Feasibility of Same-Day Discharge After Laparoscopic Roux-en-Y Gastric Bypass Using Remote Monitoring

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Abstract

Background Shortening of hospital stay to 1 night has not affected the short-term safety of patients undergoing laparoscopic Roux-en-Y gastric bypass (RYGB). Whether the RYGB is feasible in an ambulatory setting (same-day discharge) without overnight hospital stay remains to be answered. We aimed to evaluate the feasibility of same-day discharge after laparoscopic Roux-en-Y gastric bypass (RYGB) using additional live video consultation and remote monitoring. Same-day discharge (SDD) was defined as surgery without postoperative overnight hospital stay.

Methods This was a single-center prospective feasibility study in a selected group of patients undergoing a RYGB. Fifty patients undergoing a primary RYGB were selected and potentially treated following the SDD protocol. After SDD discharge patients were remotely monitored after surgery for 48 h using a medical device measuring vital signs three times a day. Video consultations were performed by a doctor twice a day for 2 postoperative days. Primary outcome was the success rate (%) of SDD. Secondary outcomes were emergency room presentations, readmissions, early complications (<30 days), and patient satisfaction.

Results A total of 50 patients were selected for the SDD treatment protocol between June 2020 and November 2020. An SDD success rate of 88 % (44/50 patients) was achieved. Five patients (10%) presented at the emergency room, 2 of whom (4%) were readmitted because of a complication within 30 days after surgery. Overall, patients who followed the SDD protocol reported high satisfaction scores.

Conclusion A RYGB with SDD can be considered feasible using remote monitoring for a selected group of patients.

Keywords Roux-en-Y gastric bypass · Same-day discharge · Ambulatory · Remote monitoring · Video consultation

Introduction

Introduction of fast-track surgery and recent developments in the perioperative management has resulted in improved outcomes of patients undergoing bariatric surgery and decreased the length of hospital stay [1–3]. Shortening of hospital stay to 1 night has not affected the short-term safety of patients undergoing laparoscopic Roux-en-Y gastric bypass (RYGB) [4, 5]. In many bariatric centers, standard care for patients undergoing a RYGB is 1 overnight stay. The increasing demand of care combined with the current SARS-CoV-2 pandemic has considerably reduced the clinical capacity and resources for an overnight stay in the hospital. Surgery in an ambulatory setting could potentially increase capacity to treat patients with morbid obesity by efficient resource utilization. Whether laparoscopic RYGB in an ambulatory setting is feasible remains to be answered.

Few studies have described same-day discharge in patients undergoing bariatric surgery, with same-day discharge defined as surgery without postoperative overnight hospital stay. Same-day discharge (SDD) in patients after a laparoscopic sleeve gastrectomy (SG) has been described by Surve et al. 2018, who performed a large retrospective study of 3162 patients undergoing primary SG in SDD and who found increased morbidity and mortality rates compared to patients...
who stay for at least one night [4]. However, several small prospective studies assessed SDD after SG using a strict selection of patients did not show increased morbidity and mortality [5–11]. The only available data about SDD after RYGB is from three retrospective studies with conflicting results regarding feasibility and safety [12–14]. To our knowledge, no prospective studies have been performed on the feasibility of SDD after a primary laparoscopic RYGB. In addition, no previous prospective studies have investigated SDD in combination with remote monitoring. The use of remote monitoring of patients after bariatric surgery to substitute in-hospital monitoring is relatively new but could potentially aid in further decreasing the length of hospital stay by increasing safety [15].

The aim of this study was to evaluate the feasibility of SDD in a selected group of patients undergoing laparoscopic RYGB using additional live video consultation and remote monitoring.

**Methods**

The study population consisted of patients with morbid obesity aged between 18 and 65 years and eligible following IFSO criteria of morbid obesity undergoing primary laparoscopic RYGB [16]. Inclusion and exclusion criteria for study participation are presented in Table 1. Patients were informed about the study by providing an informative document and an (oral/video) presentation. Written informed consent was obtained according to the Guidelines of Clinical Research in Humans.

**Table 1** Inclusion and exclusion criteria for study participation

| Inclusion                                      | Exclusion                                      |
|-----------------------------------------------|-----------------------------------------------|
| • A primary laparoscopic RYGB                 | • A cardiovascular disease (e.g., myocardial infarction, heart rhythm disorder) |
| • BMI under 50                                | • Anti-coagulant use or coagulation abnormalities |
| • A severe pulmonary disease or severe OSA (AHI above 15) including CPAP therapy | • A history of major abdominal surgery via medial laparotomy |
| • History of major abdominal surgery via medial laparotomy | • Diabetes mellitus with insulin use |
| • Unable to speak or understand the Dutch spoken language or to understand or use the medical devices and mobile application | • Absence of ambulatory help during the 24 h following hospital discharge (e.g., partner, friend, roommate) |
| • A travel distance of more than 45 min from the hospital | • A primary laparoscopic RYGB |

**Preoperative Screening**

All patients were screened for eligibility for surgery by a multidisciplinary team to assess the medical history, nutritional, endocrine, and psychological status, and all patients participated in a mandatory preparatory program of 6 weeks. Multiple diagnostic tests were performed before surgery including a blood test to detect laboratory abnormalities, a stool test for identification of Helicobacter pylori infection, and a sleep polygraphy (or polysomnography) for screening of obstructive sleep apnea (OSA).

**The Surgical Procedure**

The bariatric center is a high volume center with over 1000 bariatric procedures a year. The bariatric center is part of a general hospital with ICU capacity and intervention resources, i.e., radiologist, gastroenterologist, and more in case of complications. Surgery was performed by three experienced and certified bariatric surgeons who all perform over 200 bariatric procedures annually.

The procedure during this pilot study was similar to the standard procedure at our bariatric center as previously described [17]. In short, the gastric bypass procedure has been standardized and consists of the following steps. First, a small stomach pouch of approximately 30–50 ml in volume is created using a stapling device (ECHELON FLEX™ 60-mm Powered Stapler) after calibration of the volume with a 40-french gastric tube. Next, the stapled gastrojejunostomy and jejuno-jejunostomy are created using the stapling device. The alimentary limb was created and estimated at 75 cm and the biliopancreatic limb length at 150 cm. The mesenteric defects were closed using the Novisurge staple (Endoscopic Hernia Multifeed Stapler).

**Perioperative Protocol for Anesthesia and Pain Control**

The perioperative management of anesthesia and analgesia was recorded in our local protocol based on the Enhanced Recovery After (Bariatric) Surgery (ERA(B)S) concepts [18]. Preoperative sedatives were not administered. All patients received perioperative antibiotics. Awake patient positioning was performed, and standard non-invasive monitoring was applied. For induction and maintenance, short-acting anesthetic agents were used. A nasogastric tube was inserted after airway management for gastric desufflation and pouch calibration. During surgery hypothermia and hypotension (systolic blood pressure <100 mmHg) were actively avoided. Standardized multimodal analgesia with infiltration of abdominal trocar sites (6–8ml bupivacaine 0.5% with 1:200000 adrenaline) before closing with dissolvable sutures (Monocryl 3.0) was performed.
The SDD Postoperative Treatment Protocol

The existing standard postoperative protocol for patients undergoing bariatric surgery involved at least one clinical overnight stay for postoperative monitoring and recovery. Before surgery, all patients are normally admitted to the ward where the last check-ups are performed including a preoperative blood examination to assess the hemoglobin level. In general, patients without need for ICU monitoring receive intermittent monitoring every 8 h after surgery and thrombosis prophylaxis on the day of surgery. At the ward, mobilization starts directly after surgery. The next morning, all patients are provided with information about diet, drug prescriptions, and emergency symptoms and are assessed by a bariatric surgeon before approval of discharge.

For this study, we have adjusted the existing protocol for patients undergoing bariatric surgery. Each patient with intended SDD surgery had to meet six mandatory criteria before approval of discharge on the day of surgery; these criteria are listed in Table 2. The surgeon was involved during the entire SDD protocol. Preoperative patient selection, evaluation of the patient after surgery, approval for discharge, and evaluation of the remotely monitored measurements were performed by the same surgeon. Patients successfully discharged on the day of surgery were remotely monitored for 48 h. The remote monitoring consisted of video consultations with a physician twice a day on a set time using a secured application to discuss the recovery process. Both the patient application and medical devices were purchased by the bariatric center without funding. Patients were lend the medical device called Checkme Pro [19] and the tympanic temperature device from Viper Medical (the Genius 3) to perform the measurements at home including heart rate, systolic blood pressure, oxygen saturation, and report a visual analogue scale pain score three times on day 1 and two times on day 2. All these previous measurements were recorded in the patient surveillance application (called Clinicards and designed by Synapzz, The Netherlands) using their mobile phone [20]. All filed measurements in the application were available for evaluation by the physician through a digital monitoring portal. In case of unavailable video consultation or measurements, a normal telephone call was performed. Postoperative medication consisted of standardized pain control prescriptions which consisted of acetaminophen 1000mg 4 daily, naproxen 500mg if necessary 2 daily [21], and Oxynorm 5mg only if necessary 6 daily for a maximum of 3 days. In addition oral anti-emetic drugs were prescribed if necessary. At last, patient follow-up after SDD consisted of a physical consultation with a bariatric nurse ±5 days after surgery and return of the medical devices.

Primary Outcome

Primary outcome was the number of patients that achieved successful same-day discharge without readmission within 48 h. A maximum number of 50 patients were included.

Secondary Study Parameters

To obtain information about the safety of same-day discharge and remote monitoring, adverse outcomes were analyzed including complications ranked using the Clavien-Dindo classification [23], emergency room presentations, readmissions, and mortality. A local Data Safety Monitoring Board (DSMB) was established to warrant ongoing safety of patients treated with the study protocol.

Patient satisfaction was assessed using a self-developed questionnaire before and after surgery in the absence of validated and specific questionnaire for SDD. The first questionnaire consisted of one question about the expected degree of satisfaction with SDD using a 5-point Likert scale which was provided before the operation. The second questionnaire was provided 1 week after the operation and consisted of questions about the satisfaction and experience regarding SDD (only applicable in case of SDD) or questions specific for non SDD patients, using both 4-point and 5-point Likert scale and visual analogue scales (from 1 to 10). Satisfaction between patients who followed the SDD protocol and patients who stayed at least one night was not compared.

To assess the feasibility of remote monitoring, the number of successful video or telephone consultations and the number of measurements by the patients were recorded and expressed as percentages of totals.

Statistical Analysis

All data was analyzed using SPSS 22.0 for Windows (SPSS Inc. Chicago Illinois, USA).

Patient characteristics were described as the mean ± SD, median (range), and categorical data as percentages. Normality of the variables was judged by visual inspection of histograms and Q-Q plots. Primary and secondary outcome

Table 2  Postoperative criteria for approval of same-day discharge

| Criteria                                                                 | Detail                                                                 |
|-------------------------------------------------------------------------|----------------------------------------------------------------------|
| 1. The operation took place before 11 o’clock                          | Only the first or second procedure of the day, with a minimum of 6-h postoperative monitoring |
| 2. No abnormalities or complications during or after the surgical procedure | Postoperative vital signs were normal (heart rate <100, body temperature under 38.0 °C, no hypotension defined as lower than 90 mm Hg systolic or 60 mm Hg diastolic (27)) |
| 3. Postoperative blood hemoglobin levels differ less than 1 point in mmol/l | Preoperative and postoperative blood hemoglobin levels differ less than 1 point in mmol/l |
| 4. The bariatric surgeon decides if the patient is fit for discharge (absence of vomiting, uncontrolled pain, wound problems, or doubt) | The bariatric surgeon decides if the patient is fit for discharge (absence of vomiting, uncontrolled pain, wound problems, or doubt) |
variables were described as the mean ± SD or median with range (min to max) depending on distribution based on patients who followed the SDD protocol.

**Results**

A total number of 50 patients were included. Baseline characteristics are presented in Table 3.

Forty-four (88%) patients were discharged following the SDD protocol without overnight hospital stay. Six patients (12%) stayed 1 night in the hospital and did not receive remote monitoring. Of these 6 patients, 4 patients stayed overnight due to the strong will to stay or insecure feeling, 1 patient was diagnosed with postoperative fever, and 1 patient had persistent postoperative nausea and vomiting. Out of the patients who initially achieved SDD, five patients were presented at the emergency room (ER) within 30 days (11%). Of these patients, 1 patient (2%) was called back to the ER within 48 h, to run a check-up due to repeated measurements of fever with the tympanic temperature device at home; however, no sign of fever or complication was reported at the ER. Two patients were discharged from the ER as they had mild symptoms consisting of abdominal pain and dehydration without

| Table 3  | Baseline characteristics | Total study population n= 50 |
|----------|--------------------------|-----------------------------|
| Age at surgery, years (mean, SD) (range) | 36 ± 10 (19–55) |
| Female (n, %) | 47 (94) |
| BMI (kg/m2) (mean, SD) | 42 ± 4 |
| Weight (kg) (mean, SD) | 118 ± 15 |
| Comorbidities (n, %) | |
| Hypertension | 9 (19) |
| NIDDM | 2 (4) |
| Dyslipidemia | 2 (4) |
| Mild OSA (AHI ≥ 5 and <15) | 12 (24) |
| Osteoarthritis | 6 (12) |
| History (n, %) | |
| Laparoscopic cholecystectomy | 4 (8) |
| Psychiatric diseases | 10 (20) |
| Smoking | 9 (18) |
| Postoperative outcomes | |
| Uncomplicated procedure | 50 (100) |
| Operation time (mean, SD, min) | 38 (8) |
| Start operation (mean, range, time) | 08:50 (08:00–10:30) |
| Same-day discharge | 44 (88) |
| Time of admission (mean, range) | 06:41 a.m. (06:22–7:30) |
| Time of discharge from the hospital (mean, range)* | 06:52 p.m. (05:05–9:00) |
| Emergency room presentation within 48 h | 1 (2) |
| Emergency room presentation within 30 days | 5 (10) |
| Readmission within 48 h | 0 (0) |
| Readmission within 30 days | 2 (4) |
| Postoperative complication | 2 (4) |
| Fistula between pouch and bypassed stomach | 1 (day 22) |
| Pyelonephritis and SARS-CoV-2 infection | 1 (day 24) |
| Intervention (Clavien-Dindo Classification) | |
| II (medication) | 1 (2) |
| IIIa (endoscopic intervention) | 1 (2) |
| Mortality | 0 (0) |

*Mean of patients after SDD (n=44)

n number, SD standard deviation, BMI body mass index, OSA obstructive sleep apnea, NIDDM non-insulin-dependent diabetes mellitus, OSA obstructive sleep apnea, AHI apnea hypopnea index, RYGB Roux-en-Y gastric bypass, min minutes, h hours, a.m. ante meridiem, p.m. post meridiem
the need of an intervention. The two remaining patients (4%) presented at the ER were readmitted to our hospital. The first patient presented with nausea and vomiting caused by a fistula between pouch and bypassed stomach, and the second patient presented with fever caused by pyelonephritis and SARS-CoV-2 infection. The first readmitted patient was treated with a nasal feeding tube for temporary enteral feeding and recovered after 6 weeks with disappearance of the fistula on an upper gastrointestinal series and without the need of any other interventions. The second readmitted patient was treated solely with antibiotics, whereas the SARS-CoV-2 infection was mild. Mortality rate was zero (0%).

Table 4 shows the median scores of reported experience and satisfaction of patients treated by the SDD protocol and patient without SDD. Patients treated following the SDD protocol were very satisfied about their treatment (median score of 5 with range 4–5).

Live video consultations were performed in 88% of patients on day 1 and in 90% with the patients on day 2. In the remainder of cases, normal telephone consultation was established, and all patients were reached on the agreed times (100%). On average live video consultation between the physician and patient lasted for 6 min (range 2–15 min). Measurements of vital signs were performed by patients on different time points within 48 h after surgery, i.e., three times at day 1 and two times at day 2. Compliance and percentages of performed and available measurements are listed in Table 5.

**Discussion**

The aim of this study was to evaluate the feasibility of same-day discharge (SDD) of a selected group of patients undergoing laparoscopic RYGB using additional live video consultation and remote monitoring. This is the first prospective study that suggests that same-day discharge after RYGB with additional remote monitoring is feasible in a selected group of patients. The results showed that 88% of the included patients achieved successful SDD. Only two complications and readmissions within 30 days (4%) were reported, which occurred long after the surgery and were not related to SDD.

Live video consultation was performed in 90% of all SDD patients on both postoperative days. The remainder of patients was contacted with telephone calls. The executed number of vital sign measurements by the patient was somewhat disappointing, since approximately 90% of the measurements were recorded and available for the physician instead of all instructed measurements which causes missing data and could

| Table 4 Patient-reported experience and satisfaction |
|---------------------------------|-----------|----------------------------|
| Preoperative question          | N=50      | Meaning median score       |
| Indicate to degree of expected satisfaction for undergoing surgery in SDD? | 4^¥ (4, 5) | Satisfied                  |
| Postoperative questions about SDD | N=44      |                            |
| How good or bad is your health today? | 3 (1–5)   | Good                       |
| How satisfied are you with undergoing surgery in SDD? | 5^¥ (1–5) | Very satisfied              |
| Would you recommend SDD to other patients? | 10^¥ (7–10) | -                          |
| Would you recommend home monitoring to other patients? | 10^¥ (5–10) | -                          |
| How satisfied are you with the video consultations with the doctor? | 5^¥ (2–5) | Very satisfied              |
| How satisfied are you with the remote monitoring using the medical devices? | 4^¥ (3–5) | Satisfied                  |
| Did you think the amount of consultations with a doctor were sufficient? | 1^∫ (0–3) | Exactly enough              |
| Would telephone consultations instead of video consultation be sufficient? | 4^§ (1–4) | Totally agree              |
| Did the video consultations with a doctor give you the feeling of safety? | 4^§ (3, 4) | Totally agree              |
| Did remote monitoring of vital parameters give you a feeling of safety? | 4^§ (1–4) | Totally agree              |

Postoperative questions in patients without SDD

| N=6      |                                 |
| How satisfied are you with undergoing surgery with overnight hospital stay? | 4^¥ (1–5) | Satisfied                  |
| Are you glad you stayed in the hospital afterwards | 4^§ (3, 4) | Totally agree              |

_SDD_ same-day discharge

All scores represent median scores with the range (min–max)

5-point Likert scale: very poor, poor, good, very good, excellent

∫ 4-point Likert scale: not enough, exactly enough, many, far to many

¥ 5-point Likert scale: very dissatisfied, dissatisfied, somewhat satisfied, satisfied, very satisfied

§ 4-point Likert scale: totally disagree, disagree, agree, totally agree

*VAS scale: 0–10
potentially influence the detection of complications. No abnormal vital signs were notified in relation to a complication. The overall patient satisfaction of patients who were treated following the SDD protocol was high, and most patients would recommend this way of treatment to others.

Three previously published retrospective studies have described SDD after a primary RYGB. The first retrospective study by Morton et al. published in 2014 found increased 30-day mortality in patients undergoing RYGB in an ambulatory setting compared to patients who stayed 2 nights (odds ratio: 13.02; \( P < 0.001 \)). The second study of Inaba et al. published in 2018 was based on the large MBSAQIP database (bariatric registry in the USA) comparing 319 patients undergoing primary RYGB with SDD to 9402 patients discharged on postoperative day 1 and also found more complications in the SDD group (1.31% vs. 0.84%, \( P < 0.001 \)) [12]. Both previous articles concluded that RYGB without overnight stay is not safe. However, the third and most recent retrospective study by Leepalao et al. in 2020, reviewing 398 patients undergoing RYGB, concluded that SDD was feasible when used in a selected population based on their reported low complication rate 2.5% [14]. None of these patients in these studies received additional remote care.

The rates of emergency room visits, readmissions, and interventions were comparable with previous studies who describe these rates in patients with 1 overnight hospital stay including our previously published cohort study which analyzed risk factors for prolonged hospital stay and readmission after primary bariatric surgery and found similar ER presentation rate of 9.5%, intervention rate of 1.7%, and readmission rate of 5.3% within 30 days after discharge [22, 23].

Literature lacks adequate information to make strong recommendations on which patients with obesity are suitable for ambulatory surgery. Patients with super obesity (BMI >50 m2/kg) have higher perioperative risks and are less suitable for SDD [24]. The selection criteria for SDD in the present study were based on previously published patient-specific risk factors associated with complications in bariatric surgery and prolonged hospital stay and expert opinion [23, 25].

The number of obtained measurements was disappointing, despite improved experience [15]. Several technical issues occurred including insufficient connectivity between the Checkme Pro and the application on the mobile phones, difficulties in establishing video calls, and temporary bugs within the application. During the study, most issues could be solved, for example, by establishing a telephone consultation instead of video consultation, and measurements could be orally reported directly to the physician. Yet, the logistic challenge and burden of providing video consultations multiple times a day at fixed times should not be underestimated considering the unpredictable work schedules of physicians. The explanation of the high success rate of SDD may be multifactorial. First, an important contributing factor could be the management of patient expectations by extensive information given preoperatively and throughout the perioperative SDD process. This probably increased patient confidence to go home. Secondly, the standardized perioperative anesthetic protocol using total intravenous anesthesia, multimodal analgesia (with local infiltration), may have resulted in less postoperative pain and nausea. Thirdly, patient selection is important for successful SDD, since patients without severe comorbidities are fitter and recover faster.

The present study has several limitations. First, the most obvious limitation was the small sample size and relatively few males included in this pilot study. This prevents clear and general statements about the safety of SDD. The primary

| Table 5 | Performed and reviewed home measurements \( n=44 \) |
| --- | --- |
| **Time points** | **Day 1** | **Day 2** |
| **M 1** | **M 2** | **M 3** | **M 1** | **M 2** |
| **Video consultations, \( n (\%) \)** | | | | |
| Video consultations | 38 (86) | n.a. | 40 (91) | 89% | 40 (91) | 40 (91) | 91% |
| Telephone consultations | 6 (14) | n.a. | 4 (9) | 11% | 4 (9) | 4 (9) | 9% |
| Total consultations, \( n (\%) \) | 44 (100) | n.a. | 44 (100) | 100% | 44 (100) | 44 (100) | 100% |
| **Genius 3 measurements** | | | | |
| Tympanic temperature | 44 (100) | 40 (91) | 44 (100) | 97% | 43 (98) | 38 (86) | 92% |
| **Checkme pro measurements** | | | | |
| Heart rate | 43 (98) | 41 (93) | 43 (98) | 96% | 44 (100) | 39 (89) | 95% |
| Systolic blood pressure | 35 (80) | 33 (75) | 35 (80) | 78% | 36 (82) | 30 (68) | 75% |
| Blood saturation | 43 (98) | 42 (95) | 41 (93) | 95% | 42 (95) | 36 (82) | 89% |
| VAS pain score | 44 (100) | 42 (95) | 42 (95) | 97% | 44 (100) | 38 (86) | 93% |
| Total measurements, \( n (\%) \) | 209 (95) | 198 (90) | 206 (94) | 93% | 209 (95) | 181 (82) | 89% |

\( n \) number, n.a. not applicable, M1 measurement 1, M2 measurement 2, M3 measurement 3; VAS Visual Analogue Scale
outcome of the present study was feasibility as a first step to perform a second larger study which will focus on safety. A group of at least a thousand patients will be necessary to assess safety given the overall low incidence of complications in bariatric surgery. Secondly, the use of medical devices and applications by patients is challenging. Several technical issues were reported by patients and physicians who provided remote care. Connectivity of the medical apparatus with the digital platform on the patient’s mobile phone was found to be the most prominent issue. Also the usability of the Checkme Pro was insufficient, since some of our patients reported difficulty on how to use the apparatus or failed to report part of the measurements. To guarantee patient safety, the used form of remote monitoring should have flawless connection and reliable measurements. Finally, during the study, the additional value of remote monitoring could not be assessed since no abnormalities were recorded in the patients who were diagnosed with a complication.

Early remote detection of vital sign abnormalities precluding to a postoperative complication should be analyzed in future studies. The value and cost-effectiveness of remote monitoring in this particular group should be addressed in order to assess if it is scalable. In future studies, the choice of the remote monitoring program including the medical devices or wearables should be carefully selected considering the extensive requirements and regulations applicable in health care. Future studies should focus on the yield of remote monitoring. Developments in the field of wearables will provide new insights regarding different ways of remote monitoring in the bariatric population [26]. A large prospective cohort study on SDD is currently being performed to assess safety.

In conclusion, this study suggests that SDD is feasible in a selected group of patients undergoing RYGB supported with additional remote monitoring. Larger studies should be performed to evaluate the safety, costs, generalizability of SDD after RYGB, and the value of additional remote monitoring for early detection of postoperative complications.

Declarations

Ethical Approval Statement This study has been approved by the institutional research ethics committee, and all procedures have been performed in accordance with the Declaration of Helsinki originally adopted in 1964 and its later amendments or comparable ethical standards.

Informed Consent Statement All patients voluntarily participated. Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare no competing interests.

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