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# Evaluation of Gasless Laparoscopy as a Tool for Minimal Access Surgery in Low-to Middle-Income Countries: A Phase II Noninferiority Randomized Controlled Study

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- BACKGROUND:** Minimal access surgery is not available to most people in rural areas of low-to middle-income countries. This leads to an increase in morbidity and economic loss to the poor and marginalized. Gasless laparoscopic (GAL) procedures are possible in rural areas because they can be performed under spinal anesthesia. In most cases, it does not require the logistics of providing gases for pneumoperitoneum and general anesthesia. The current study compares GAL with conventional laparoscopic (COL) operations for general surgical procedures.
- METHODS:** A single-center, nonblinded randomized controlled trial was conducted to evaluate non-inferiority of GAL vs COL at a teaching hospital in New Delhi, India. Patients were allocated into 3 groups and underwent minimal access surgery (cholecystectomies and appendectomies). The procedures were performed by 2 surgeons choosing randomly between GAL and COL. The data were collected by postgraduates and analyzed by a biostatistician.
- RESULTS:** One hundred patients who met the inclusion criteria were allocated into 2 groups. No significant difference was observed in the mean operating time between the GAL group (52.9 minutes) and the COL group (55 minutes) ( $p = 0.3$ ). Intraoperative vital signs were better in the GAL group ( $p < 0.05$ ). The postoperative pain score was slightly higher in the GAL group ( $p = 0.01$ ); however, it did not require additional analgesics.
- CONCLUSIONS:** No significant differences were found between the 2 groups. GAL can be considered as non-inferior compared with COL and has the potential to be adopted in low-resource settings. (J Am Coll Surg 2020;231:511–519. © 2020 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

The invention of laparoscopy in the late 20th century revolutionized the way operations were performed. It is an important milestone invention that transformed surgical practice. However, the benefits of minimal access surgery (MAS) are not available to most of the rural population in India and similar low-to middle-income countries (LMICs). Although no formal access to care study is available for India, it is estimated that

only 2% of the population in LMICs can access affordable MAS services.<sup>1</sup> Open operation is the first line of treatment for conditions such as acute abdomen, gallstone disease, and appendicitis. Lack of any access to operations leads to prolonged illness, death, and loss of livelihood for poor people.<sup>2</sup> MAS has the potential to provide better access to operations in such settings.

## Disclosure Information: Nothing to disclose.

Disclaimer: This trial was not registered at the time of study initiation, and due to a policy change by the Clinical Trials Registry India, retrospective registration was not allowed. Written informed consent for participation in this study was obtained from the patients. The study was approved by the Institutional Ethics Committee vide F.1/IEC/MAMC/(63/03/2018/358) dated November 14, 2018. The study was conducted in accordance with the Declaration of Helsinki 1964.

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### Abbreviations and Acronyms

COL	=	conventional laparoscopy
GAL	=	gasless laparoscopy
LMIC	=	low-to middle-income country
MAS	=	minimal access surgery
VAS	=	visual analogue scale

The recurring cost of expensive laparoscopic instruments, logistics of providing medical-grade gases in remote areas, and nonavailability of general anesthetics<sup>3</sup> make it difficult to adopt MAS in low-resource settings.

The gas insufflation-less laparoscopic (GAL) procedures offer a solution to the challenges associated with conventional laparoscopy (COL). It mechanically elevates the abdominal wall and allows laparoscopic visualization through a single incision, providing diagnostic and therapeutic procedures.

Ideally, for low-resource settings the optimum comparison would be between open procedure and GAL. However, considering the ethical issues, we planned a noninferiority study to compare GAL using a STAN Laparoscopy Positioner device (STAN Biomedical Engineering) (Fig. 1) with COL for general surgical procedures.

## METHODS

The study was conducted as a single-center, nonblinded noninferiority, randomized controlled study. Ethical clearance was granted by the Institutional Ethical Committee on November 14, 2018 (vide letter number F.1/IEC/MAMC/[(63/03/2018/358]). Patients requiring elective laparoscopic general surgery for therapeutic or diagnostic purposes were approached to participate in the study. Patients with an American Society of Anesthesiologists Physical Status Classification score of 3 or higher, BMI of more than 28 kg/m<sup>2</sup>, multiple intra-abdominal conditions, or history of abdominal operations were excluded from the study. Those who consented to participate were enrolled into the study.

The chosen sample size of 100 was more than the calculated sample size of 78, using operative time as the primary parameter (power 80%,  $\alpha = 0.05$ ,  $\sigma = 20$ , sampling ratio: 1).<sup>4</sup> A noninferiority margin of 1% (+6 minutes, assuming mean operative time of 60 minutes) was chosen.

The primary end point was operative time for GAL and COL. The secondary outcomes of interest were intraoperative vital signs; postoperative pain; and surgeon satisfaction for cholecystectomy, diagnostic laparoscopy, and appendectomy.

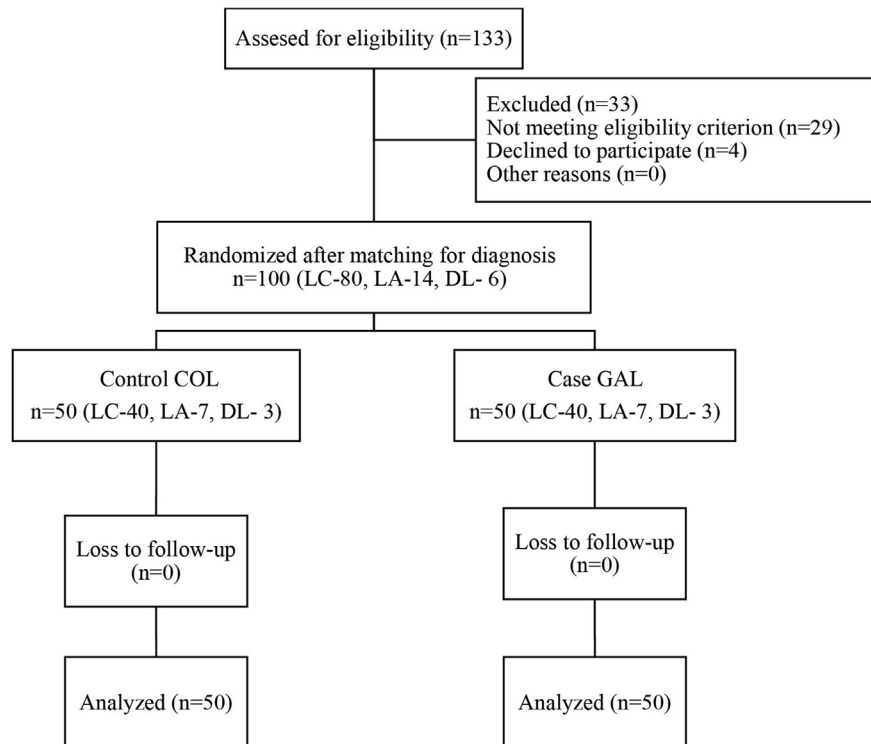


**Figure 1.** Gasless laparoscopy apparatus. (STAN Laparoscopy Positioner). L, lift; M, middle piece; R, ring.

Patients were randomly allocated to COL or GAL using computer-generated random numbers and sealed envelopes. Cases were grouped according to diagnosis to avoid unequal distribution in the 2 groups. The procedures were performed by 2 laparoscopic-proficient surgeons (A.M. and L.B.) with more than 5 years of experience. Surgeons underwent 1 month of training and familiarization of the technique and equipment. General anesthesia was used for all patients as the standard operating technique practiced in the institute. The only variation was the creation of intraperitoneal space.

Standard 4-port technique was used for the COL group.<sup>5</sup> In the GAL group, the peritoneal cavity was accessed through a 2-cm infra-umbilical midline incision. After entering the peritoneal cavity, a finger sweep was done to rule out any adhesions to the anterior abdominal wall and to create a safe space for the ring of the STAN Laparoscopy Positioner device.<sup>6</sup> The ring was placed carefully to avoid trapping of surrounding structures between the ring and the abdominal wall. The vertical limb of the ring is attached to the middle piece and the STAN Laparoscopy Positioner is raised by 5 to 10 cm to create an intra-abdominal space. A laparoscope is introduced into the abdominal cavity and the ring is inspected. Additional trocars are placed as per the needs of the surgeon. A video of the technique is available online.<sup>7</sup>

Both groups received similar postoperative care. Patients received 75 mg of diclofenac sodium



**Figure 2.** Consolidated Standards of Reporting Trials diagram. COL, conventional laparoscopic operation; DL, diagnostic laparoscopy; GAL, gasless laparoscopic operation; LA, laparoscopic appendectomy; LC, laparoscopic cholecystectomy.

intramuscularly within 1 hour of the postoperative period. Any subsequent analgesia was given as required and was recorded.

In a paper form, data were recorded on demographic characteristics, clinical profile, operative times, vital signs, use of analgesia, efficiency, procedure safety, and patient and surgeon satisfaction. For the GAL group, the operating surgeon was asked to rate their satisfaction on a Likert scale of 1 to 10 (10 being satisfied). All recorded data were transferred to a Microsoft Excel file and analyzed using descriptive statistics. Chi-square test and Student's *t*-test were used in IBM SPSS Software, version 25. A strict safety monitoring framework was adopted to ensure no harm was done to participating patients. Critical "red flag" events were identified at the beginning of, and were adhered to during, the whole period of study.

## RESULTS

Of 133 patients screened, 29 were excluded due to the exclusion criteria and 4 did not consent. Those who met inclusion criteria were randomized into 2 groups (Fig. 2). The groups matched in terms of their demographic and base surgical characteristics, as shown in Table 1.

## Operative time

The mean (SD) time for setting up GAL was 11.8 (5.3) minutes (range 5 to 25 minutes), which was statistically similar to that of the conventional procedure (mean [SD] 12.4 [5.6] minutes; range 5 to 25 minutes). The mean operating time from incision to closure was shorter in the GAL group (52.9 minutes) compared with the COL group (55 minutes), but this was not statistically significant ( $p = 0.3$ ) (Table 2).

## Conversion

In the GAL group, 3 cases of cholecystectomy were converted to standard (COL) due to inadequate operative space in 1 case and complicated anatomy in the other 2 cases. One of the latter cases was subsequently converted to an open procedure. There were no cases of conversion in appendectomy or diagnostic laparoscopy cases. In the COL group, the 3 cases were converted to an open procedure due to technical difficulties.

## Intraoperative vital signs

Vital signs were comparatively more stable in the GAL group. The mean maximum heart rates recorded were 94.7 beats/min in the GAL group and 97.9 beats/min in

**Table 1.** Demographic and Operative Characteristics

Characteristic	GAL (n = 50)	COL (n = 50)	Overall (n = 100)	p Value
Sex, n (%)				0.63
Male	11 (22)	10 (20)	21 (21)	
Female	39 (78)	40 (80)	79 (79)	
Age, y, mean (SD), range	32.4 (10.71), 16–60	34.7 (13.07), 15–70	33.5 (11.95), 15–70	0.165
BMI, kg/m <sup>2</sup> , mean (SD), range	20.94 (2.79), 16–27	21.44 (2.96), 15–27	21.19 (2.87), 15–27	0.39
Abdominal wall thickness, cm, mean (SD), range	2.9 (0.85), 1.5–4.5	3.06 (0.80), 1.5–4.6	2.98 (0.83), 1.5–4.6	0.323
ASA score, n (%)				0.2398
1	45 (90)	48 (96)	93 (93)	
2	5 (10)	2 (4)	7 (7)	
Comorbidity, n (%)	1 (2)	1 (2)	2 (2)	1
Heart disease	1 (2)	0 (0)	1 (1)	0.315
Diabetes	0 (0)	1 (2)	1 (1)	0.315
Other	0 (0)	0 (0)	0 (0)	0
Ongoing medication n (%)	4 (8)	2 (4)	6 (6)	0.4
Antiplatelet	1 (2)	0 (0)	1 (1)	0.315
Antitubercular	3 (6)	2 (4)	5 (5)	0.646
Other	0 (0)	0 (0)	0 (0)	0
No. of deliveries/births, n (%)				0.903
0	12 (24)	15 (30)	27 (27)	
1 to 2	22 (44)	19 (38)	41 (41)	
>2	16 (32)	16 (32)	32 (32)	
Smoker, n (%)	3 (6)	5 (10)	8 (8)	0.461
Alcohol use, n (%)	2 (4)	3 (6)	5 (5)	0.646
Procedure, n				
Cholecystectomy	40	40	80	—
Appendectomy	7	7	14	1
Diagnostic laparoscopy	3	3	6	—

ASA, American Society of Anesthesiologists Physical Status Classification; COL, conventional laparoscopic operation; GAL, gasless laparoscopic operation.

the COL group. The range between the highest and lowest recorded heart rates was better in the GAL group (15.9 vs 18.8 beats/min) ( $p = 0.049$ ) (Fig. 3 and Table 2).

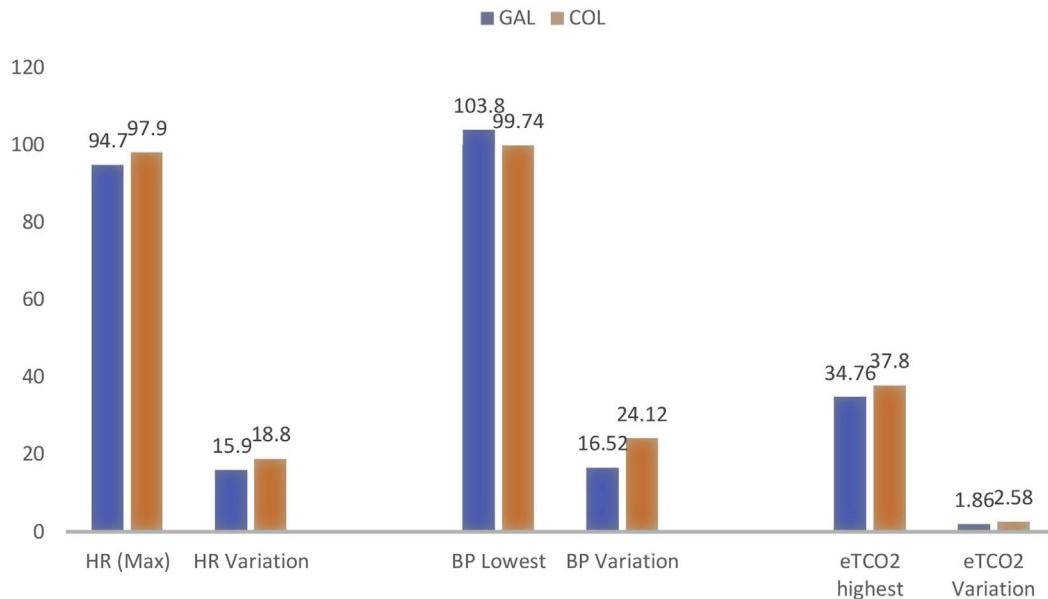
The GAL group had a lower variation in blood pressures (16.52 vs 24.14 mmHg) and the mean lowest blood pressures were higher in the GAL group (103.8 vs 99.74

**Table 2.** Intraoperative Parameters

Characteristic	GAL (n = 50)	COL (n = 50)	Overall (n = 100)	p Value
Setup time, min, mean (SD), range	11.8 (5.3), 5–25	12.4 (5.6), 5–25	12.1 (5.4), 5–25	0.29
Operative time, min, mean (SD)	52.98 (24.5)	55 (21.7)	53.99 (23.0)	0.33
Conversion to standard, n (%)	3 (6)	NA	NA	NA
Conversion to open, n (%)	2 (4)	3 (6)	NA	NA
HR (maximum), beats/min, mean	94.7	97.9	—	0.021*
HR variation (difference of HR <sub>maximum</sub> and HR <sub>minimum</sub> ), beats/min, mean	15.9	18.8	—	0.0499*
Systolic BP lowest, mmHg, mean	103.8	99.74	—	0.015*
BP variation, mmHg, mean	16.52	24.12	—	0.0004*
eTCO <sub>2</sub> highest, %, mean	34.76	37.8	—	< 0.00001*
eTCO <sub>2</sub> variation, %, mean	1.86	2.58	—	0.014*

\*Statistically significant.

BP, blood pressure; COL, conventional laparoscopic operation; eTCO<sub>2</sub>, end-tidal carbon dioxide; GAL, gasless laparoscopic operation; HR, heart rate; NA, not applicable.



**Figure 3.** Vital parameters in 2 groups. BP, blood pressure; HR, heart rate; eTCO<sub>2</sub>, end-tidal carbon dioxide.

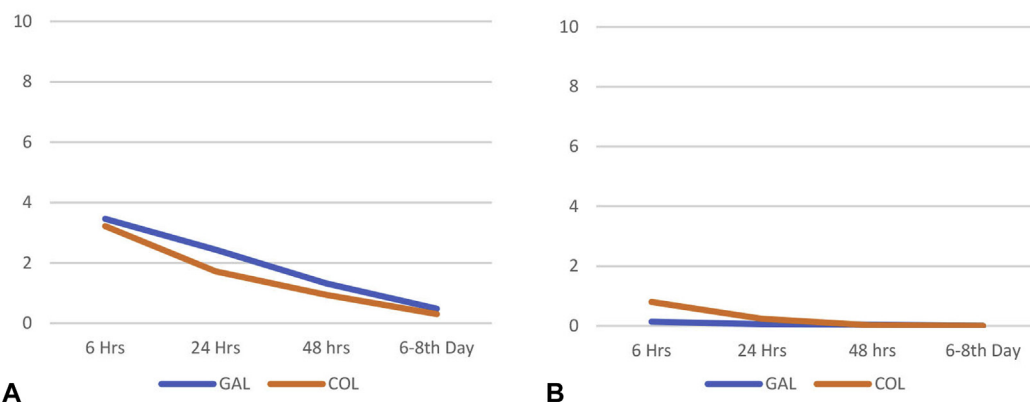
mmHg). Similarly, end-tidal CO<sub>2</sub> concentration was found to be significantly better in the GAL group (1.86%;  $p = 0.014$ ), as shown in Table 2.

### Postoperative pain

Overall, in both groups the pain was not severe (ie more than 5 on visual analogue scale [VAS]) at any time. The mean (SD) VAS score for pain around the umbilicus was recorded as 3.34 (1.5) at 6 hours after surgery (range 1 to 10). The VAS scores were recorded as less than 1 by the second day. The VAS scores at 24 hours and 48 hours were found to be higher in the GAL group. A mild shoulder tip pain was found to be higher in the COL group (Fig. 4).

Seventy-three patients did not require additional analgesia after the first dose as per protocol (Table 3). During the entire hospital stay, a similar analgesic was required—103.5 mg and 99 mg in GAL and COL groups, respectively ( $p = 0.31$ ).

No significant difference was noted for postoperative recovery and hospital stay (Table 4). No intraoperative complications or mortality were experienced in either group during the study and follow-up period of 7 days. The overall incidence of surgical site infection and delayed wound healing was 10% and 11%, respectively, with no difference between the 2 groups. Most of these complications were mild and healed without any interventions.



**Figure 4.** Trends of postoperative pain in 2 groups: (A) abdominal and (B) shoulder. COL, conventional laparoscopic surgery; GAL, gasless laparoscopic operation.

**Table 3.** Pain Parameters in 2 Groups

Characteristic	GAL (n = 50)	COL (n = 50)	Overall	p Value
Abdominal pain, mean (SD), range				
6 h	3.46 (1.7), 1–8	3.22 (1.3), 1–6	3.34 (1.5) 1–8	0.16
24 h	2.44 (1.7), 1–7	1.72 (0.9) 1–5	2.08 (1.4) 1–7	0.0093*
48 h	1.32 (1.2) 0–6	0.94 (0.5) 0–2	1.13 (0.9) 0–6	0.0388*
6 to 8 d	0.48 (0.7) 0–3	0.3 (0.4) 0–1	0.39 (0.6) 0–3	0.1467
Shoulder pain, mean (SD), range				
6 h	0.14 (0.7) 0–4	0.8 (1.20) 0–5	0.47 (1.02) 0–5	0.0012*
24 h	0.06 (0.31) 0–2	0.24 (0.59) 0–3	0.15 (0.48) 0–3	0.061*
48 h	0.04 (0.22) 0–2	0.02 (0.28) 0–1	0.03 (0.22) 0–2	0.656
6 to 8 d	0	0	0	0
Analgesia requirement (over the prescribed)				
Nil	35	38	73	—
Once	14	8	22	—
Twice	1	1	2	—
3 to 4 times	0	3	3	—
>4 times	0	0	0	—
Mean analgesia required, mg	103.5	99	101.25	0.31

\*Statistically significant.

COL, conventional laparoscopic operation; GAL, gasless laparoscopic operation.

Mean surgeon satisfaction score with GAL was 6.4. The score gradually improved as the number of cases increased, forming a linear relation (Fig. 5). The scores for the first 25 case and second 25 cases were 5.56 and 7.24, respectively.

## DISCUSSION

Adverse effects of MAS are known and related to the use of carbon dioxide gas under pressure causing increased intra-abdominal pressure and hypercarbia and subsequent acidosis. Other risks include gas embolism, hypothermia if the gas is not preconditioned and by convection effects, oliguria, decrease in gut perfusion, subcutaneous emphysema, pneumothorax, pneumomediastinum, fogging issues, desiccation of peritoneum by dry gas, loss of space issues, and increased likelihood of deep vein thrombosis due to pooling of blood.<sup>8,9</sup>

In low-resource setting in LMICs, there is lack of trained anesthesiologists, logistics of a constant supply of gases, and sophisticated monitoring equipment.

GAL procedures are possible under the less expensive option of spinal anesthesia and do not lead to the hemodynamic and physiologic derangement associated with COL. It would make laparoscopy available to most places in low-resource settings of LMIC in which COL procedures are difficult to adopt.

A recent multicentric cohort study concluded that MAS is beneficial and has the potential to improve patient outcomes in low-resource settings and future studies on GAL should be promoted.<sup>10</sup>

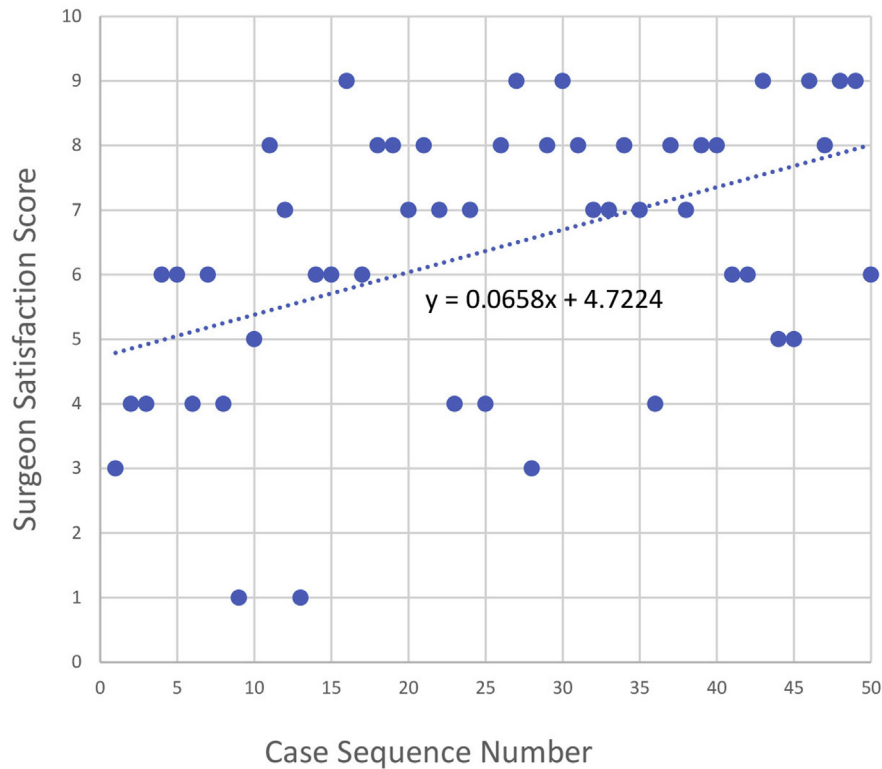
Gasless MAS was started in the early 1990s primarily for the physiologic advantages it offered. A variety of devices were designed using intra-abdominal or subcutaneous retraction with a point, linear, planar, or spiral lifting methods. They were used for gynecologic,<sup>11–13</sup> upper gastrointestinal,<sup>14,15</sup> lower gastrointestinal,<sup>4,16,17</sup> and exploratory diagnostic procedures.<sup>18</sup> They proved the feasibility of GAL in terms of safety, cost-effectiveness, and anesthetic requirements. Other studies concluded

**Table 4.** Postoperative Parameters

Characteristic	GAL (n = 50)	COL (n = 50)	Overall (n = 100)	p Value
Wound infection, n (%)	6 (12)	4 (8)	10 (10)	0.505
Grade 1	5 (10)	2 (4)	7 (7)	—
Grade 2	1 (2)	2 (4)	3 (3)	0.435
Grade 3	0 (0)	0 (0)	0 (0)	—
Delayed wound healing, n (%)	5 (10)	6 (12)	11 (11)	0.749
Hospital stay, d	2.62	2.48	—	0.397

COL, conventional laparoscopic operation; GAL, gasless laparoscopic operation.





**Figure 5.** Relation between surgeon satisfaction score and number of cases.

that GAL cholecystectomy resulted in uneventful, faster immediate and late postoperative recovery than conventional carbon dioxide pneumoperitoneum.<sup>19</sup>

A meta-analysis of 19 RCTs ( $n = 791$ ) indicated that patients who underwent GAL had significantly shorter postoperative time to return to work, lower incidence of postoperative nausea and vomiting, and lower postoperative PaCO<sub>2</sub> levels compared with patients who underwent COL.<sup>20</sup>

In another meta-analysis on GAL cholecystectomy, Liu and colleagues<sup>21</sup> concluded that procedures using abdominal wall lifts appear to decrease respiratory and cardiovascular complications of laparoscopy compared with conventional procedures.

Yet another study by Ge and colleagues<sup>4</sup> found that gasless and conventional approaches are comparable in terms of operative duration, complications, and total hospital stay for laparoscopic appendectomy, and the former might have an advantage due to reduced hospital cost and reduced need for analgesia.

Despite the many advantages, GAL did not become popular as a result of suboptimal exposure due to tenting, difficulty in handling the instruments, and longer operating time.<sup>20</sup>

Our study found that the operating time is similar with GAL and COL, the time lost with setting up is recovered with maintained operating space, as there is no gas loss and quick specimen extraction.

We found that the GAL group experienced marginally higher pain scores. However, did not require additional analgesics.

Anesthesiologists preferred the fewer fluctuations in vital signs, including heart rate, blood pressure, and end-tidal CO<sub>2</sub>. The hemodynamic stability observed during GAL could encourage more surgeons to take up laparoscopic procedures in low-resource settings. Urban centers can also consider using the technique for patients with American Society of Anesthesiologists Physical Status Classification 3 to 4. However, additional studies are required to understand safety in this patient group.

As there is no issue around the gas leak and loss of operative space in GAL, the procedure can be performed easily without sophisticated ports by directly introducing the camera and instruments through the incision. However to avoid repeated injury and soiling of the laparoscope on entry, we recommend use of a valveless sleeve made of abdominal drains/reusable metal sleeve as the port. They are a readily available and cost-effective alternative to commercially



available ports. It makes it extremely convenient for a surgeon who is providing services in a resource-constrained area. Also, because there is no gas insufflation, the surgeon can apply unlimited suction and use conventional open instruments to facilitate laparoscopic procedures.

Both surgeons were satisfied with the experience and ease of working with GAL. After 5 to 8 cases, they were confident and satisfaction score gradually improved. They were satisfied in terms of intra-abdominal space, ease of setting up and dismantling, and maneuvering.

GAL is not expected to have the versatility of laparoscopic procedures under standard pneumoperitoneum technique. Yet, it can be invaluable as a bridge to a surgeon transitioning from open to laparoscopic procedure.

Cost-effectiveness is another added benefit of using the gasless technique. Although it was not evaluated in this study, it was highly indicative that we did not require new and costly access ports. We could work with less costly alternatives, for example, a basic sleeve and cut drain pieces. The cost of saved gas and monitoring equipment makes a strong case for gasless procedures.

During the COVID-19 pandemic, various guidelines are issuing caution about the use of high-pressure gas in laparoscopic procedures, as it can increase chances of cross-infection due to aerosol formation. Use of gasless has the potential to decrease the viral spread as it avoids the use of gas under pressure. This role can be a topic for future research.

### Limitations

The study was not blinded, so subjective outcomes such as pain might have reporting bias. Operating surgeons are coauthors of the study, which introduces bias. Our hospital is a tertiary teaching hospital in the metropolis and does not simulate a rural resource-limited setting. Results might not be directly applicable to this setting. Still, it can offer insight into the potential benefits for use in limited-resource settings.

The current study included patients with a maximum BMI of 28 kg/m<sup>2</sup>. Additional study in patients with higher BMIs is needed to evaluate the safety and advocate its wider use.

### CONCLUSIONS

GAL is a noninferior alternative to COL in terms of operative time and pain. The STAN Laparoscopic Positioner offers exposure comparable with traditional laparoscopic procedures and surgeon satisfaction. GAL scores better with intraoperative hemodynamic stability. It is safe and can be easily mastered. We advocate for its wider use in

low-resource settings to extend the benefits of MAS over open operation to selective patients in the population. This technique, if implemented, can revolutionize rural surgery and achieve the goal of safe and affordable surgical procedures for all.

### Author Contributions

Study conception and design: Mishra, Jesudin  
 Acquisition of data: Mishra, Bains, Singh, Shashi  
 Analysis and interpretation of data: Mishra, Bains, Singh  
 Drafting of manuscript: Mishra, Bains  
 Critical revision: Mishra, Bains, Jesudin, Aruparayil, Singh, Shashi

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