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Preoperative low-residue diet in gynecological surgery

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ABSTRACT

Objective: To evaluate the impact of preoperative low-residue diet on intra- and postoperative outcomes among gynecological surgical patients.
Methods: This is a surgeon-blind, randomized controlled trial enrolling patients undergoing elective surgery for either benign disease or endometrial carcinoma. Patients were preoperatively randomized to receive either low-residue diet (arm A) or free diet (arm B) starting from three days before surgery. The primary outcome was the quality of the surgical field (scored using a 5-point scale, from poor to excellent). Secondary outcomes were postoperative pain (assessed through VAS scale), postoperative complications, operative time, time to first passage of flatus, length of hospital stay. Perioperative data were collected and compared between groups.
Results: A total of 96 patients were enrolled and randomized in arm A (n = 49; 51%) and arm B (n = 47; 49%). The mean age was 47.8 ± 15.6 years in arm A and 48.1 ± 11.3 years in arm B. Endometrial cancer patients were 16.3% in arm A and 10.6% in arm B, and patients with benign disease were 83.7% and 89.4%, respectively. The surgical evaluation of the small intestine was scored < 3 in 2.0% of arm A patients versus 31.9% in arm B (Odds Ratio (OR), 0.04 [95% CI, 0.01–0.35]; p < 0.001), and in 6.1% and 44.7% (OR, 0.08 [95% CI, 0.02–0.30]; p < 0.001), respectively, for large intestine. The mean operative time was 90.4 ± 33.4 min in arm A versus 111.6 ± 37.5 in arm B (Mean Difference (MD): −21.20 [95% CI, −35.43, −6.97]; p = 0.003). The number of patients who reported the time to first flatus within 24 h after surgery was significantly higher in arm A compared with arm B (77.6% vs 44.7%; OR, 4.28 [95% CI, 1.77–10.35]; p = 0.002). No significant differences in terms of post-operative complications, pain, and length of hospital stay were observed between the two groups.
Conclusion: Introducing a preoperative low-residue diet could improve the quality of the surgical field and reduce both the operative duration and the time to first passage of flatus among patients undergoing gynecological surgery. Further large-scale studies are required to confirm these findings.

Introduction

Mechanical bowel preparation (MBP), including oral and/or rectally administered solutions, has been widely used in almost all gynecological procedures for several decades [1–3]. This preoperative routine practice was believed to reduce the risk of infections and anastomotic leak after bowel surgery, since it reduces the stool burden and may improve the quality of the operative field by easing bowel handling [4,5]. Indeed, the small size of the pelvis and its relatively inextensible skeletal structure could prevent from obtaining an optimal surgical field. However, this theoretical benefit remains controversial and, in addition to the patient discomfort, the use of MBP may cause pre-operative dehydration and electrolyte imbalance, which have been potentially associated with adverse post-operative outcomes. The Enhanced Recovery After Surgery (ERAS) Society guidelines do not recommend the routine use of MBP for gynecological surgery, even if bowel resections are expected [6,7]. However, there is no evidence on the potential efficacy of using pre-operative low-residue diet to improve perioperative outcomes after gynecological surgery with respect to both MBP and fasting only.

The aim of the present study is to evaluate the impact of preoperative low-residue diet on intra- and postoperative outcomes of gynecological surgical patients not undergoing MBP.

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Materials and methods

The present study is a surgeon-blind randomized controlled trial. The study was reported following the Consolidated Standards of Reporting Trials (CONSORT) guideline [8]. From October 2017 to November 2020, patients scheduled for gynecological surgery at the Department of Gynecology of Policlinico Umberto I (Sapienza University of Rome) were enrolled in the study. Written informed consent was obtained from all subjects and the study was approved by the local Institutional Review Board.

Inclusion criteria were as follows: (a) elective surgery for either benign gynecological pathology (e.g., uterine fibroids, endometriosis, ovarian cyst) or endometrial carcinoma; (b) patients without gastrointestinal disorders; (c) no previous pelvic radiotherapy. Exclusion criteria included: (a) ovarian cancer; (b) cervical cancer; (c) vulvar and vaginal cancers; (d) urgent/emergent surgery; (e) incomplete medical records. Both laparotomic and laparoscopic surgical procedures were considered. One week before surgery patients were randomized to receive preoperative low-residue diet (see Table 1 and Table 2) starting three days before surgery (Arm A) or free diet (Arm B). A low-residue diet simply reduces fiber intake by eliminating or limiting high-fiber foods such as raw fruits and vegetables [9]. Randomization assignment was performed using the block randomization method (block size of 4) to ensure a balance in sample size across groups over time.

Preoperatively, all patients were submitted to general and gynecologic history, complete physical and gynecological examination, pelvic ultrasound, blood exams, EKG, Chest X-Ray. All patients received antibiotic prophylaxis with cephazolin 2 g 30 min before incision and antithrombotic prophylaxis with low-molecular-weight heparins 12 h before surgery. Liquid and solid fasting was maintained starting from 8 h before the intervention. All patients followed a liquid diet for 12 h after surgery. All surgeries were performed by the same surgical team. The surgeons were not aware of which diet the patients had followed before surgery.

The primary outcome was the quality of the surgical field. Secondary outcomes were postoperative pain, postoperative complications, time to first passage of flatus, and length of hospital stay. During surgery surgeons was asked to evaluate the degree of small and large bowel preparation and the overall appropriateness of the surgical field using a 5-point scale (poor, sufficient, medium, good, excellent) [10]. All patients were asked to indicate their degree of nausea/vomiting at 24 h postoperatively and pain at 12, 24 and 48 h postoperatively, through a VAS scale. The operative time, the time to first passage of flatus, postoperative hospital stay were recorded as well as the request and administration of analgesics (IV or IM) and any short-term postoperative complication.

Table 1
List of allowed and not allowed foods.

Foods	Allowed	Not allowed
Flour	White bread, crackers	Whole wheat bread, pasta, rice, cornflakes, foods containing bran or corn, oat flour, whole grain cereals.
Desserts	Ice pops, white yogurt	Chocolate, dried fruit, seeds, coconut, fruit yogurt, popcorn.
Fruits	Cooked or puréed fruit (apples and pears) and ripe bananas	Uncooked fruit, berries, dried fruits, seeds, nuts
Vegetables and legumes	Boiled potatoes and carrots	All other vegetables, both cooked and raw, legumes like broccoli, cabbages, cauliflower, spinach, peas, lettuce, tomatoes and any other vegetables with seeds, beans, chickpeas, etc.
Meat	Chicken and turkey meat, fish, eggs	Red meal, salami and sausages
Broth	Vegetable broth	Puréed vegetable soups, creams, and soups.
Drinks	Tea, chamomile, herbal tea, skimmed milk, all decaffeinated drinks, fruit juices without pulp	Espresso, cappuccino, whole or partially skimmed milk, fruit juice with pulp and all alcoholic beverages.

Table 2
Preoperative low-residue diet (starting 3 days before surgery).

Natural oligomineral water; toasted bread.	
BREAKFAST	• Lemon juice (4 ml)• Rusks (30 gr, 124 kcal)• Tea (1.5 gr)
LUNCH	FIRST DISHES (max 1): • Rice (80 gr, 285 kcal) with oil (13 ml, 119 kcal) • Pasta (80 gr, 287 kcal) with oil (13 ml, 119 kcal) • Liquid semolina in filtered vegetable broth (80gr, 280 kcal) SECOND DISHES (max 1): • Fillets of plaice (200 gr, 182 kcal) • Slice of chicken breast (200 gr, 220 kcal) • Slice of turkey breast (200 gr, 238 kcal) • White cattle meatballs (100 gr, 231 kcal) • Pork chop (150 gr, 270 kcal) • Grilled slices of beef (150 gr, 216 kcal) • Steamed hamburger (110 gr, 199 kcal) • Cod fillet dressed with olive oil (200 gr, 166 kcal) • Homogenized meat (200 gr, 168 kcal) CONTOURS (max 1): • Carrots (150 gr, 41 kcal) dressed with olive oil (10 gr, 119 kcal) • Potatoes (80 gr, 83 kcal) dressed with olive oil (13 ml, 119 kcal) • Courgettis (150 gr, 55 kcal) dressed with olive oil (13 ml, 119 kcal) FRUIT (max 1): • Banana(89 kcal) • Fruit mousse (100 gr, 60 kcal) • Fruit juice without sugar (200 ml, 100 kcal)
DINNER	FIRST DISHES (max 1): • Rice (80 gr, 285 kcal) with oil (13 ml, 119 kcal) • Pasta (80 gr, 287 kcal) with oil (13 ml, 119 kcal) • Liquid semolina in filtered vegetable broth (80 gr, 280 kcal) SECOND DISHES (max 1): • Slice of chicken breast (200 gr, 220 kcal) • Slice of turkey breast (200 gr, 238 kcal) • Platessa fillet (200 gr, 118 kcal) with oil (13 ml, 119 kcal) • Raw ham (100 gr, 238 kcal) • White cattle meatballs (100 gr, 231 kcal) • Slice of grilled cattle (200 gr, 220 kcal) • Homogenized meat (200 gr, 168 kcal) • Parmesan cheese (50 gr, 196 kcal) CONTOURS (max 1): • Carrots (150 gr, 41 kcal) dressed with olive oil (10 gr, 119 kcal) • Potatoes (80 gr, 83 kcal) dressed with olive oil (13 ml, 119 kcal) • Courgettis (150 gr, 55 kcal) dressed with olive oil (13 ml, 119 kcal) FRUIT (max 1): • Banana (89 kcal) • Fruit mousse (100 gr, 60 kcal) • Fruit juice without sugar (200 ml, 100 kcal)

The sample size was calculated according to the primary outcome. When the score was < 3 the quality of the surgical field was considered as poor and when > 3 as good. We assumed a proportion of events (score < 3) in the free diet group of 0.4 (40%) and an expected decline of 0.25 (proportion of events of 0.15) in the low residue diet group leading to an effect size of 0.574. A sample size of 96 subjects (48 subjects for each group) is needed to detect a difference in the proportions with a power of 80% assuming a (two-sided) α of 0.05.

Continuous data were summarized by mean, median, standard deviation. Categorical data were summarized by counts and percentage. Parametric tests were used after evaluation of the normal distribution of the data to be analyzed. Student's *t*-test was used for continuous parametric variables, and the x^2test was used for categorical variables. The Mann-Whitney test was used for nonparametric data. Statistical significance was set at a *P* value of < 0.05.

Results

In total, 168 patients were initially identified and assessed for eligibility (Fig. 1). Of these, 72 were excluded: 40 because they did not

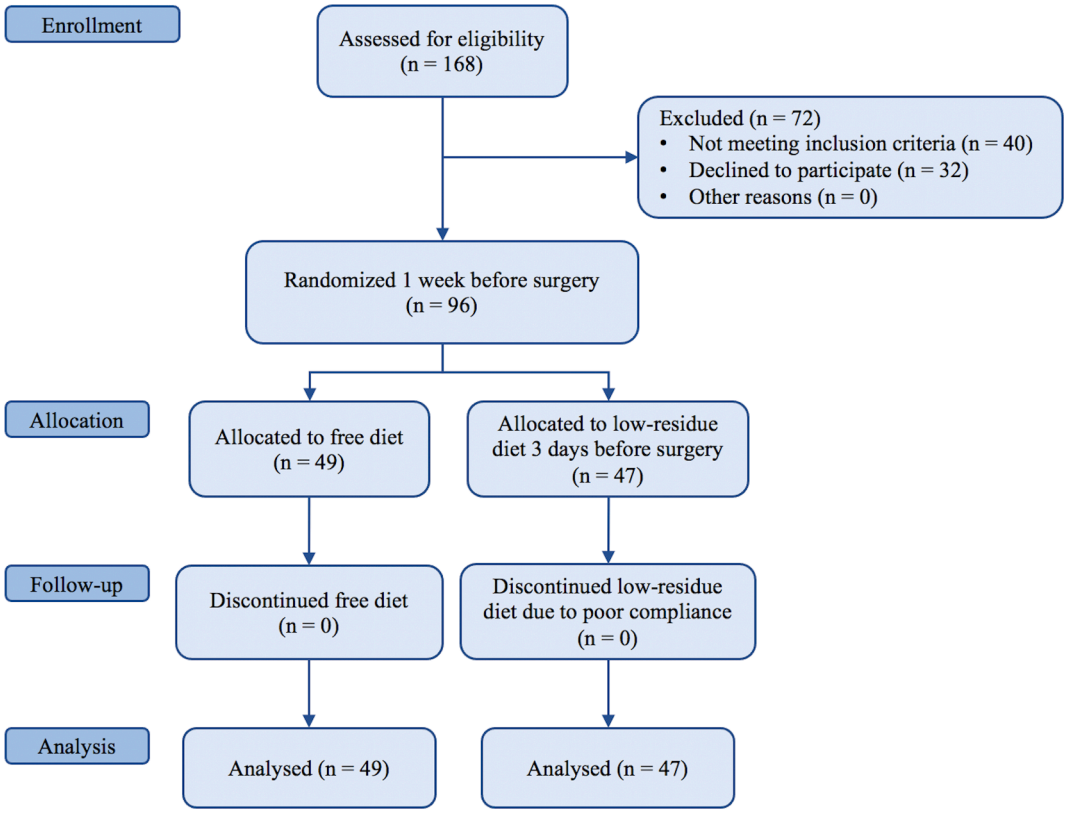

Fig. 1. CONSORT flow diagram.

meet inclusion criteria and 32 because they declined to participate to the study. One week before surgery, 96 patients were randomized either to free diet arm A (49 patients) or low-residue diet arm B (47 patients).

Patient characteristics are detailed in Table 3. Demographic and clinical data were similar between the two arms. Briefly, the mean age was 47.8 ± 15.6 years in arm A and 48.1 ± 11.3 years in arm B (p = 0.778). Endometrial cancer patients were 16.3% in arm A and 10.6% in arm B, and patients with benign disease were 83.7% and 89.4%, respectively. The presence of ovarian cysts was the most frequent surgical indication, being 42.9% and 42.6%, respectively, in arm A and arm B, followed by leiomyomas, being 24.5% and 34.0%, respectively.

Table 3
Clinical characteristics of enrolled patients.

Variable	Low-residue diet n = 49	Free diet n = 47	*p* value
Age (years)			0.778
Mean ± SD	47.8 (15.6)	48.1 (11.3)	
Median (range)	47 (37; 58)	48 (40; 54)	
Weight (kg)			0.430
Mean ± SD	64 (13.4)	61.6 (16.0)	
Median (range)	60 (54; 68)	58 (50; 70)	
Height (cm)			0.753
Mean ± SD	161.9 (6.4)	162.1 (5.8)	
Median (range)	160 (158; 166)	160 (159; 167)	
BMI (kg/m^2)			0.600
Mean ± SD	24.1 (4.9)	23.5 (6.3)	
Median (range)	24 (20; 26)	22.6 (21; 31)	
Disease			0.612
Endometrial cancer	8 (16.3%)	5 (10.6%)	
Benign disease	41 (83.7%)	42 (89.4%)	
Ovarian cyst	21 (42.9%)	20 (42.6%)	
Leiomyomas/Fibromatosis	12 (24.5%)	16 (34.0%)	
Endometrial cyst	4 (8.2%)	2 (4.3%)	
Endometriosis	3 (6.1%)	1 (2.1%)	
PID	1 (2.0%)	1 (4.2%)	
Comorbidity			
Hypertension	10 (20.6%)	9 (19.1%)	1.000
Diabetes	0	3 (6.5%)	0.226
Thyroid disease	7 (14.3%)	12 (25.5%)	0.260
Previous neoplasms	4 (7.5%)	2 (4.3%)	0.712
Depression	0	2 (4.3%)	0.457
Other	12 (24.5%)	15 (31.9%)	0.561

BMI, body mass index; PID, pelvic inflammatory disease; NS, not significant; SD, standard deviation.

Intraoperative surgical data are summarized in Table 4. No major intraoperative complications were reported. The surgical evaluation of the small intestine was scored < 3 in 2.0% of arm A patients versus 31.9% in arm B (Odds Ratio (OR), 0.04 [95% CI, 0.01–0.35]; p < 0.001), and for large intestine, respectively, in 6.1% and 44.7% (OR, 0.08 [95% CI, 0.02–0.30]; p < 0.001). The mean operative time was 90.4 ± 33.4 min in arm A versus 111.6 ± 37.5 in arm B (Mean Difference (MD): −21.20 [95% CI, −35.43, −6.97]; p = 0.003).

Postoperative surgical data and complications are detailed in Table 5. No significant differences in terms of postoperative complications and length of hospital stay were observed between the two groups. The mean time to first passage of flatus was 20.9 ± 11.1 in arm A and 23.4 ± 8.9 in arm B (MD: −2.50 [95% CI, −6.52, 1.52]; p = 0.220). The number of patients who reported the time to first flatus within 24 h after surgery was significantly higher in arm A compared with arm B (77.6% vs 44.7%; OR, 4.28 [95% CI, 1.77–10.35]; p = 0.002). Postoperative nausea/vomit and pain were similar between the two arms. However, the analgesic request was marginally lower among arm A patients compared with arm B (4.1% vs 17.1%; OR, 0.21 [95% CI, 0.04–1.03]; p = 0.060).

Discussion

The idea of a study comparing a free preoperative diet with a low-residue diet started three days before surgery arose from the belief that some perioperative parameters both related to the patient (pain, nausea/vomiting, time to first passage of flatus) and to the surgeons

Table 4
Intraoperative variables and quality of the surgical field.

Variable	Low-residue diet n = 49	Free diet n = 47	*p* value
Surgical procedure			
MSO/BSO	25 (51.0%)	21 (44.7%)	0.530
Hysterectomy ± BSO	17 (34.7%)	16 (34.0%)	0.951
Myomectomy	6 (12.2%)	7 (14.9%)	0.700
Other	1 (2.1%)	3 (6.4%)	0.314
Surgical approach			
LPS	22 (44.9%)	24 (51.1%)	0.550
LPT	16 (32.7%)	14 (29.8%)	0.761
LAVH	6 (12.2%)	4 (8.5%)	0.550
LPS + LPT	5 (10.2%)	5 (10.6%)	0.941
Preoperative Hb (g/dl)	12.7 (1.1)	12.8 (1.4)	0.407
Mean ± SD	12.8 (12.1; 13.6)	13.1 (11.7; 13.7)	
Median (range)			
Postoperative Hb (g/dl)			0.128
Mean ± SD	11.1 (1.4)	11.3 (1.2)	
Median (range)	10.9 (10.3; 11.9)	11.6 (10.6; 12.3)	
Operative time (min)			0003
Mean ± SD	90.4 (33.4)	111.6 (37.5)	
Median (range)	80 (60; 120)	105 (82; 140)	
Quality of the surgical field			
Small intestine			<0.001
Score < 3	1 (2.0%)	15 (31.9%)	
Large intestine			<0.001
Score < 3	3 (6.1%)	21 (44.7%)	

BSO, bilateral salpingo-oophorectomy; LAVH, laparoscopic-assisted vaginal hysterectomy; LPS laparoscopy; LPT, laparotomy; MSO, monolateral salpingo-oophorectomy; NS, not significant; SD, standard deviation.

Table 5
Postoperative variables and complications.

Variable	Low-residue diet n = 49	Free diet n = 47	*p* value
Postoperative complications	4 (8.2%)	1 (2.1%)	0.136
Fever/Infection	1 (2.0%)	0	
Anemia	2 (4.1%)	1 (2.1%)	
Reoperation	1 (2.0%)	0	
Time to first flatus			0.002
< 24 h	38 (77.6%)	21 (44.7%)	
PVAS 12 h			0.348
Mean ± SD	2.9 (2.1)	2.9 (1.5)	
Median (range)	2 (2; 4)	3 (2; 3)	
PVAS 24 h			0.309
Mean ± SD	3.6 (2.8)	2.7 (1.8)	
Median (range)	2 (1; 6)	2 (2; 4)	
PVAS 48 h			0.502
Mean ± SD	1.8 (1.8)	2.0 (1.6)	
Median (range)	1 (0; 3)	2 (1; 3)	
NVAS 24 h			0.640
Score < 3	46 (93.9%)	46 (97.9%)	
Days of hospital stay			0.091
Mean ± SD	3.1 (2.1)	2.5 (1.0)	
Median (range)	3 (2; 3)	2 (2; 3)	
Analgesic request	2 (4.1%)	8 (17.0%)	0.060

NVAS, nausea visual analog scale; PVAS, pain visual analog scale; SD, standard deviation.

(quality of the operating field) could be modified with a very minimal intervention [11,12]. The results of this study are rather encouraging, since either the surgical evaluation of the operative field, the operative time and the canalization time were significantly better in patients subjected to preoperative low-residue diet compared with free diet. Furthermore, although no significant differences in terms of post-operative complications and hospital stay were observed between the two groups, we reported a trend towards a lower analgesic request in patients receiving a low-residue diet before surgery and this is probably due to the reduced canalization time and operative time.

This is the first study assessing the efficacy of a simple and non-invasive approach, i.e., pre-operative low-residue diet, in improving the perioperative outcomes of gynecological surgical patients. The limitations include the small sample size and the intrinsic bias related to surgeon-dependent and patient-reported outcomes.

Literature evidence on preoperative low-residue diet mostly derives from the colorectal surgery. The European Society of Gastrointestinal Endoscopy (ESGE) recommends a normocaloric low-residue diet on the day preceding colonoscopy [9] as it has demonstrated to be the most effective approach to bowel preparation in colorectal cancer screening colonoscopy [13]. Few studies have been published in the field of gynecological surgery. In 2009, Lijoi et al. showed that, when compared with MBP, preoperative low-residue diet before laparoscopic gynecological surgery provided similar quality of surgical field exposure and was better tolerated by patients, thus increasing compliance [14]. The quality of the surgical field was evaluated as “good” or “excellent” in 69% women in the low-residue group and 75% in the MBP group (p = 0.697) and the patients’ compliance was adequate in 86% and 68%, respectively. In 2013, Won et al. reported that fasting only without any preoperative diet or MBP was a preferable alternative for laparoscopic gynecological surgery, given the greater compliance of the patients [15]. Unlike ours, these studies evaluated only the laparoscopic approach and considered the MBP or fasting as references instead of the free diet.

Since the introduction of evidence-based medicine into routine clinical practice, several traditional procedures have been abandoned in favor of more valid clinical behaviors. Even if the role of MBP is still controversial, studies have failed to identify the benefit of this procedure in reducing the risk of infection and improving visualization and management of surgical field [16,17]. In light of these data, no patient was submitted to MBP in the present study. The aim and results of this study are also part of a historical moment that gives particular attention to the improvement of perioperative care pathways, aiming to optimize post-operative recovery, minimize patient discomfort and reduce complications. Indeed, the ERAS program has been proposed and continues to be implemented in many institutions.

The ERAS program was designed as a multidisciplinary perioperative protocol to reduce the time of hospital stay after colorectal surgery, and it is based on: pain reduction; stress reduction with local anesthesia, early enteral nutrition, early postoperative mobilization, single dose of preoperative antibiotic prophylaxis, limited preoperative fasting, early administration of fluids in the postoperative time, presence of post-operative drainages, early removal of urinary catheters, administration of antiemetics; discharge criteria [18–21]. Since the review of the literature published by Kehlet et al. [22], several centers have published their clinical experiences and the outcomes of ERAS programs on colorectal, gynecological, and gynecological-oncological surgery.

Starting an ERAS program requires constant effort by the entire operating team. The benefits of these efforts are well established, with most clinical units now reporting steadily reductions in healthcare costs and complications [23]. More and more centers are now showing interest in the development of the ERAS program. Our hope is that this set of recommendations will help to bridge the gap that often exists when trying to translate guidelines into clinical practice.

Conclusion

The present study provides evidence that starting a low-residue diet three days before gynecological surgery could improve the quality of surgical field and reduce both the operative duration and the time to first passage of flatus when compared with free-diet. Implementing an adequate diet according to the patient clinical characteristics and the medical objectives may help to improve everyday surgical practice. Both preoperative and postoperative diets should be introduced as part of a perioperative management protocol. Larger and well-designed studies are needed to confirm these findings.

CRediT authorship contribution statement

Innocenza Palaia: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **Violante Di Donato:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **Giuseppe Caruso:** Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Annarita Vestri:** Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Maria Scudo:** Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Danilo Alunni Fegatelli:** Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Valerio Galli:** Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Alessandra Cavalli:** Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Giorgia Perniola:** Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft, Writing – review & editing. **Pierluigi Benedetti Panici:** Project administration, Validation, Supervision, Writing – review & editing. **Ludovico Muzii:** Project administration, Validation, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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