical outcomes), and small sample size for continuous outcomes), inconsistency, indirectness, and others (e.g. improper statistical analytical tests). For imprecision, we used the null effect approach for outcomes reported as risk ratios, but we used the clinical minimally important difference (MID) approach for outcomes reported as mean differences. We considered MID as 30 min for operation time (9), as 500 mL for blood loss (10), and as 15mg morphine equivalent daily dose for opioid used (11).

Low-certainty evidence indicates that our confidence in the overall effect estimate is limited. Conversely, high-certainty evidence indicates we are very confident in the overall effect estimate, which results from studies with a low overall risk of bias and without downgrading from the above domains. Elements of the domains and the decision tree are detailed in Appendix A:.

3.5 Meta-analysis

We used data from the systematic review. However, we conducted our own meta-analysis for LOS because we were interested in LOS by surgery type, and the published meta-analysis by Reijnders-Boerboom et al. (4) did not address that. Moreover, we corrected the LOS by Josphipura et al.(12): it was reported in hours instead of days.

- We used data (mean difference, standard deviation, and number of patients for each group) already extracted by Reijnders to estimate our pooled MD with their 95% confidence intervals (CI) for LOS.
- A random-effects model (restricted maximum likelihood) was used since the preliminary literature review showed that the populations and interventions were not sufficiently similar across the trials.
- Individual and pooled estimates with their 95% CI were presented in forest plot.
- We assessed the heterogeneity in the effect estimates and between-study by calculating I^2 and τ^2 statistics and inspecting the forest plots. Substantial heterogeneity was defined as $I^2 > 60$ and possible sources of heterogeneity were investigated, when plausible as the number of studies was small.
- Post-hoc analyses were performed to evaluate the impact of the IAP on LOS by surgery types.
- Bilateral p-values of 0.05 and confidence intervals were used to assess statistical significance. All analyses were performed with software R v4.4.2.

3.6 Budget Impact Analysis

We requested the financial analysis on cholecystectomy from the 2023/2024 fiscal year from André Guigui, Deputy to the Director of Finance at the MUHC. We extracted information on the annual number of cholecystectomy surgeries, the average encounter cost per patient, the percentage of variable costs that could contribute to potential savings, and the average LOS. We estimated the hospitalization avoidance rate using our meta-analysis on the impact of low-pressure on LOS among cholecystectomy patients. Steeve Gaudreault, Nurse Advisor for Specialized Operating Room Products, provided the estimated device cost for each patient. Subsequently, we calculated the avoidance costs and the net cost per patient, and the annual cost reduction by using low-pressure compared to standard-pressure laparoscopy.

4. RESULTS

4.1 Impact on Clinical Outcomes

We identified 876 studies from inception until 2025 (Figure 1). There are five systematic reviews and meta-analyses published in the past five years. The meta-analysis by Reijnders-Boerboom et al., published in 2021, remains the only one relevant to our PICO. We also found eight more recent RCTs (13-20) published between 2021 and 2025 that met our PICO. The characteristics of these RCTs are summarized in Table 2.

4.1.1 Summary of the meta-analysis by Reijnders-Boerboom et al

- We summarized the meta-analysis and risk of bias assessment for each outcome from Reijnders-Boerboom et al. and evaluated their certainty of evidence using our in-house tool (Table 3).
- Using data from Reijnders-Boerboom et al, we conducted our own meta-analysis for LOS, the overall and by surgery types (Figure 2), and presented the summary of the level of certainty in Table 4.
- The risk of bias assessment of the meta-analysis by Reijnders-Boerboom et al revealed low concerns regarding study eligibility criteria, identification and selection of studies, as well as data collection and study appraisal domains. For synthesis and findings, the concern was high due to the following reasons:
  - They included RCTs with per-protocol analysis without any mention of it. Sensitivity analysis should have been done by including only studies with intention-to-treat analysis.
  - They included RCTs with co-intervention with no possibility of separating the effect of low IAP or standard IAP from the effect of the co-intervention
  - Their PROSPERO protocol is generic; there was no detailed analytic plan
  - They acknowledged heterogeneity but did not address it in any sensitivity analysis
  - The risk of bias was evaluated for the overall study, not for each outcome
  - Sensitivity analysis was only done in certain outcomes

4.1.1.1 Clinical outcomes

Post-operative shoulder pain at 12-24 hours

- Pooled estimates from the meta-analysis by Reijnders et al. (8 RCTs with 180 events from 794 subjects) showed that low intra-abdominal pressure (<10 mmHg) was associated with a 36% lower risk of post-operative shoulder pain at 12-24 compared to higher pressure (RR 0.64, 95% CI 0.44, 0.94).

- The certainty of the evidence was low: it was downgraded due to high risk of bias (2/8 of the included RCTs were rated as poor quality by Reijnders and colleagues), indirectness (i.e., including RCTs with per-protocol analysis or co-intervention) and imprecision (large effect size but with < 300 total events).
- Taken together, this suggests that low pressure **may reduce** post-operative shoulder pain at 12-24 hours.

Post-operative (shoulder) pain at 24-72 hours

- The meta-analysis (6 RCTs; 110 events, 662 participants) by Reijnders and colleagues reported a relative risk of 0.61 (95% CI 0.33, 1.13).
- The certainty of the evidence was low: it was downgraded due to high risk of bias (2/6 of the included RCTs were considered to be poor quality by Reijnders and colleagues), indirectness (i.e., including RCTs with per-protocol analysis or co-intervention) and imprecision (wide confidence interval).
- Taken together, this indicates the effect of low-pressure laparoscopy on post-operative shoulder pain at 24-72 hours is **uncertain**.

Opioid use at 12-24 hours

- Results from 7 RCTs (704 participants) indicate that low-pressure laparoscopy was associated with a reduced post-operative opioid use of 1.73 mg of morphine equivalents at 12-24 hours compared to ≥10 mmHg IAP (mean difference (MD) -1.73, 95% CI -2.36 to -1.10 mg).
- The certainty of the evidence was moderate: it was downgraded due to indirectness (i.e., including RCTs with per-protocol analysis or co-intervention).
- While the results suggest low-pressure laparoscopy probably reduces opioid use at 12–24 hours, the magnitude of this reduction is **not considered clinically meaningful**.

Opioid use at 24-72 hours

- Based on 2 RCTs (241 participants), the mean difference in opioid use was -0.45 mg (95% CI -2.05 to 1.15) (moderate certainty evidence).
- The certainty of the evidence was moderate: it was downgraded due to indirectness (i.e., including RCTs with per-protocol analysis or co-intervention).
- Taken together, this indicates that low-pressure laparoscopy **probably has little or no effect** on post-operative opioid use at 24–72 hours.

Post-operative nausea and vomiting at 12-24 hours

- A meta-analysis of 2 RCTs (34 events, 238 participants) reported a relative risk of 0.61 (95% CI 0.18 to 2.13) for post-operative nausea and vomiting with low-pressure laparoscopy compared to higher pressure (low certainty evidence).

- The certainty of the evidence was low: it was downgraded due to high risk of bias (1/2 of the included RCTs were considered as having a poor quality by Reijnders and colleagues), indirectness (i.e., included RCTs with per-protocol analysis or with co-intervention), imprecision (wide confidence interval), inconsistency due to heterogeneity (included studies suggest opposite effect).
- Taken together, this suggests that the effect of low-pressure laparoscopy on nausea and vomiting at 12–24 hours **is uncertain**.

Post-operative nausea and vomiting at 24-72 hours

- Results from 2 RCTs (19 events, 429 participants) showed a relative risk of 0.46 (95% CI 0.19 to 1.14) (low certainty evidence).
- The certainty of the evidence was low: it was downgraded because of high risk of bias (1/2 of the included RCTs were considered as having a poor quality by Reijnders and colleagues), indirectness (i.e., included RCTs with per-protocol analysis or with co-intervention), imprecision (wide confidence interval), inconsistency due to heterogeneity (included studies suggest opposite effect).
- Taken together, this indicates that the effect of low-pressure laparoscopy on nausea and vomiting at 24–72 hours **remains uncertain**.

Length of stay

- All surgeries:
    - Our meta-analysis from 21 RCTs and 2,508 subjects) found that low-pressure laparoscopy was associated with a mean reduction in hospital stay of 0.33 days (95% CI -0.55 to -0.11) (moderate certainty evidence).
    - The certainty of the evidence was moderate: it was downgraded for indirectness (i.e., included RCTs with per-protocol analysis or with co-intervention).
    - Taken together, this suggests that low-pressure laparoscopy **probably reduces** hospital length of stay by approximately 8 hours.
- Laparoscopic cholecystectomies:
    - Our meta-analysis for cholecystectomy laparoscopy from 9 RCTs and 955 subjects) found that low-pressure laparoscopy was associated with a reduced LOS of 0.31 days with <10 mmHg vs. ≥10 mmHg IAP (MD -0.31, 95%CI -0.51 to -0.11).
    - The certainty of the evidence was moderate: it was downgraded for indirectness (i.e., included RCTs with per-protocol analysis or with co-intervention).
    - Taken together, this suggests that low-pressure laparoscopy **probably reduces** hospital stay following cholecystectomy.

Duration of surgery

- The meta-analysis by Reijnders and colleagues with the pooled effect size from 54 RCTs, including 5,047 subjects reported a mean difference in surgical duration of 1.75 minutes (95% CI -0.15 to 3.64) for low-pressure compared to higher pressure laparoscopy.
- The certainty of the evidence was low: it was downgraded due to high risk of bias (i.e., almost one-third (16/54) of the included RCTs were considered as having a poor quality by Reijnders and colleagues), indirectness (i.e., included RCTs with per-protocol analysis or with co-intervention, no clear definition of surgery duration), and inconsistency (confidence interval did not overlap for all studies and large I^2).
- Taken together, this suggests that low-pressure laparoscopy **does not appear to have a clinically meaningful effect** on surgery duration.

4.1.1.2 Safety

Conversion to a higher pressure

- The meta-analysis by Reijnders and colleagues from 16 RCTs reported a relative risk of 4.71 (95% CI 2.88 to 7.69) for conversion to higher pressure with low-pressure laparoscopy.
- The certainty level of the evidence was low: It was downgraded due to high risk of bias (four of the sixteen included RCTs were considered to have a poor quality by Reijnders and colleagues), indirectness (i.e., including RCTs with per-protocol analysis or co-intervention) and imprecision (wide confidence interval showing a very large effect size with a small number of events).
- Taken together, this suggests that low-pressure laparoscopy **may increase** the likelihood of conversion to a higher intra-abdominal pressure.

Blood loss

- The meta-analysis by Reijnders (8 RCTs including 861 subjects) reported a mean difference in blood loss of 16.30 mL (95% CI -9.40 to 41.99) for low-pressure compared to higher pressure laparoscopy.
- The certainty of the evidence was low: it was downgraded due to risk of bias (1/8 included RCTs was considered to have a poor quality by Reijnders and colleagues), indirectness (i.e., including RCTs with per-protocol analysis or co-intervention) and inconsistency (included studies suggest opposite effects).
- Taken together, this indicates that low-pressure laparoscopy **does not appear to have a clinically meaningful effect** on blood loss.

Perioperative complications (measured with CDI)

- Pooled estimates from Reijnders et al. (12 RCTs with 50 events of 1,507 participants) found a relative risk of 1.25 (95% CI 0.71 to 2.20) for serious perioperative complications (Clavien-Dindo grade 3–4).
- The certainty of the evidence was low: it was downgraded due to risk of bias (1/12 included RCTs was considered to have a poor quality by Reijnders and colleagues), indirectness (i.e., included RCTs with per-protocol analysis or with co-intervention) and imprecision (wide confidence interval).
- Taken together, this indicates that the effect of low-pressure laparoscopy on serious perioperative complications **is uncertain**.

Intraoperative complications

- From the meta-analysis by Reijnders and colleagues which included 16 RCTs (91 events in 1,661 participants), the relative risk of intraoperative complications was 1.15 (95% CI 0.77 to 1.73).
- The certainty of the evidence was low: it was downgraded due to risk of bias (a quarter (4/16) of the included RCTs were considered to have a poor quality by Reijnders and colleagues), indirectness (i.e., including RCTs with per-protocol analysis or with co-intervention), imprecision (wide confidence interval) and inconsistency (the included studies suggest opposite effects).
- This suggests that the effect of low-pressure laparoscopy on intraoperative complications **remains uncertain.**

4.1.2 Recent RCTs not included in Reijnders et al.

Of the eight recent RCTs, six reported on conversion to higher pressure, six on surgery duration, two on intraoperative complications and LOS, while the remaining outcomes were each reported by a single study (Table 2**)**. Given the majority of moderate to high risk of bias and relatively small sample sizes across these trials, we did not update the meta-analysis by Reijnders-Boerboom et al., as their inclusion would be unlikely to improve the overall certainty of evidence regarding the effects of low intra-abdominal pressure.

4.2 HTA and Guidelines

We did not identify any published HTA reports or guidelines on low-pressure laparoscopy.

4.3 Budget Impact Analysis

We included the following inputs for the budget impact analysis for cholecystectomy patients at the MUHC (Table 5):

- Additional cost of low pressure devices: $100/patient, entirely attributed to procurement of low pressure trocar devices (source: MUHC procurement)
- Average length of stay for cholecystectomy patients at the MUHC: 2.9 days (source: MUHC Finance)
- Average encounter cost for cholecystectomy at the MUHC: $4,450, but only 30% ($1,135) of these costs constitute variable costs that could contribute towards potential savings (source: MUHC Finance)
- Reduction in LOS: 0.31 days (95% CI: -0.51 to -0.11) (source: our meta-analysis of 9 RCTs)

Based on these data, we estimated that using low-pressure insufflation would result in:

- Cost savings per patient of $43 (-$162 to +$72) or
- Cost savings for 437 cholecystectomy patients annually of $18,663 (ranging from cost savings of $58,897 to a cost increase of $21,571).

5. DISCUSSION

This health technology assessment evaluated the clinical effectiveness and potential economic impact of low-pressure (<10 mmHg) insufflation in laparoscopic surgery, based primarily on a high-quality meta-analysis by Reijnders-Boerboom et al.

5.1 Clinical Benefit

- Low intra-abdominal pressure (<10 mmHg) in laparoscopic surgery may modestly reduce post-operative pain and hospital length of stay, compared to IAP ≥10 mmHg (4). These patient-centered benefits support the potential role of low IAP in enhanced recovery protocols. Estimates from our analysis indicate it has no clinically meaningful impact on opioid use or surgical duration.
- However, these findings were based on low to moderate certainty evidence, often downgraded due to indirectness, risk of bias, and imprecision.

5.2 Safety Considerations

- While this evaluation showed a notable increase in conversion to higher pressure**,** this may reflect surgeon experience or patient-specific factors rather than intrinsic safety concerns. The increased likelihood of conversion to higher insufflation pressure due to compromised visualization is a recognized limitation of low-pressure laparoscopy (<10 mmHg IAP).(14)(16)(24) From the surgeon's perspective, some studies suggest that conversion decisions may reflect variability in surgeon experience and preference rather than an inherent limitation of the technique. (18)(25, 26)
- Newer insufflation systems that can dynamically adjust the pressure offer additional safety and flexibility, enabling surgeons to begin at low pressure and escalate if necessary.
- Other outcomes such as intraoperative and perioperative complications showed no clear increase in risk**,** but wide confidence intervals and methodological limitations preclude firm conclusions. Blood loss and surgical duration did not differ meaningfully between low and standard-pressure approaches.
- If adopted at the MUHC, implementation should be accompanied by local evaluation of conversion, intra- and perioperative complication rates, patient-reported outcomes, and surgeon-reported outcomes.

5.3 Limitations of the evidence

The meta-analysis by Reijnders-Boerboom was well-conducted in terms of study selection and appraisal, but the synthesis was limited by inclusion of trials with co-interventions and per-protocol analyses, lack of outcome-specific risk of bias assessments, and limited sensitivity analyses. These limitations, along with variability in surgical procedures and outcome definitions, contributed to the overall low to moderate certainty of evidence across most outcomes.

5.4 Cost and Budget Impact

From a cost perspective, low-pressure insufflation may offer modest but meaningful cost savings. Although the cost of advanced insufflation devices may be higher, the meta-analysis suggests that these could be offset by the benefits of notably reduced pain and hospital stay without clinically meaningful compromises in safety.

At the MUHC, implementing low-pressure pneumoperitoneum for laparoscopic cholecystectomy could lead to modest annual cost savings of approximately $18,600, based on shorter LOS. Even when considering the upper bound of the confidence

interval, which suggests a potential cost increase of $21,571, the impact remains relatively small in the context of the 437 cholecystectomy patients treated annually.

6. CONCLUSIONS

- The best available evidence, derived from a recent, large meta-analysis, indicates that:
    - For **Clinical benefit**: There is low certainty evidence that low-pressure pneumoperitoneum (<10 mmHg) modestly reduces post-operative pain, opioid use, and length of stay, with no clinically meaningful impact on surgical duration or blood loss.
    - For **Safety** impact: Low-pressure pneumoperitoneum may increase the likelihood of conversion to higher pressure. Evidence on intraoperative and serious perioperative complications is inconclusive due to wide confidence intervals and low certainty.
- In terms of budget impact for laparoscopic cholecystectomies at the MUHC, adopting low-pressure insufflation could yield modest annual cost savings (~$18,600) from projected reduced length of hospital stays.

7. RECOMMENDATIONS

- The TAU Policy Committee, comprising stakeholders from across the McGill University Health Centre, reviewed the evidence and issued the following recommendation for the adoption of insufflation devices that allow both low- and standard/high-pressure settings: Approved
- This recommendation was reached based on the following:
    - The best available evidence, although generally of low certainty, suggests that low-pressure pneumoperitoneum (<10 mmHg) may offer patient benefits, including reduced pain and shorter hospital stays, without increasing safety risks. The impact on hospital budget is minimal, with potential for long-term cost savings.
    - The new insufflation devices under consideration can accommodate both low and standard/high intra-abdominal pressures, therefore leaving the choice of pressure level to the discretion of the surgical team.
    - Recognition that conversion to higher pressure may decrease with increased surgeon experience.
- The Committee emphasized the importance of collecting local data to guide future use and to identify the surgical populations most likely to benefit.

FIGURES

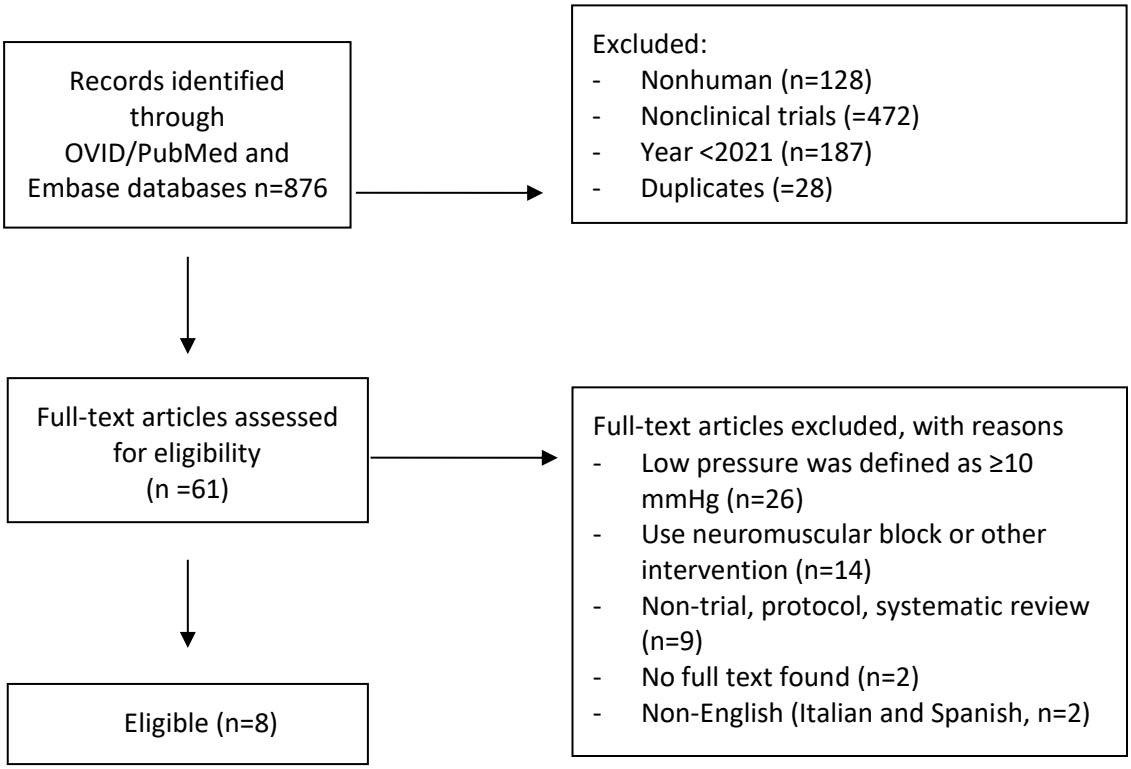


Figure 1. PRISMA Flowchart of the systematic reviews evaluating low intra-abdominal pressure laparoscopy

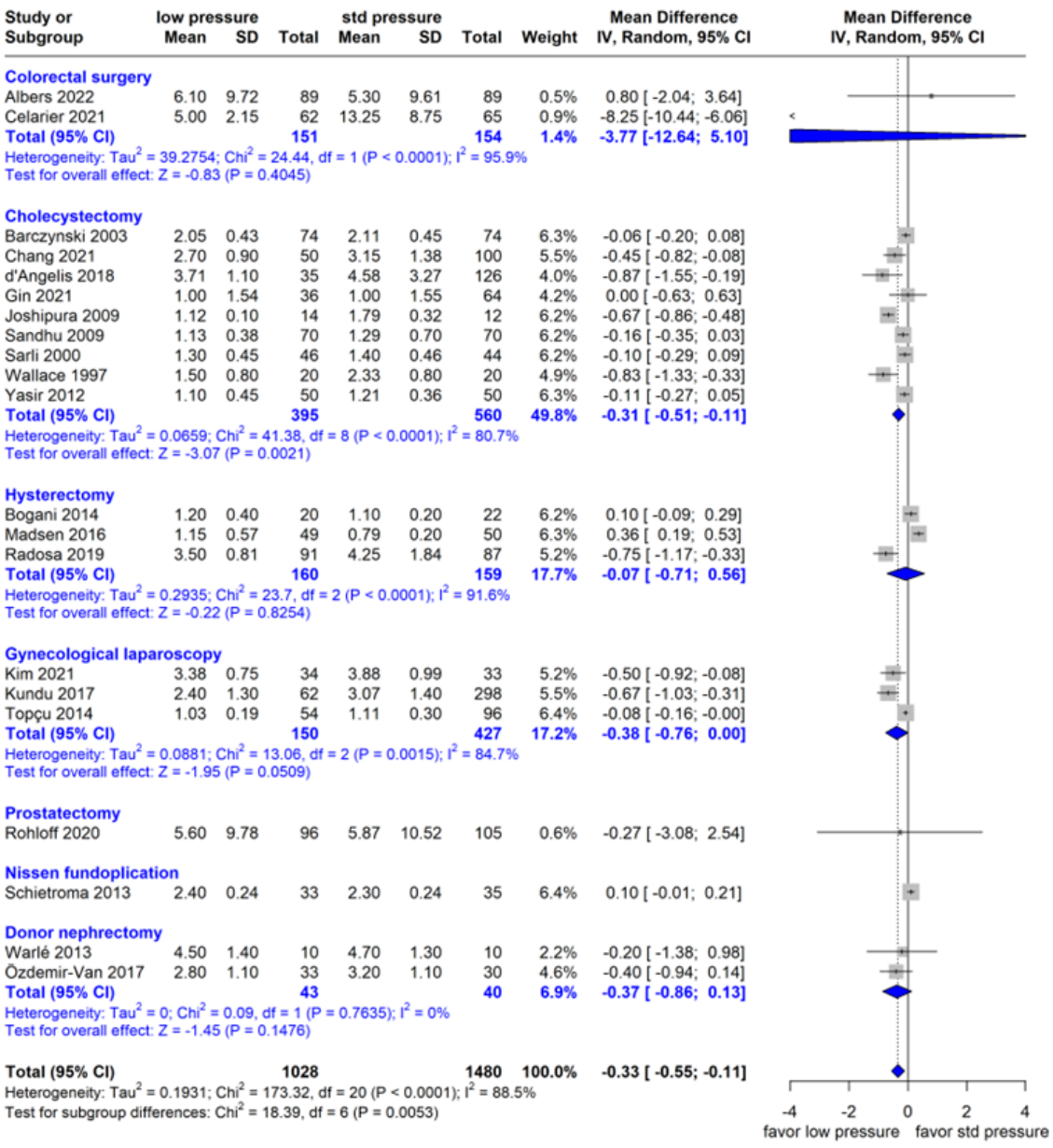


Figure 2. Forest plot of studies assessing the length of hospital stay in laparoscopy patients using low (<10 mmHg) compared to standard or high (10≥ mmHg) intra-abdominal pressure, stratified by the surgery types.

TABLES

Table 2. Characteristics of the recent RCTs on low intra-abdominal pressure laparoscopy published between 2021 and 2025

References	Low (n)	Standard (n)	Population (surgery types)	List of outcomes	Overall risk of bias
Kaya, 2022, Turkey	8 mmHg (36)	14 mmHg (31)	Laparoscopic nephrectomy	Conversion to a higher pressure	Moderate due to unclear concealment, and unequal deviations from the intended interventions
Manici, 2024, Turkey	8 mmHg (22)	12 mmHg (21)	Robot-assisted laparoscopic radical prostatectomy (RARP)	Conversion to a higher pressure, intraoperative complications, blood loss, operation time, post-operative complications (Clavien-Dindo class ≥2), LOS	Moderate for all outcomes due to lack of concealment information and unclear missing data
Marton, 2021, Brazil	6-8 mm Hg (31)	10-12 mm Hg (33)	Laparoscopic cholecystectomy	Operation time	Low
Park, 2023, Korea	4 mmHg (96)	12-14 mmHg (95)	Robotic-assisted laparoscopic cholecystectomy	Conversion to a higher pressure	Moderate due to lack of concealment information
Ponduru, 2022, India	6-8 mmHg (75)	13-15 mmHg (73)	Laparoscopic surgeries.	Conversion to a higher pressure, operation time	Moderate for all outcomes due to lack of concealment information, unequal deviations from intended interventions
Sandhu, 2023, India	9 mmHg (42)	13 mmHg (42)	Laparoscopic cholecystectomy	Conversion to a higher pressure, intraoperative complications, operation time, post-operative shoulder tip pain, post-operative nausea/vomiting	High due to lack of concealment information, and unclear randomization method
Serrano,2024, Spain	8 mmHg (47)	≥12 mmHg (48)	Laparoscopic cholecystectomy	Conversion to a higher pressure, LOS, operation time	Moderate for conversion due to unequal deviations from the intended intervention, and low for the other outcomes
Sharma, 2025	8 mmHg (35)	12 mmHg (35)	Laparoscopic cholecystectomy	Duration of pneumoperitoneum	Low

Table 3. Level of Certainty of the Impact of Low Intra-abdominal Pressure Laparoscopy from a Meta-analysis by Reijnders-Bloem et al

№ of studies	Certainty assessment						Effect			Quality of Evidence
	Risk of bias (RoB) by Reijnders*	Controlled study	Imprecision	Inconsistency	Indirectness	Others	№ of events LP/SP	№ of individuals LP/SP	Pooled Estimates (95% CI)	
Perioperative complications (Clavien-Dindo grade 3-4)										
12	No downgrading (1/12 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	26/24	691/816	RR=1.25 (0.71, 2.20)	Low
Intraoperative complications										
16	No downgrading (4/16 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	Heterogeneity	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	44/47	723/938	RR=1.15 (0.77, 1.73)	Low
Conversion to a higher pressure										
16	No downgrading (4/16 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	No downgrading	Included RCTs with co-intervention	No downgrading	107/12	708/703	RR=4.71 (2.88, 7.69)	Low
Duration of surgery										
54	High risk (16/54 poor)	RCTs, no downgrading	No downgrading	Heterogeneity	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	NA	2280/2767	MD=1.75 (-0.15, 3.64) minutes	Low
Blood loss										
8	No downgrading (1/8 poor)	RCTs, no downgrading	No downgrading	Heterogeneity	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	NA	360/501	MD=16.30 (-9.40, 41.99)	Low
Post-operative shoulder pain 12-24 hrs										
8	No downgrading (2/8 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	54/126	355/439	RR=0.64 (0.44, 0.94)	Low
Post-operative shoulder pain 24-72 hrs										
6	High risk (2/6 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	32/78	304/358	RR=0.61 (0.33, 1.13)	Low
Opioid use 12-24 hrs										

№ of studies	Certainty assessment						Effect			Quality of Evidence
	Risk of bias (RoB) by Reijnders*	Controlled study	Imprecision	Inconsistency	Indirectness	Others	№ of events LP/SP	№ of individuals LP/SP	Pooled Estimates (95% CI)	
7	No downgrading (0/7 poor)	RCTs, no downgrading	No downgrading	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	NA	341/363	MD -1.73 (-2.36, -1.10)	Moderate
Opioid use 24-72 hrs										
2	No downgrading (0/2 poor)	RCTs, no downgrading	No downgrading	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	NA	122/119	MD -0.45 (-2.05, 1.15)	Moderate
Post-operative nausea & vomiting 12-24 hrs										
2	High risk (1/2 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	Heterogeneity	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	12/22	121/117	RR=0.61 (0.18, 2.13)	Low
Post-operative nausea & vomiting 24-72 hrs										
2	High risk (1/2 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	Heterogeneity	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	6/13	213/216	RR=0.46 (0.19, 1.14)	Low

***** RR: relative risk, MD: mean difference. *Assessed according to the Cochrane risk of bias Tool; three or more bias items scored ‘unclear bias’ or ‘high risk’.

Table 4. Level of Certainty of the Impact of Low Intra-abdominal Pressure Laparoscopy on Length of Stay

№ of studies	Certainty assessment						Effect		Certainty of Evidence
	Risk of bias (RoB) by Reijnders*	Controlled study	Imprecision	Inconsistency	Indirectness	Others	№ of individuals LP/SP	Pooled Mean Difference (95% CI)	
Colorectal surgery									
2	High risk (2/2 poor)	RCTs, no downgrading	Wide confidence interval, small number of events	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	151/154	-3.77 (-12.64 to 5.10)	Low
Cholecystectomy									
9	No downgrading (2/9 poor)	RCTs, no downgrading	Wide confidence interval	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	395/560	-0.31 (-0.51 to -0.11)	Moderate
Hysterectomy									
3	No downgrading (0/3 poor)	RCTs, no downgrading	Wide confidence interval	Heterogeneity	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	160/159	-0.07 (-0.71 to 0.56)	Low
Gynecological laparoscopy									
3	No downgrading (0/3 poor)	No downgrading	CIs suggest that the possible effect size **ranged from a reduction up to a null effect**	No downgrading	No downgrading	No downgrading	150/427	-0.38 (-0.76 to 0.00)	Moderate
Prostatectomy									
1	No downgrading (0/1 poor)	RCTs, no downgrading	Wide confidence interval, only 1 RCT	No downgrading	No downgrading	No downgrading	96/105	-0.27 (-3.08 to 2.54)	Low
Nissen Fundoplication									
1	High risk (1/1 poor)	RCTs, no downgrading	Wide confidence interval, only 1 RCT	No downgrading	No downgrading	No downgrading	33/35	0.10 (-0.01 to 0.21)	Low
Donor nephrectomy									
2	No downgrading (0/2 poor)	RCTs, no downgrading	Wide confidence interval	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	43/40	-0.37 (-0.86 to 0.13)	Low
Overall									
21	No downgrading (5/21 poor)	RCTs, no downgrading	No downgrading	No downgrading	Included RCTs with per-protocol analysis or with co-intervention	No downgrading	1028/1480	-0.33 (-0.55 to -0.11)	Moderate

*Assessed according to the Cochrane risk of bias Tool; three or more bias items scored ‘unclear bias’ or ‘high risk’.

Table 5. Budget impact of the low intra-abdominal pressure laparoscopy

	Standard pressure	Low Pressure	
		Per patient	Per year (437 patients/year)
Device cost			
1. Cost of device	-	+$100	+43,700
Average encounter cost for cholecystectomy patients			
2. Fixed costs	3,115$	3,115$	1,361,182$
3. Variable costs (Potential saving) [1]	1,335$	1,335$	583,364$
Average LoS	2.9 days	-	
Reduction in LoS [2]	N/A	-0.31 days (95% CI: -0.51 to -0.11)	
Relative reduction in LoS with use of low pressure	(2.9-0.31) /2.9=11%		
4. Avoided cost (avoidance rate x variable costs)	N/A	143$ (51$ to 235$)	62,363$ (22,129$ to 102,597$)
Net cost (1+2+3-4)			
Additional cost (savings) of low pressure	N/A	-43$ (-162 to +72)	-18,663$ (-58,897 to + 21,571)

[1] Approximately 30% of costs are variable allowing for potential savings. Source: MUCH Finance

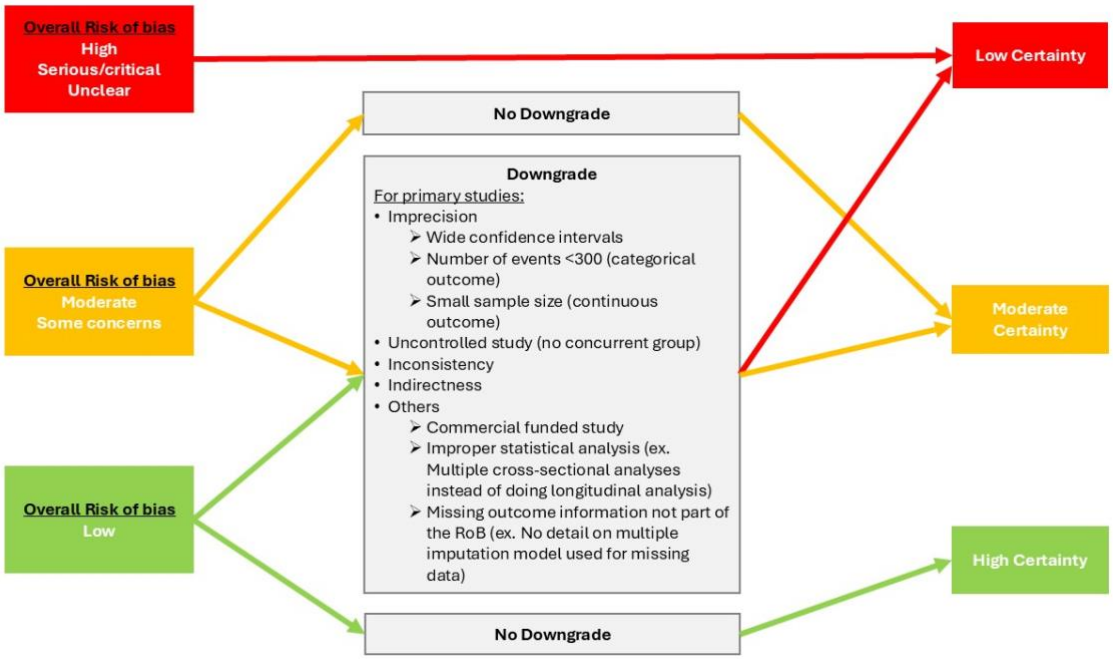
[2] Obtained from our meta-analysis (see Figure xx)

APPENDICES

APPENDIX A: QUALITY ASSESSMENT ALGORITHM

Our in-house tool incorporated the following dimensions to evaluate the evidence quality:

i. Overall risk of bias of the included studies (based on controlling bias due to confounding, selection, misclassification, reporting and analytic concerns)
ii. Uncontrolled study (no comparator group)
iii. Imprecision (bias arising from small sample size)
   - Wide confidence intervals
   - Low number of events (<300 for categorical outcomes)
   - Small sample size (for continuous outcomes)
iv. Inconsistency (results vary widely between studies)
v. Indirectness (extrapolating results from indirect comparisons)
vi. Others
   - commercially funded study
   - improper statistical analytical tests (e.g., multiple cross-sectional analyses for a longitudinal data)
   - missing outcome information that is not part of RoB (e.g. no details on multiple imputation models used for missing data)



Low certainty evidence:

- This indicates that our confidence in the overall effect estimate is limited.

- Studies with a high overall risk of bias were, by default, considered low certainty evidence.

Moderate certainty evidence:

- Moderate certainty evidence suggests that we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- Included studies with a low or moderate overall risk of bias could be downgraded and considered a lower certainty of evidence if one of these domains were met
    - Imprecision (i.e. confidence intervals, low number of events (<300 for categorical outcomes), or small sample size (for continuous outcomes))
    - Uncontrolled study (no comparator group)
    - Inconsistency (i.e. studies have inconsistent effects, or are too heterogenous to compare)
    - Indirectness (i.e. studies reporting outcomes that indirectly answer our research question)
    - Others
        - commercially funded study
        - improper statistical analytical tests (e.g., multiple cross-sectional analyses for a longitudinal data)
        - missing outcome information that is not part of RoB (e.g. no details on multiple imputation models used for missing data)

High certainty evidence:

- High certainty evidence indicates that we are very confident that the true effect lies close to that of the estimate of the effect.
- When studies are not downgraded for any of the elements considered above and overall risk of bias is low, this would indicate an overall high certainty evidence.

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