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ORIGINAL ARTICLE

The morbidity of laparoscopic radical cystectomy: analysis of postoperative complications in a multicenter cohort by the European Association of Urology (EAU)-Section of Uro-Technology

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Abstract

Purpose To analyze postoperative complications after laparoscopic radical cystectomy (LRC) and evaluate its risk factors in a large prospective cohort built by the ESUT across European centers involved in minimally invasive urology in the last decade.

Methods Patients were prospectively enrolled, and data were retrospectively analyzed. Only oncologic cases were included. There were no formal contraindications for LRC: Also patients with locally advanced tumors (pT4a), serious comorbidities, and previous major abdominal surgery were enrolled. All procedures were performed via a standard laparoscopic approach, with no robotic assistance. Early and late postoperative complications were graded according to the modified Clavien–Dindo classification. Multivariate logistic regression was performed to explore possible risk factors for developing complications.

Results A total of 548 patients were available for final analysis, of which 258 (47 %) experienced early complications during the first 90 days after LRC. Infectious,

gastrointestinal, and genitourinary were, respectively, the most frequent systems involved. Postoperative ileus occurred in 51/548 (9.3 %) patients. A total of 65/548 (12 %) patients underwent surgical re-operation, and 10/548 (2 %) patients died in the early postoperative period. Increased BMI ($p = 0.024$), blood loss ($p = 0.021$), and neoadjuvant treatment ($p = 0.016$) were significantly associated with a greater overall risk of experiencing complications on multivariate logistic regression. Long-term complications were documented in 64/548 (12 %), and involved mainly stenosis of the uretero-ileal anastomosis or incisional hernias.

Conclusions In this multicenter, prospective, large database, LRC appears to be a safe but morbid procedure. Standardized complication reporting should be encouraged to evaluate objectively a surgical procedure and permit comparison across studies.

Keywords Clavien · Complications · Cystectomy · Laparoscopy

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Introduction

Radical cystectomy is a crucial phase in the management of muscle invasive and high-risk non-muscle invasive bladder cancer. For decades, an open approach has been used with favorable outcomes and is still today the gold standard [1]; however, open radical cystectomy (ORC) is a morbid procedure, with a significant rate of postoperative complications [2]. Over 10 years ago, pioneers explored the feasibility of a laparoscopic approach to radical cystectomy [3]. Despite inevitable selection criteria, series on laparoscopic radical cystectomy (LRC) have been published reporting favorable postoperative complication rates [4, 5]. However, the majority of such studies were the result of single-center experiences, and the lack of standardization in complication grading made these results of difficult interpretation.

To address this issue, multicenter data with uniform and validated complication reporting systems are advocated [6]. Recently, the International Robotic Cystectomy Consortium reported the complication outcomes after robotic-assisted radical cystectomy (RARC) in over 900 patients from centers worldwide, which today represents the largest data on the topic [7]. However, in this study group, only robotic-assisted procedures are included and no data on pure LRC are available. Given the interest of laparoscopy in Europe, where the robotic platform has a minor distribution compared to the USA, the EAU-Section of Uro-Technology (ESUT) decided to build a large database of LRC procedures performed across European centers [8]. The oncologic outcomes of such large cohort have been previously published, and in depth analysis of recurrence, cancer-specific survival, and overall survival are illustrated in such manuscript [9]. Now, we have focused on early and late postoperative complications: Aim of the current study is to analyze in detail complications after LRC. Risk analyses have been conducted in an effort to identify possible risk factors for such complications; events have been reported via the modified Clavien–Dindo classification [10], in an attempt to compare our outcomes to other series of open and minimally invasive cystectomy; moreover, given its interest after radical cystectomy, postoperative ileus (POI) has been specifically addressed as an early complication.

Patients and methods

Starting in 2000, the ESUT began to construct a large, prospective database of patients undergoing LRC, which now encloses over 700 patients. Data were retrospectively analyzed. LRC was performed to treat muscle invasive and high-risk non-muscle invasive bladder cancer. Informed consent for the procedure was obtained, and the principles of the Helsinki Declaration were followed. No formal contraindications for LRC were imposed: Also locally advanced tumors (pT4a) were included in the cohort. Prior history of abdominal surgery was not considered as a contraindication to laparoscopic surgery. Clearly, patients unfit to support a pneumoperitoneum or a long Trendelenburg position (mainly a consequence of serious cardiopulmonary comorbidities) were not considered candidates for LRC. Neoadjuvant chemotherapy was administered in 54 patients (10 %). No patient received neoadjuvant radiotherapy. American Society of Anesthesiologists (ASA) score was evaluated by a senior anesthesiologist. After excluding patients with incomplete data regarding estimated blood loss (EBL), OR time, complications, pathologic and follow-up data, a total of 548 patients were available for final analysis.

All procedures were performed via a laparoscopic approach, with no robotic assistance being used. The surgical technique and extent of lymph node dissection varied according to the surgeon and the department in which LRC was performed. The majority of surgeons began their experience performing only standard LN dissection, including obturator, external and internal iliac nodes; however, now most centers regularly follow an extended template, including at least the nodes of the common iliac vessels up to the aortic bifurcation. LNs were generally excised en bloc. In the present cohort, urinary diversion was performed mainly via an extracorporeal approach: Only in 22 patients (5 %), a full laparoscopic intracorporeal technique was applied. When a neobladder was constructed, pneumoperitoneum was re-insufflated and urethral anastomosis was performed by a laparoscopic approach. Nasogastric tube was removed at the end of procedure; early mobilization and oral feeding were encouraged starting on post-op day 1.

Postoperative complications were retrospectively noted by a junior medical doctor by review of patient notes, biochemical and imaging examinations. Complications were reported according to the modified Clavien–Dindo classification [10], and further divided into minor (Clavien I–II) and major complications (Clavien III–V). Any event occurring during the first 90 days after surgery was considered an early complication. Any death following hospital re-admission for any postsurgical complication was attributed to bladder cancer. Complications were also categorized according to organ system involved. Given its interest after radical cystectomy [11, 12], POI was specifically addressed as a complication and defined as a time to normalization of bowel function ≥5 days postoperatively. Follow-up was scheduled on a minimal semester basis during

Table 1 General characteristics of the cohort

Preoperative	
Number of patients	548
Age (years)	
Median (IQR)	68 (62–74)
Mean ± SD	68 ± 9
Sex	
M	452 (82 %)
F	96 (18 %)
BMI (kg/m^2)	
Median (IQR)	26 (23.6–28.7)
Mean ± SD	26.3 ± 7.0
Smoker	
No	99 (18 %)
Yes	223 (41 %)
Unknown	226 (41 %)
ASA	
1	106 (19 %)
2	245 (45 %)
3	98 (18 %)
4	4 (1 %)
Unknown	95 (17 %)
CIS	
No	377 (69 %)
Yes	79 (14 %)
Unknown	92 (17 %)
Neoadjuvant treatment	
No	494 (90 %)
Chemotherapy	54 (10 %)
Pathologic	
Cancer histology	
Urothelial cell carcinoma	540 (99 %)
Squamous cell carcinoma	5 (1 %)
Adenocarcinoma	3 (1 %)
pT	
pT0	62 (11 %)
pT1	90 (16 %)
pT2	155 (28 %)
pT3	184 (34 %)
pT4	57 (10 %)
pN	
pN0	416 (76 %)
pN1	59 (11 %)
pN2	67 (12 %)
pN3	6 (1 %)
Total LN retrieved	
Median (IQR)	13 (9–17)
Mean ± SD	14 ± 7
Surgical margins	
Negative	514 (94.2 %)
Positive	34 (5.8 %)

the first 2 years, then on a minimal yearly schedule. The 10 points of the Martin's criteria on surgical complications are respected in the present study [13].

Subgroup analyses were performed to explore possible risk factors for any complication and for major ones. After excluding patients with unknown ASA score ($n = 95$), uni- and multivariate logistic regressions were performed to assess the association between possible risk factors and the outcomes of overall complications and high-grade complications, both relative to the absence of any complication. Variables tested included: age, BMI, sex, neoadjuvant therapy, ASA score, OR time, EBL, urinary diversion, and pathologic tumor stage (pT). Age and BMI were explored as continuous variables; EBL and OR time were categorized dichotomically in <median versus >median (i.e., EBL <450 ml versus >450 ml; OR time <318 min versus >318 min). Urinary diversion was also categorized in incontinent (ileal conduit and ureterocutaneostomy) versus continent diversion (neobladder, Mainz II, and Indiana pouch). pT was categorized as organ-confined (pT0–pT2) versus locally advanced (pT3–pT4). All statistical analyses were performed using Stata 11.1; a *p* value ≤0.05 was considered statistically significant.

Results

General characteristics of the cohort are illustrated in Table 1. On final specimen analysis, 56 % of patients had organ-confined disease (pT ≤ 2) and 44 % had locally advanced disease (pT3–4), while 24 % had positive nodes. Of note, median LN retrieval was 13 (9–17), positive surgical margin rate was 5.8 %, and median follow-up was 49 months (IQR 19–87 months).

Overall, 258 (47 %) patients experienced complications during the first 90 days after LRC (Table 2), for a total of 318 complications reported. Globally, 29 % (159/548) of the entire cohort had minor complications (Clavien I–II), while 18 % (99/548) experienced major complications (Clavien ≥ III). Infectious, gastrointestinal, and genitourinary were, respectively, the systems most frequently involved (Table 2). POI occurred in 51/548 (9.3 %) patients. Of these, 3/51 were reoperated after >10 days to perform adhesiolysis. Conversion to an open approach occurred in 12 patients (2 %), mainly as a consequence of extensive intra-abdominal adherences (5/12) or due to massive bleeding (6/12). Finally, in one patient, conversion occurred due to the presence of a large pT4 cancer. Median hospital stay was 14 days (IQR 11–20).

Concerning major complications, 65 patients were reoperated under general anesthesia during the early postoperative period. Indications for surgical re-operation were the following: digestive leak ($n = 18$), abdominal wound revision ($n = 10$), urinary leak/fistula ($n = 8$), mechanical

Table 1 continued

Perioperative

Total OR time (min)	
Median (IQR)	318 (270–380)
Mean ± SD	336 ± 89
EBL (ml)	
Median (IQR)	450 (250–800)
Mean ± SD	643 ± 600
Urinary diversion	
Bricker	372 (68 %)
Orthotopic neobladder	144 (26 %)
Ureterocutaneostomy	13 (2 %)
Mainz II	15 (3 %)
Continent pouch (Kock, Indiana)	4 (1 %)
LOS (days)	
Median (IQR)	14 (11–20)
Mean ± SD	18 ± 15

Table 2 Early (≤90 days) postoperative complications after laparoscopic radical cystectomy

Number of patients with ≥1 early complications	258 (47 %)
One complication	204
Two complications	48
Three complications	6
Early complication rate stratified per organ system	
Infective	71 (28 %)
Gastrointestinal	45 (17.5 %)
Genitourinary	29 (11 %)
Hemato/bleeding	14 (5 %)
Vascular	13 (5 %)
Abdominal wall	12 (4.5 %)
Cardiac	10 (4 %)
Pulmonary	5 (2 %)
Electrolyte disturbance	4 (1.5 %)
Neurologic	3 (1 %)
Drain extraction under anesthesia	1 (0.5 %)
Unknown	51 (20 %)
Grade of worst early complication	n (% of total population)
Clavien I	39 (11 %)
Clavien II	120 (22 %)
Clavien III	
IIIa	22 (4 %)
IIIb	58 (11 %)
Clavien IV	
IVa	7 (1 %)
IVb	2 (0.5 %)
Clavien V (death)	10 (2 %)

ileus ($n = 3$), hemorrhage ($n = 3$), drainage of infected intra-abdominal collections ($n = 3$), ureteral reimplantation ($n = 2$), drainage of a lymphocele ($n = 1$), and repair of a rectovaginal fistula ($n = 1$). Moreover, three patients had a lower leg compartment syndrome requiring fasciotomy, one needed endarterectomy, and one required circumcision for prepuce necrosis. Finally, in 11 patients, the cause for reoperation was unknown.

Concerning Clavien Grade IV complications, we observed two respiratory failures, two major peritonitis, one cardiac failure, one acute renal failure requiring dialysis, and one massive stroke. Finally, 12 patients experienced septic multi-organ failures (MOF), of which 10 (1.8 % of entire cohort) died postoperatively.

When exploring possible risk factors for early complications after LRC, subanalyses were restricted to 453 patients, excluding 95 patients for which ASA score was unavailable. On multivariate logistic regression, increased BMI ($p = 0.024$) and increased EBL ($p = 0.021$) were significantly associated with a greater overall risk of experiencing complications (Table 3). Moreover, patients who had undergone neoadjuvant chemotherapy experienced a significant twofold increased risk of developing postoperative complications (OR 2.36, 95 % CI 1.17-4.77, $p = 0.016$). Age ($p = 0.06$), sex ($p = 0.56$), ASA ($p \geq 0.13$), OR time ($p = 0.88$), pT status ($p = 0.21$), and urinary diversion ($p = 0.69$) were not significant predictors of overall complication risk. When exploring the risk of major complications on multivariate logistic regression, the only significant association found was with an ASA score of IV, which proved to be, as expected, a highly significant predictor ($p = 0.003$) (Table 3). Differences in complication rates across patients who did and did not receive neoadjuvant chemotherapy are exposed in Table 4.

Late complications, occurring >90 days after surgery, are exposed in Table 5. Of note, these most frequently involved uretero-ileal stenosis and incisional hernias.

Discussion

Minimally invasive cystectomy is a challenging procedure which should have the benefits of reduced morbidity and enhanced recovery in comparison with the standard, open approach [14]. In the current study, we analyzed postoperative complications in a large cohort of patients undergoing LRC in 10 European centers, using a standardized classification system. Indeed, standardization is fundamental in order to allow comparison of results across studies, and is recommended by current guidelines [6]. The oncologic outcomes of this cohort have been addressed in a previous article [9]; here, we assess the safety of LRC, reporting an acceptable postoperative complication rate, comparable

Table 3 Multivariate logistic regression exploring risk factors for **a** overall complications, **b** major complications (Clavien III–V)

	OR	95 %CI	*p* value
a			
Age	0.79	0.61–1.01	0.06
Sex	1.17	0.69–2.00	0.56
BMI	**1.07**	**1.01–1.14**	**0.024**
ASA			
I	Ref.	Ref.	Ref.
II	1.07	0.65–1.75	0.78
III	1.20	0.66–2.18	0.55
IV	6.00	0.57–62.8	0.13
Neoadjuvant therapy	**2.36**	**1.17–4.77**	**0.016**
OR time	0.97	0.64–1.46	0.88
EBL	**1.62**	**1.08–2.44**	**0.021**
Urinary diversion	1.10	0.68–1.79	0.69
pT	1.29	0.86–1.92	0.21
b			
Age	0.73	0.52–1.01	0.06
Sex	1.95	0.87–4.40	0.11
BMI	1.04	0.96–1.12	0.34
ASA			
I	Ref.	Ref.	Ref.
II	1.66	0.82–3.34	0.16
III	1.77	0.78–4.00	0.17
IV	**38.64**	**3.41–437.56**	**0.003**
Neoadjuvant therapy	1.33	0.52–3.39	0.55
OR time	1.43	0.82–2.47	0.21
EBL	1.09	0.63–1.87	0.76
Urinary diversion	0.88	0.46–1.67	0.69
pT	1.35	0.80–2.28	0.26

Bold values indicate statistically significant risk factors

Table 4 Complication rates according to neoadjuvant chemotherapy

	No neoadjuvant	Neoadjuvant	*p* value*
Overall complications	222/494 (45 %)	36/54 (80 %)	0.002
Major complications (Clavien ≥ III)	91/494 (18 %)	8/54 (15 %)	0.51
Clavien I	48/494 (10 %)	11/54 (20 %)	0.016
Clavien II	126/494 (26 %)	22/54 (41 %)	0.017
Clavien III	80/494 (16 %)	8/54 (15 %)	0.79
Clavien IV	10/494 (2 %)	1/54 (2 %)	0.93
Clavien V	10/494 (2 %)	0/54 (0 %)	0.29

* χ^2

to that reported by other investigators [7]. Interestingly, neoadjuvant chemotherapy, increased BMI, and increased EBL appeared to be significantly associated with the risk of developing any complication.

The present article analyzed only standard LRC cases. Although there is growing interest for the robotic approach to RC, many hospitals across Europe do not own a robotic platform: As such, these results may be of relevance to surgeons without access to a surgical robot who are developing or wish to implement LRC in their department. Moreover, to our knowledge, this represents the largest cohort of LRC available to date.

In our series, around half of patients (47 %) experienced complications during the first 90 postoperative days. Among all, infectious complications were the most frequent, followed by gastrointestinal and genitourinary events. This is in line with data available from large, contemporary ORC cohorts, in which complication rates range from 28 to 67 % [2, 15–17]. Recently, Bochner et al. [18] compared open to RARC. In this randomized trial, no clear advantage of the minimally approach was found, with similar complication rates and hospital stays across the two groups. Results from minimally invasive cystectomy series yielded similar outcomes, with an overall morbidity between 23 and 52 % [5, 19, 20]. In particular, the largest multicentre cohort of RARC was recently published by Johar et al. [7], providing details on complications of over 900 patients. In their study, complications occurred in 48 % of patients and high-grade events were registered in 19 %. Similarly to our study, neoadjuvant chemotherapy and higher BMI were found to be significantly associated with the risk of developing complications. Huang, in a cohort of 171 Chinese patients undergoing LRC, detected a lower rate of complications, specifically 23.4 % (40/171) [5]. Tyritzis, in 70 patients operated in their department in Sweden of RARC with totally intracorporeal neobladder reconstruction, reported 38 % complication rate, with 14 % of patients experiencing >1 complication [20].

Maximum effort should be done to avoid major complications. Clearly, a technically optimal procedure is insufficient to avoid such events: correct patient selection, adequate preoperative preparation, and careful postoperative care are fundamental to reduce such events. In this study, major complications were experienced by 18 % of patients: Of these, 10 (1.8 %) patients died in the early postoperative setting. Large ORC trials report similar or slightly higher mortality rates (1.7–3 %), most probably as a consequence of higher comorbidity and more advanced disease treated [2, 17, 21]. In our cohort, however, we included 34 and 10 % of pT3 and pT4a cancers, respectively; these rates are higher than other minimally invasive cystectomy reports [5, 22].

The early reoperation rate in our series was 13 %, mainly due to bowel leaks, urinary leaks, or wound dehiscence. This is comparable to other reports with similar disease stages: Torrey et al. evaluated 34 RARC patients with extracorporeal Indiana pouch, with a 38 % rate of pT3–4

Table 5 Late (>90 days) postoperative complications after laparoscopic radical cystectomy

Total late complications (>90 days)	64 (12 %)
Uretero-ileal stricture	22 (4 %)
Incisional hernia	15 (3 %)
Stoma correction	7 (1 %)
Pouchitis	5 (1 %)
Adhesiolysis	5 (1 %)
Entero-cutaneous fistula	4 (1 %)
Urethral stricture	4 (1 %)
Lymphocele	1 (0.2 %)
Non-functional kidney	1 (0.2 %)
Grade of late complication	
Clavien II	6
Clavien IIIa	17
Clavien IIIb	40
Clavien V	1

cancers. They found 16 % of early major complications (Clavien III–V), with a 14 % re-operation rate, due to ureterocolic anastomotic stricture, adhesiolysis, and wound dehiscence. Similarly, Guillotreau analyzed 146 patients undergoing LRC, among which 7.5 % were reoperated mainly due to complications associated with the neobladder substitution [23]. Finally, in a matched pair analysis comparing open to LRC, we previously reported a 13 % rate of Clavien III complications [24].

POI is a frequent complication after radical cystectomy. Despite conflicting results, investigators have found that minimally invasive surgery may reduce POI compared to the open approach, with an enhanced bowel recovery and a shorter time to flatus and bowel movements [12]. We report an incidence of POI of 9.3 %, defined as a time to normalization of bowel function greater than 5 days postoperatively. Indeed, there are multiple factors other than surgical approach which should be taken into account in the return to normal bowel function after major abdominal surgery: These include anesthesia, pain control, comorbidities, mobilization, enhanced recovery protocols, and BMI [25, 26]. Benefits of minimally invasive surgery include decreased bowel manipulation and exposure, and reduced fluid imbalances. Our findings are consistent with other previously published work: Ramirez et al. [12] in a systematic review concluded that average POI rate after radical cystectomy is 9.86 %. Guillotreau et al. [27] reported rates of POI of 11 % in 38 patients undergoing LRC, whereas Nix et al. [28], in a small prospective randomized trial comparing ORC to RARC, reported a rate of 9.5 %.

In the present cohort, the majority of patients (95 %) underwent an extracorporeal urinary diversion: Although an intracorporeal technique is definitely feasible [29],

we believe that the extracorporeal approach is faster and allows a safe control of the reconstructive phase of the surgery, including the bowel anastomosis which may be source of serious complications. The incision is 4–7 cm long and is performed merging trocar orifices around the umbilicus; moreover, minimal traction is applied on the abdominal wall, thus minimizing trauma. Intracorporeal laparoscopic diversion with no robotic assistance should be reserved to highly skilled surgeons. Hospital stay in our cohort (median 14 days) may seem long to an American reader, as most studies from the USA report a median stay between 5 and 8 days [4, 22]. Nonetheless, our LOSs are in line with other European centers [30], and the multiple social and cultural differences existing across our continents are probably accountable for the longer hospital stay we herein report. Of note, our patients are discharged only when all drains and catheters have been removed.

In the present article, we have not addressed "oncologic" complications. Indeed, in urothelial cancers, laparoscopy and the pneumoperitoneum may be a potential source of tumor cell spread [31]. This must be avoided by respecting the oncologic principles of open surgery, including not opening the urinary tract, gentle manipulation of tissue, and the use of an endobag. As such, LRC should be undertaken by surgeons with a valid training and experience, in order to avoid oncologic catastrophes. Despite the aforementioned precautions, some patients did present early recurrences and a manuscript is currently being drafted analyzing such adverse oncologic events.

Finally, it is worth to comment on late complications. After a median follow-up of 4 years, these regarded mainly uretero-ileal strictures and incisional hernias. Each surgeon used its own technique, both for uretero-ileal anastomosis and for fascial closure: Therefore, no recommendation for these two steps can be given. Ureteral anastomotic strictures were the most common late complications also in the report of Huang on 171 patients, after a median follow-up of 3 years [5].

We must acknowledge limitations to the present study. First, being a multicentre trial with multiple surgeons involved, differences across protocols are inevitable: These include patient selection, anesthesia, technical steps, and postoperative recovery protocols. Although this heterogeneity can be seen as a drawback, it offers also a real snapshot of the patients currently undergoing LRC in Europe. Second, one could argue that 10 centers should have enrolled more patients, given the length of the study period. However, not all the centers began to implement LRC in 2000, and in addition to this some of the departments have now shifted to a robotic-assisted approach. Another limitation is the high number of

patients with missing data, especially concerning ASA score. The median number of retrieved lymph nodes (i.e., 13, IQR 9–17) may seem low; however, the reader should bear in mind that this cohort includes patients operated also in the beginning of 2000, the exploratory years of LRC: In these patients, only limited/standard node dissection was performed, thus decreasing our median, which remains nonetheless in line with other series with long-term follow-up [32]. Nonetheless, as demonstrated by other investigators, in trained hands minimally invasive pelvic node dissection is not inferior to the open approach [33]. Moreover, late complications may be underreported, as some patients may have demanded care in other departments years after the primary surgery. Finally, a minimal selection bias cannot be excluded. We agree that not all patients are good candidates for a laparoscopic procedure, and we believe that wise selection is necessary in order to achieve good results; however, we feel that selection criteria should be more liberal for undergoing minimally invasive cystectomy. In this context, the current study represents a wide application of this technique. Nonetheless, mastering laparoscopy is fundamental in order to obtain, in addition to enhanced recovery, valid oncologic results [9].

Conclusions

Radical cystectomy is a morbid procedure, even when performed via a laparoscopic approach. In this multicentre European cohort, LRC presented complication rates comparable to those currently published after ORC and RARC. Minor complications account for the majority of complications reported. The benefits of the minimally invasive approach must be balanced against the dangers of this challenging surgery, which remains morbid irrespectively of the technique adopted. The use of a standardized reporting method may have determined artificially higher rates as compared to the other available studies.

Compliance with Ethical Standards

Conflict of interest The authors declare they have no conflict of interests.

Ethical standards statement The present study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Patients gave their informed consent prior to their inclusion in the study.

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