

# Post-operative complications between patients undergoing videolaparoscopic and robot-assisted gastroplasty

*Complicações pós-operatórias entre pacientes submetidos à gastroplastia videolaparoscópica e à robô-assistida*

*Complicaciones posoperatorias en pacientes sometidos a gastroplastia videolaparoscópica y asistida por robot*

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**ABSTRACT: Objective:** To compare the occurrence of post-operative complications between patients undergoing gastroplasty by robot-assisted and video-laparoscopic (VLP) approaches. **Methods:** This is a case-control study. The electronic medical records of adult patients who underwent robot-assisted gastroplasty (case group) and VLP (control group) were included after electronic consent. Records of patients who had surgical technique conversion were excluded. The project was approved by the Research Ethics Committee of the institution where the research was conducted. **Results:** A total of 135 medical records were analyzed. The mean anesthetic time was 3h49 in the case group, compared to 2h10 in the control group ( $p<0.001$ ). The average surgical time was 3h in the case group and 1h37 in the control group ( $p<0.001$ ). The mean time spent in the post-anesthesia recovery room was 1h10 in the case group, compared to 1h07 in the control group ( $p=0.013$ ). The occurrence of post-operative complications was similar between the study groups, with the most frequent being: pain (82; 60.7%), nausea (38; 28.1%), and vomiting (15; 11.1%). **Conclusion:** The post-operative complications assessed were similar between the groups. Patients undergoing VLP gastroplasty had significantly shorter anesthetic-surgical times compared to those undergoing robot-assisted surgeries.

**Keywords:** Video-assisted surgery. Robotic surgical procedures. Bariatric surgery. Nursing.

**RESUMO: Objetivo:** Comparar a ocorrência de complicações pós-operatórias entre pacientes submetidos à gastroplastia pelas vias robô-assistida e pela via videolaparoscópica (VLP). **Métodos:** Trata-se de um estudo caso-controle. Incluíram-se os prontuários eletrônicos de pacientes adultos submetidos à gastroplastia robô-assistida (grupo casos) e VLP (grupo controle), após consentimento eletrônico. Foram excluídos os prontuários de pacientes em que houve conversão da técnica cirúrgica. O projeto foi aprovado pelo Comitê de Ética em Pesquisa da instituição sede da pesquisa. **Resultados:** Foram analisados 135 prontuários. O tempo anestésico médio foi de 3h49 entre casos, em comparação a 2h10 entre os controles ( $p<0,001$ ), o tempo cirúrgico médio foi de 3h entre casos e 1h37 entre controles ( $p<0,001$ ). O tempo médio de permanência na sala de recuperação anestésica foi de 1h10 entre casos, em comparação a 1h07 entre controles ( $p=0,013$ .) A ocorrência de complicações pós-operatórias foi semelhante nos grupos de estudo e as mais frequentes foram: dor (82; 60,7%), náuseas (38; 28,1%) e vômito (15; 11,1%). **Conclusão:** As complicações pós-operatórias avaliadas foram semelhantes entre os grupos. Pacientes submetidos à gastroplastia VLP apresentaram tempo anestésico-cirúrgico significativamente menores do que aqueles submetidos às cirurgias robô-assistidas.

**Palavras-chave:** Cirurgia videoassistida. Procedimentos cirúrgicos robóticos. Cirurgia bariátrica. Enfermagem.

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**RESUMEN: Objetivo:** Comparar la ocurrencia de complicaciones posoperatorias entre pacientes sometidos a gastroplastia por vía asistida por robot y por vía videolaparoscópica (VLP). **Métodos:** Se trata de un estudio de casos y controles. Se incluyeron las historias clínicas electrónicas de pacientes adultos sometidos a gastroplastia asistida por robot (grupo de casos) y por VLP (grupo de control), tras consentimiento electrónico. Se excluyeron las historias clínicas de pacientes en los que hubo conversión de la técnica quirúrgica. El proyecto fue aprobado por el Comité de Ética en Investigación de la institución sede del estudio. **Resultados:** Se analizaron 135 historias clínicas. El tiempo anestésico promedio fue de 3h49 en los casos, en comparación con 2h10 en los controles ( $p<0,001$ ); el tiempo quirúrgico promedio fue de 3h en los casos y 1h37 en los controles ( $p<0,001$ ). El tiempo promedio de permanencia en la sala de recuperación anestésica fue de 1h10 en los casos y 1h07 en los controles ( $p=0,013$ ). La ocurrencia de complicaciones posoperatorias fue similar entre los grupos de estudio y las más frecuentes fueron: dolor (82; 60,7%), náuseas (38; 28,1%) y vómitos (15; 11,1%). **Conclusión:** Las complicaciones posoperatorias evaluadas fueron similares entre los grupos. Los pacientes sometidos a gastroplastia por VLP presentaron tiempos anestésico-quirúrgicos significativamente menores que aquellos sometidos a cirugías asistidas por robot.

**Palabras clave:** Cirugía asistida por vídeo. Procedimientos quirúrgicos robotizados. Cirugía bariátrica. Enfermería.

## INTRODUCTION

Obesity is defined by the World Health Organization (WHO) as an excessive accumulation of body fat to a degree that is detrimental to health and may be classified using the body mass index (BMI)<sup>1</sup>. It is a multifactorial disease, with either endogenous or exogenous origins, and is associated with dietary, behavioral, cultural, social, and lifestyle factors<sup>2</sup>.

Obesity is currently a major public health concern due to its association with an increased risk of various health conditions, including hypertension, type 2 diabetes mellitus, cardiovascular diseases, dyslipidemia, and musculoskeletal disorders<sup>3-5</sup>. In the United States, the prevalence of obesity is projected to rise by 42%, with severe obesity expected to increase by 9% by the year 2030<sup>3</sup>.

Multiple approaches are available for the treatment of obesity, taking into account the severity of the condition, the presence of comorbidities, and the history of previous treatments<sup>6</sup>. Clinical management includes lifestyle modifications, when necessary, along with pharmacological interventions to promote weight loss and address associated health conditions, such as psychiatric disorders<sup>3,6</sup>. In selected cases, a surgical approach may be indicated following a thorough patient evaluation. Candidates typically include individuals aged 18 to 65 years with BMI greater than 35 kg/m<sup>2</sup>, at least one high-risk comorbidity, and documented failure of consistent clinical treatment over a period of at least two years<sup>3,6</sup>.

Currently, the most commonly employed surgical techniques for gastroplasty include: adjustable gastric banding — a restrictive technique; sleeve gastrectomy — a restrictive-metabolic technique; Roux-en-Y gastroduodenal diversion

(gastric bypass) — a mixed restrictive technique; and duodenal switch — a mixed malabsorptive technique<sup>7,8</sup>. Gastroplasty has demonstrated safety and effectiveness in promoting long-term weight reduction, as well as in achieving remission or improved control of associated comorbidities<sup>6</sup>.

Gastroplasty can be performed using three distinct surgical approaches: conventional or “open,” videolaparoscopic (VLP), and robotic. The conventional approach involves a single large incision through which internal structures are accessed; however, its use has declined due to the higher incidence of complications associated with longer operative times and extended postoperative hospital stays<sup>6-8</sup>.

In this context, minimally invasive approaches such as VLP, which involves small abdominal incisions for the insertion of surgical instruments, have been widely adopted due to their association with shorter hospital stays and fewer postoperative complications<sup>8</sup>. Robot-assisted surgery is another minimally invasive technique, in which instruments are attached to robotic arms and operated by the surgeon via a console. Owing to its less invasive nature and enhanced precision of movement, this method also results in reduced hospital stays and fewer postoperative complications when compared to the conventional approach<sup>9</sup>.

Regardless of the surgical approach employed, postoperative complications may occur, including pain, nausea, vomiting, surgical site infection, prolonged stay in the post-anesthesia recovery room, and extended postoperative hospitalization, with varying incidence rates<sup>10</sup>. A systematic review with meta-analysis comparing postoperative complications in patients undergoing robot-assisted *versus* VLP prostatectomy demonstrated a lower likelihood of complications in those who underwent the robotic procedure<sup>11</sup>. However, findings

related to postoperative complications in patients undergoing VLP gastropasty compared to those undergoing robot-assisted gastropasty remain limited and inconsistent<sup>10-12</sup>.

In light of the above, it is pertinent to investigate whether differences exist in the occurrence of postoperative complications among patients undergoing gastropasty using the two minimally invasive techniques. Accordingly, this study poses the following research question: Are there differences in the incidence of surgical complications between patients undergoing robot-assisted gastropasty and those undergoing VLP gastropasty?

## OBJECTIVE

To compare the incidence of postoperative complications in patients undergoing gastropasty using robot-assisted *versus* VLP approaches.

## METHOD

### Study design and location

This is a case-control study<sup>13</sup> conducted in a private, large-scale hospital with approximately 700 active beds, located in the city of São Paulo. The hospital is equipped with two Surgicenters (SC), comprising a total of 36 operating rooms (OR), 45 beds in the post-anesthesia care unit (PACU), two sterile processing departments (SPD), and a backup unit for hospitalization under the Day Clinic regime.

### Population and sample

The study population consisted of medical records of patients who underwent gastropasty using either the VLP or robot-assisted approach. The sample was selected based on convenience. The case group (robot-assisted technique) included data from 45 patients, while the control group (VLP technique) included data from 90 patients. Therefore, the case-to-control allocation ratio was 1:2.

### Case inclusion criteria

The study included the medical records of patients over 18 years of age who underwent gastropasty using the

robot-assisted technique, allowing researchers access to the electronic medical records.

### Inclusion criteria of controls

The study included the medical records of patients over 18 years of age who underwent gastropasty using the VLP technique, providing researchers access to the electronic medical records.

### Exclusion criteria for cases and controls

The medical records of patients who underwent VLP or robot-assisted bariatric surgery, in which there was a conversion of the surgical technique, were excluded, that is, those where the planned technique was not completed due to complications during the procedure.

### Case group definition

The medical records of patients who underwent gastropasty using the robot-assisted technique were included. This minimally invasive procedure is performed through small abdominal incisions, through which trocars are inserted. The instruments are attached to robotic arms and controlled remotely by the surgeon via a console<sup>14</sup>.

### Control group definition

The medical records of patients who underwent gastropasty using the VLP technique were included. This technique involves the introduction of trocars through small abdominal incisions. Pneumoperitoneum is created by injecting carbon dioxide (CO<sub>2</sub>) gas to distend the abdomen, facilitating the visualization of the organs and cavity. The microcamera and surgical instruments are inserted through the trocars. In this minimally invasive approach, the surgeon manually controls the instruments and performs the procedure while viewing it on a monitor<sup>8</sup>.

### Study outcomes

The analyzed variables included the occurrence and intensity of pain, assessed using the visual analogue scale<sup>15</sup>; the occurrence of nausea and vomiting<sup>16</sup> and length of stay in the PACU<sup>17</sup>; need for postoperative intensive care unit admission; and duration of postoperative hospitalization<sup>18</sup>.

## Data collection procedure

Following approval by the Institutional Review Board (IRB) of the hospital where the study was conducted, a list of medical record numbers of patients who underwent gastropasty between January 2015 and December 2020 was obtained. Before accessing the electronic medical records, patients were invited to participate in the study through a digital Informed Consent sent via email. Additionally, the IRB granted an exemption from the requirement to obtain digital informed consents from patients who did not respond to any of the five email contact attempts, which were made at one-week intervals. Data collection was carried out by researchers during the second half of 2021.

For data collection, the authors developed an instrument designed to capture information relevant to clinical outcomes in the postoperative period of VLP and robot-assisted gastropasty. The instrument was reviewed by three nurses with recognized expertise in perioperative and robotic nursing prior to data collection. It was completed manually by the authors based on data extracted from the participants' electronic medical records.

## Ethical aspects

This study was conducted in accordance with the Guidelines and Regulatory Standards for Research Involving Human Subjects, as established by Resolution 466/2012 of the National Health Council<sup>19</sup>. The research project was approved by the IRB of the hospital where the investigation was conducted, under opinion number 5.287.997.

## Data storage and analysis

The data were stored by the researchers in a manner that ensured participant confidentiality and privacy, using a password-protected spreadsheet in Excel for Windows®, version 16.86 (Microsoft Corp., Redmond, WA, USA). The data were then exported to RStudio® version 1.2.5019 (RStudio, Boston, MA, USA) for analysis. Associations between categorical variables were assessed using Pearson's  $\chi^2$  test or Fisher's exact test, as appropriate. Comparisons of means between the two groups were conducted using Student's t-test for independent samples or the nonparametric Wilcoxon-Mann-Whitney test. A significance level of 5% was adopted for all statistical analyses.

## RESULTS

A total of 135 medical records were included, comprising 45 cases of patients who underwent robot-assisted gastropasty, and 90 controls of patients who underwent VLP gastropasty.

Regarding baseline characteristics, a significant difference was observed in the mean age between the case and control groups, 44.9 years and 38.4 years, respectively ( $p=0.002$ ). In terms of gender distribution, the majority of patients in the case group were male (30; 66.7%), whereas the control group was predominantly female (55; 61.1%) ( $p=0.003$ ). The overall mean BMI across the study groups was 39.1 kg/m<sup>2</sup> (SD 6.2 kg/m<sup>2</sup>) (Table 1).

Regarding intraoperative characteristics, statistically significant differences were observed between the surgical techniques used in the study groups. Among the controls, 32 patients (61.5%) underwent sleeve gastrectomy, whereas in the case group, 21 patients (61.8%) underwent Roux-en-Y gastroduodenal bypass ( $p=0.047$ ). Most patients were classified in stratum II of the American Society of Anesthesiologists (ASA) physical status score and all patients underwent measures to prevent surgical site infection and deep venous thromboembolism. The mean anesthetic time was approximately two hours longer in the case group compared to the control group (3h49 vs. 2h10, respectively;  $p<0.001$ ). Similarly, the mean surgical time was significantly longer in the case group, with an average duration of 3 hours, compared to 1h37 in the control group ( $p<0.001$ ). The mean length of stay in the PACU was also slightly longer in the case group (1h10 versus 1h07, respectively;  $p=0.013$ ) (Table 2).

Regarding the postoperative outcomes analyzed, most patients experienced at least one complication, with the most frequent being pain (82; 60.7%), nausea (38; 28.1%), and vomiting (15; 11.1%). However, no statistically significant differences were observed between the case and control groups for these outcomes (Table 3).

## DISCUSSION

The results of this investigation indicate similar rates of postoperative complications between patients undergoing gastropasty via the robotic and VLP approaches. Among these complications, moderate-intensity pain was particularly notable.

This finding is consistent with the results of a study in which patients undergoing robotic gastropasty or VLP

**Table 1.** Baseline characteristics of patients undergoing gastropasty according to surgical approach. São Paulo (SP), Brazil, 2024.

Characteristics	Overall (n=135)	Cases – Robot-assisted (n=45)	Controls – VLP (n=90)	p-value
Age, years, mean (SD)	40.6 (11.6)	44.9 (12.2)	38.4 (10.8)	0.002
Gender				
Female, n (%)	70 (54.8)	15 (33.3)	55 (61.1)	0.003
Male, n (%)	65 (48.1)	30 (66.7)	35 (38.9)	
Weight, kg, mean (SD)	115.6 (21.2)	119.41 (19.4)	113.73 (21.9)	0.144
Height, m, mean (SD)	1.7 (0.1)	1.75 (0.1)	1.70 (0.9)	0.015
Body mass index, kg/m <sup>2</sup> , mean (SD)	39.1 (6.2)	39.19 (5.9)	39.16 (6.3)	0.976
Physical activity, n (%)	26 (19.2)	9 (20.0)	17 (18.9)	1.000
Smoking				
Never smoked, n (%)	109 (80.7)	34 (75.6)	75 (83.3)	0.479
Former smoker, n (%)	15 (11.1)	7 (15.6)	8 (8.9)	
Current smoker, n (%)	11 (8.1)	4 (8.9)	7 (7.8)	
History of previous abdominal surgery, n (%)	78 (57.7)	26 (57.8)	52 (57.8)	1.000
Comorbidities				
Hypertension, n (%)	46 (34.1)	22 (48.9)	24 (26.7)	0.127
Dyslipidemia, n (%)	21 (15.5)	11 (24.4)	10 (11.1)	0.044
Hypothyroidism, n (%)	20 (14.8)	5 (11.1)	15 (16.7)	0.452
Diabetes Mellitus, n (%)	15 (11.1)	9 (20.0)	6 (6.7)	0.038
Sleep apnea, n (%)	14 (10.4)	6 (13.3)	8 (8.9)	0.55
Fatty liver, n (%)	9 (6.7)	5 (11.1)	4 (4.4)	0.159
Depression, n (%)	9 (6.7)	1 (2.2)	8 (8.9)	0.271
Asthma, n (%)	4 (2.9)	0 (0.00)	4 (4.4)	0.301
Cardiopathy, n (%)	8 (5.9)	5 (11.1)	3 (3.3)	0.116
Medications used at home				
Antihypertensive diuretics, n (%)	5 (3.7)	1 (2.2)	4 (4.4)	0.664
Antihypertensive cardiotonics, n (%)	40 (29.6)	20 (44.4)	20 (22.2)	0.01
Oral antidiabetics, n (%)	19 (14.0)	9 (20.0)	10 (11.1)	0.192
Injectable antidiabetics, n (%)	3 (2.2)	0 (0.00)	3 (3.3)	0.55
Antiarrhythmics, n (%)	1 (0.7)	1 (2.2)	0 (0.0)	0.333
Anticoagulants, n (%)	4 (2.9)	2 (4.4)	2 (2.2)	0.6
Loop diuretics, n (%)	9 (6.6)	4 (8.9)	5 (5.6)	0.481
Antidepressants, n (%)	39 (28.8)	13 (28.9)	26 (28.9)	1.000
Antifungals, n (%)	1 (0.7)	0 (0.00)	1 (1.1)	1.000
Anti-inflammatories, n (%)	31 (22.9)	6 (13.3)	25 (27.8)	0.082
Gastric protectors, n (%)	30 (22.9)	11 (24.4)	19 (21.5)	0.668
Hypolipidemic agents, n (%)	24 (17.8)	12 (26.7)	12 (13.3)	0.093
Antihistamines, n (%)	13 (9.6)	1 (2.2)	12 (13.3)	0.039

VLP: videolaparoscopic; SD: standard deviation.

experienced moderate-intensity pain as the most common postoperative complication<sup>20</sup>. Additionally, a retrospective cohort study, which included 97 patients undergoing VLP gastropasty, estimated that 75% of patients reported moderate to high-intensity pain within the first 24 hours<sup>21</sup>.

The effects of acute pain in the postoperative period can be widespread. A literature review suggests several negative outcomes associated with acute pain, including increased

morbidity, the development of chronic pain, impaired daily activities, delayed postoperative recovery, reduced quality of life, higher healthcare costs, and prolonged opioid use<sup>22</sup>. Additionally, studies have indicated that patients undergoing gastropasty are at a higher risk of opioid addiction, which may be linked to a greater incidence of depression and chronic pain compared to the general population<sup>23</sup>. In response, new protocols are being developed to improve acute pain

**Table 2.** Intraoperative data of patients undergoing gastropasty according to the surgical approach. São Paulo (SP), Brazil, 2024.

Characteristics	Overall (n=135)	Cases – Robot-assisted (n=45)	Controls - VLP (n=90)	p-value
Surgical technique				
Vertical sleeve gastrectomy, n (%)	45 (52.3)	13 (38.3)	32 (61.5)	0.047
Gastrojejunostomy in Roux-en-Y, n (%)	41 (47.7)	21 (61.8)	20 (38.5)	
Not informed, n (%)	49 (36.3)	11 (24.4)	38 (42.2)	
American Society of Anesthesiologists physical status score				
ASA I, n (%)	8 (5.9)	3 (6.7)	5 (5.6)	0.958
ASA II, n (%)	105 (77.8)	35 (77.8)	70 (77.8)	
ASA III, n (%)	22 (16.3)	7 (15.6)	15 (16.7)	
Type of venous thrombosis prophylaxis				
Compression stockings, n (%)	12 (8.9)	4 (8.9)	8 (8.9)	1.000
Pneumatic compression device, n (%)	2 (1.5)	0 (0.0)	2 (1.5)	
Compression stockings and pneumatic compression device, n (%)	117 (86.7)	40 (88.9)	117 (86.7)	
Pneumatic compression device and pharmacological therapy, n (%)	1 (0.7)	0 (0.0)	1 (0.7)	
Compression stockings, pneumatic compression device, and pharmacological therapy, n (%)	3 (2.22)	1 (2.2)	3 (2.2)	
Anesthesia time, hours, mean (SD)	2:43 (1:10)	3:49 (01:20)	2:10 (0:40)	<0.001
Surgical time, hours, mean (SD)	2:04 (1:09)	3:00 (1:23)	1:37 (0:37)	<0.001
Post-anesthesia recovery time, mean (SD)	1:08 (1:34)	1:10 (0:33)	1:07 (1:54)	0.013

VLP: videolaparoscopic; ASA: American Society of Anesthesiologists; SD: standard deviation.

**Table 3.** Post-operative outcomes of patients undergoing gastric bypass according to the surgical approach. São Paulo (SP), 2024.

Characteristics	Overall (n=135)	Cases – Robot-assisted (n=45)	Controls VLP (n=90)	p-value
Complications, n (%)	93 (68.9)	30 (66.7)	63 (70.0)	0.698
Pain, n (%)	82 (60.7)	28 (62.2)	54 (60.0)	0.853
Pain score, mean (SD)	6.19 (2.6)	6.07 (2.4)	6.27 (2.7)	0.718
Nausea, n (%)	38 (28.1)	11 (24.4)	27 (30.0)	0.548
Vomiting, n (%)	15 (11.1)	5 (11.1)	10 (11.1)	1.000
ICU requirement, n (%)	2 (1.5)	0 (0.0)	2 (2.2)	0.552
Post-operative hospital stay, days, mean (SD)	2.1 (0.9)	2.4 (1.32)	2.0 (0.6)	0.085

VLP: videolaparoscopic; SD: Standard deviation; ICU: Intensive Care Unit.



management and rationalize opioid use among bariatric surgery patients. One such protocol is the Enhanced Recovery After Bariatric Surgery (ERABS), an adjusted version of the Enhanced Recovery After Surgery (ERAS) protocol<sup>24</sup>.

Regarding the occurrence of postoperative complications among patients undergoing robotic and VLP procedures, a case-control study involving 77,991 patients who underwent Roux-en-Y gastropasty and 189,503 patients who underwent sleeve vertical gastrectomy found that patients undergoing robot-assisted sleeve vertical gastrectomy had higher rates of hospital readmission, a greater need for mechanical ventilation beyond 48 hours postoperatively, and a higher incidence of surgical site infections<sup>25</sup>. However, the findings of this study are consistent with those of a systematic review with meta-analysis, which included data from 13,752 patients undergoing robotic radical prostatectomy and VLP. This review found no significant differences in the occurrence of intraoperative hemorrhage or serious complications between the two approaches<sup>26</sup>.

In this study, a longer anesthetic and surgical time was observed in patients undergoing robot-assisted gastropasty compared to those undergoing VLP. A similar result was reported in another study<sup>25</sup>, where the surgical time was significantly longer for patients undergoing robot-assisted surgery compared to VLP. Similarly, a retrospective cohort study involving 146 patients who underwent either robot-assisted hysterectomy or VLP showed that the surgical time was significantly longer for those undergoing robot-assisted surgery, with a difference of approximately 45 minutes. However, the occurrence of complications and the length of hospital stay were comparable between the two groups<sup>27</sup>.

The main limitation of this study is its retrospective design. Additionally, the investigation of complications may have been hindered by difficulties in identifying them within the electronic medical records of some patients. Moreover, the lack of statistically significant differences in the occurrence of complications between the groups may be attributable to the sample size. Therefore, it is recommended that future studies be conducted to further clarify whether postoperative complications occur similarly between the different study groups.

## CONCLUSION

No significant differences were found in the occurrence of postoperative complications between the study groups. The most frequent postoperative complication in both groups was moderate-intensity pain. Patients undergoing robot-assisted gastropasty had longer mean surgical and anesthetic times, as well as a longer stay in the post-anesthesia recovery room, compared to those undergoing VLP gastropasty.

The results of this study may assist perioperative nurses in making informed clinical and administrative decisions to optimize care, such as improving postoperative pain management in patients undergoing gastropasty.

## FUNDING

None.

## CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

## AUTHORS' CONTRIBUTION

RAO: Project administration, Formal analysis, Conceptualization, Data curation, Methodology, Writing – review & editing, Validation. BC: Project administration, Formal analysis, Data curation, Investigation, Writing – original draft, Validation. AGCSA: Project administration, Formal analysis, Methodology, Writing – review & editing, Validation. VBP: Project administration, Formal analysis, Conceptualization, Writing – review & editing, Validation.

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