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Randomized Control Trials

Controlled enteral nutrition in critical care patients – A randomized clinical trial of a novel management system

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SUMMARY

Purpose: Nutritional therapy is essential to ICU care. Successful early enteral feeding is hindered by lack of protocols, gastrointestinal intolerance and feeding interruptions, leading to impaired nutritional intake. smART+ was developed as a nutrition management feeding platform controlling tube positioning, reflux, gastric pressure, and malnutrition. This study evaluated the potential of this new ICU care platform to deliver targeted nutrition and improve ICU outcomes.

Methods: Critically ill patients ≥18 years-old, mechanically ventilated and enterally fed, were randomized to receive ESPEN-guideline-based nutrition or smART+ -guided nutrition for 2–14 days. Primary endpoint was average deviation from daily targeted nutrition determined via calculation of energy targets per calorimetry. Secondary endpoints included gastric residual volumes, length of stay (LOS) and length of ventilation (LOV).

Results: smART+ achieved a mean deviation from daily targeted nutrition of 10.5% (n = 48) versus 34.3% for control (n = 50), p < 0.0001. LOS and LOV were decreased in the smART+ group versus control (mean LOS: 10.4 days versus 13.7; reduction 3.3 days, adjusted HR 1.71, 95% CI:1.13,2.60, p = 0.012; mean LOV: 9.5 days versus 12.8 days reduction of 3.3 days, adjusted HR 1.64, 95% CI:1.08–2.51, p = 0.021). Feeding goals were met (within ±10%) on 75.7% of days for smART+ versus 23.3% for control (p < 0.001). No treatment-related adverse events occurred in either group. The study was stopped due to success in a planned interim analysis of the first 100 patients.

Conclusion: The smART+ Platform improved adherence to feeding goals and reduced LOS and LOV versus standard of care in critically ill patients.

Trial registration: NCT04098224; registered September 23, 2019.

1. Introduction

Enteral nutrition in critically ill patients has been guided by international recommendations regarding timing and progressive energy/protein goals [1–3]. However, technology used to deliver enteral nutrition has not advanced in decades, is reliant on manual adjustment, suffers from lack of personalization and precision, and features frequent interruptions [4–6]. Gastrointestinal intolerance and significant underfeeding for prolonged periods in the ICU are common outcomes [6–8].

A new technology platform has been developed with the aim of overcoming the established limitations of traditional enteral feeding in critical care. The smART+ Platform (ART MEDICAL, Netanya, Israel) is a nutrition management system designed for use in the intensive care unit (ICU). The smART+ Platform comprises a control unit that runs the nutritional management software directed via a dual-port delivery feeding pump. The system also includes disposable treatment kits that include a smart nasogastric

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tube (NGT) with impedance sensors that assist tube localization and detect subsequent tube movement and also reflux episodes, a VCO_2 module for resting energy expenditure (REE) measurement, a residual bag to weigh gastric content expelled during reflux episodes, feeding delivery sets and a smART+ urine bag.

The smART+ design enables detection of both minor and massive reflux, which can be controlled and managed via pausing feeding, inflation of an esophageal balloon and reducing gastric pressure respectively. The duration of balloon inflation and expelled gastric content is tuned to ensure that reflux does not reach the oropharynx area, which would otherwise result in aspiration.

Recognizing the importance of reflux, the NGT is also used to control gastric feeding. Missing energy and proteins that have been discarded or missed due to procedures are gradually fed back to the patient as fresh feeding material (compensation) and paced throughout the duration of the planned feeding program (usually 24 h). Thus, the system is designed to deliver almost all of the planned nutritional load. A diagram of the smART Platform is shown in Supplemental Fig. 1. The design of the NGT is shown in Supplemental Fig. 2.

This study reported here was designed to compare the feeding efficiency of the smART+ Platform versus standard-of-care nutrition in critically ill patients planned to stay more than 48 h in the ICU with early enteral feeding, and to evaluate how feeding optimization impacts patient outcome. Safety assessments were also conducted.

2. Methods

2.1. Trial oversight

The study (NCT04098224), conducted between September 2019 and February 2022, was a sponsor-initiated and funded (ART MEDICAL Ltd), single-center, randomized, unblinded, prospective trial conducted in the ICU of the Rabin Medical Center. The trial protocol, written by the investigators and the sponsor (see Supplemental material), was approved by the Rabin Medical Center Review Board. An independent data and safety monitoring board and the study statistician provided study oversight. The trial was conducted in accordance with the principles of the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice Guidelines. The authors confirm responsibility for the accuracy and completeness of the data, analyses, and report.

2.1.1. Patients

Patients ≥18 years-old admitted to the ICU were eligible for inclusion if they were receiving mechanical ventilation planned for ≥48 h, were about to commence or had commenced naso-orogastric enteral nutrition within the past 48 h. Patients were excluded if death was considered imminent. Patients were also excluded for pregnancy and abnormalities of the feeding canal from nose/mouth to stomach that could have hindered placement of the NGT.

All patients provided informed consent, or, in cases of sedation, consent was provided by an independent physician and post-hoc personal consent was provided on regain of consciousness.

2.1.2. Trial procedures

Patients were allocated, in a 1:1 ratio, using a computerized randomization program to receive nutrition as European Society for Clinical Nutrition and Metabolism (ESPEN)-defined standard-of-care [2] or via the smART+ Platform. The block randomization was stratified according to APACHE (Acute Physiological And Chronic Health Evaluation) II score [9].

The smART Platform was configured according to the description in the Introduction. Missing calories and protein were compensated over 24 h as 50% and 100% of the total measured losses for gut and procedural losses respectively. EE was calculated according to the Weir formula ($REE = [3.9(VO_2) + 1.1\ (VCO_2)]1.44$) [10]. In the absence of an oxygen sensor, constant respiratory quotient was assumed as $RQ = VCO_2/VO_2$ with 0.89 as default. For control of massive reflux, feeding halt was initiated, gastric pressure released, and NGT balloon was inflated to 30 mmHg for ≤5 min. Position of sensors and balloon is shown in Supplemental Fig. 2.

Control nutrition was regulated using indirect calorimetry (Q-NRG, Cosmed, Rome, Italy) [11] and a polyurethane naso-gastric tube connected to a peristaltic pump (Kangaroo, Cardinal Health, USA). Gastric residues in the control group were evaluated periodically and weighed.

For both treatment groups, nutritional targets were set according to ESPEN guidelines [2] at 30%, 50% and 70% for Days 1, 2 and 3 respectively. Enteral feeding formulas included Peptamen A/F (Nestle, Switzerland), Jevity, Nephrocare and Glucerna (Abbott, USA). In the control group, the formula was chosen from the above selection by the treating physician. For the smART+ group, the formula was selected by the care team according to calculated energy and protein requirements that factored protein and energy deficits prioritized by the control software.

2.2. Outcomes

The primary endpoint was average deviation from the daily feeding target between Days 2–14, defined as mean 100 × absolute value of (net nutrition delivered (mL) − volume to be delivered (VTBD; mL)/VTBD) % over all study days other than those when enteral feeding was stopped on medical order. In calculating this mean, partial feeding days (e.g. on day of discharge from ICU) were down-weighted accordingly. The value for net nutrition delivered takes into account the amount of gastric residual volume (GRV) expelled into a collection bag.

GRV, VTBD, energy requirements, energy administered, insulin requirements, prokinetics requirements and ICU mortality were collected daily up to 14 days follow-up, discharge, or death. Ventilation Associated Events (VAE) were defined per the Centers for Disease Control (CDC) as elevations of Fraction of Inspired Oxygen (FIO_2) >0.2 or Positive End-Expiratory Pressure (PEEP) > 3 cm H_2O) [12].

Baseline characteristics were collected at the time of randomization, including APACHE II and Sequential Organ Failure Assessment (SOFA) scores. At the end of the feeding period, ICU Length Of Stay (LOS; admission to decision to discharge), length of ventilation (LOV; defined as number of hours of end-tidal CO_2), and results of an adverse event questionnaire were collected.

Participation to the study was ended if the patient reached 14 days of participation, if the patient was transferred to a different ward, if consent was withdrawn, if a related adverse event was observed or in case of death. All except two patients who completed less than 2 days of participation were included in the intent-to-treat (ITT) analysis but not in the per protocol (PP) analysis. The exceptions were 1. a patient who was discovered to have COVID-19 on the first day of participation, was withdrawn from the ICU, and 2. a patient who could not be connected to the smART+ Platform despite several attempts; neither of these patients provided any data on the primary endpoint.

Feeding tube placement was verified via the smART+ feeding tube sensors and further verified by x-ray in the study group. Replacement of feeding tube was allowed in case of feeding tube blockage, alarm or warning related to the tube according to the use

manual, medical decision, routine procedures such as need for gastroscopy or placement of an additional duodenal tube. After replacing the tube, the patient remained on study. The control group was fed with a standard nasogastric tube.

2.3. Statistical analysis

The study was designed to detect an effect size of 0.45 for n = 100 patients per group (N = 200 total enrollment) using a two-group test with a 0.05 two-sided significance level. A single interim analysis was planned after 100 patients. In the event, the trial was stopped after this analysis because the primary outcome showed a highly statistically significant benefit to the smART+ group (see Results section). Even though no statistical stopping guidelines had been written in the protocol, the level of significance was so strong that any commonly-used guideline (e.g. Pocock $p < 0.0294$ [13]; Haybittle-Peto $p < 0.001$ [14]; O'Brien-Fleming $p < 0.0051$ [15]) would have led to the recommendation to stop.

The primary endpoint was compared between the two treatment groups using a non-parametric Wilcoxon rank sum test, since the distribution of average feeding deviation was somewhat skewed. The proportions of feeding days with feeding deviation less than 10%, 10–20%, 20–40% and >40% in each group were estimated and compared using a multinomial random effects logistic regression model that accounted for the differing days of stay in the ICU for each participant. This was implemented using the R *mlogit* package. LOS and LOV were compared between the treatment groups, unadjusted, and also adjusting for age, gender, APACHE II, weight, and reason for admission, using a Cox proportional hazards model. All tests were conducted at a two-tailed, 5% significance level.

Data on feeding deviation were analyzed using R v4.1.0 [16], and other data using SAS v9.4 or higher (SAS Institute, Cary North Carolina). Analyses were repeated for both the intent-to-treat (ITT) and per protocol (PP) populations; only the ITT analyses are reported here.

3. Results

3.1. Characteristics of the patients

The CONSORT diagram of patient flow is shown in Supplemental Fig. 3. The study did not complete enrolment because of statistical power on the primary endpoint was met at n = 100 enrolled (n = 50 per treatment group). Demographic and baseline characteristics are shown in Table 1. There were no clinically meaningful differences between treatment groups; however, there was a statistically significant difference in EE ($p = 0.001$). Most patients (40 smART+ and 41 control) were admitted for medical reasons. Others were admitted for trauma (nine control and seven smART+) or post-surgical complications (three smART+ only).

Energy target and energy delivered are shown in Table 2. The energy delivered do not show a significant difference between the 2 groups.

Mean feeding deviation (±SD) between days 2–14 (primary endpoint) was 10.5% (±13.0) for smART+ group (n = 48) versus 34.3% (±18.0) for the controls (n = 50) ($p < 0.0001$) (Table 3). The proportion of days with feeding delivery within 90–110% of target was 75.7% for smART+ versus 23.3% for control ($p < 0.0001$; Fig. 1). Within the control group, on a large proportion (29.1%) of the total feeding days there was a major deviation (either >140% or <60%) from the nutritional plan. These deviations were rare in the smART+ group (4.8%). Total days of feeding was 313 days for smART+ versus 462 days for control (Fig. 1 and Supplemental Table 1), the difference being linked to the difference in length of stay (see below).

The frequency of over-feeding and, in particular, the magnitude of under-feeding were improved for smART+ versus control (Table 3). In the smART+ group, over-feeding occurred in only 1 patient whose nutrition delivery was just 2.7% above target. For control patients, n = 13 patients were over-fed by a mean (±SD) of 33.7 ± 17.0%. For underfeeding, corresponding values were n = 47, 10.6 ± 13.1% for smART+ versus n = 37, 34.5 ± 18.6% for control. Substantial deviations from feeding targets were rare in the early days of admission for patients receiving smART+ nutrition, but deviations were evenly spread throughout ICU stays for control patients (Supplementary Table 2).

ICU length of stay (LOS) was substantially reduced (mean 10.4 days versus 13.7, reduction 3.3 days; unadjusted hazard ratio [HR] 1.53, $p = 0.036$ (Fig. 2); adjusted hazard ratio [HR] 1.71, 95%CI: 1.13–2.60, $p = 0.012$). Length of ventilation (LOV) was also reduced (mean 9.5 days versus 12.8 days, reduction of 3.3 days; unadjusted HR 1.45, $p = 0.065$ (Fig. 2); adjusted HR 1.64, 95% CI: 1.08–2.51, $p = 0.021$). SOFA scores, daily insulin requirements and mean daily fluid administered were not significantly different between the treatment groups at any time during the study (Supplementary Table 3).

3.1.1. Safety

The smART+ feeding tube was inserted successfully into all but one patient without any adverse effects or related complications. No obstruction of the tube was observed. All the patients fed with the smART + feeding tube terminated the trial. Similar sedation and analgesia were administered to the 2 groups (Table S4 of the Supplemental material). Daily total and maximal gastric volumes were significantly decreased in for smART+ compared with control (Supplemental Fig. 4; $p < 0001$). Minor and massive reflux events peaked at Day 6 (Fig. 3). Use of metoclopramide was significantly reduced for smART+ (2 days) versus control (25 days; odds ratio

Table 1
Demographic and baseline characteristics (ITT population).

Parameter	smART+						Control					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Age, years	50	59.4	17.5	25.0	62.0	92.0	50	62.1	16.0	24.0	66.0	97.0
Weight, kg	50	86.7	22.2	30.0	86.0	158.0	50	84.2	23.3	57.0	78.5	164.0
Height, m	50	1.72	0.08	1.55	1.67	1.87	50	1.69	0.08	1.55	1.70	1.85
BMI, kg/m^2	50	29.2	7.3	12.5	28.9	48.8	50	29.5	8.8	19.6	27.1	68.3
APACHE II	50	22.4	6.9	10.0	22.0	36.0	50	22.3	7.0	9.0	22.0	36.0
SOFA	50	8.36	3.36	3.00	8.00	17.00	50	8.82	3.35	3.00	9.00	19.00
Time to ICU admin., hours	50	24.5	11.7	6.0	20.5	47.0	50	28.3	11.4	0.8	29.5	46.0
REE	47	1725	390				45	2028	514			

APACHE II, Acute Physiology and Chronic Health Evaluation II; BMI, body mass index; ICU, intensive care unit; Max, maximum, Med, median; Min, minimum; REE resting energy expenditure; SD, standard deviation; SOFA, Sequential Organ Failure Assessment.

Table 2
Daily prescribed and delivered energy in the study and the control group in Kcal/d. Nb Pts is the number of patients in the specific day.

Date	Study Group					Control group				
	Nb Pts	Prescribed	SE	Delivered	SE	Nb Pts	Prescribed	SE	Deliered	SE
D1	45	542	46	501	53	47	1161	66	804	57
D2	45	1145	85	1081	90	47	1363	68	1182	64
D3	44	1245	92	1134	95	47	1421	64	1167	82
D4	39	1259	92	1134	95	43	1449	78	1270	86
D5	35	1297	104	1107	99	40	1510	71	1326	93
D6	33	1405	103	1356	118	39	1655	71	1344	92
D7	29	1274	135	1154	135	37	1813	67	1321	99
D8	21	1354	138	1241	138	34	1871	66	1315	108
D9	16	1414	225	1310	229	34	1878	66	1092	115
D10	12	1508	225	1368	253	29	1761	90	1087	120
D11	9	1670	219	1520	174	22	1818	79	1404	119
D12	7	1347	353	1174	301	21	1853	88	1475	111
D13	4	1524	317	1492	344	19	1926	114	1578	98
D14	4	382	146	389	135	18	1988	71	965	160

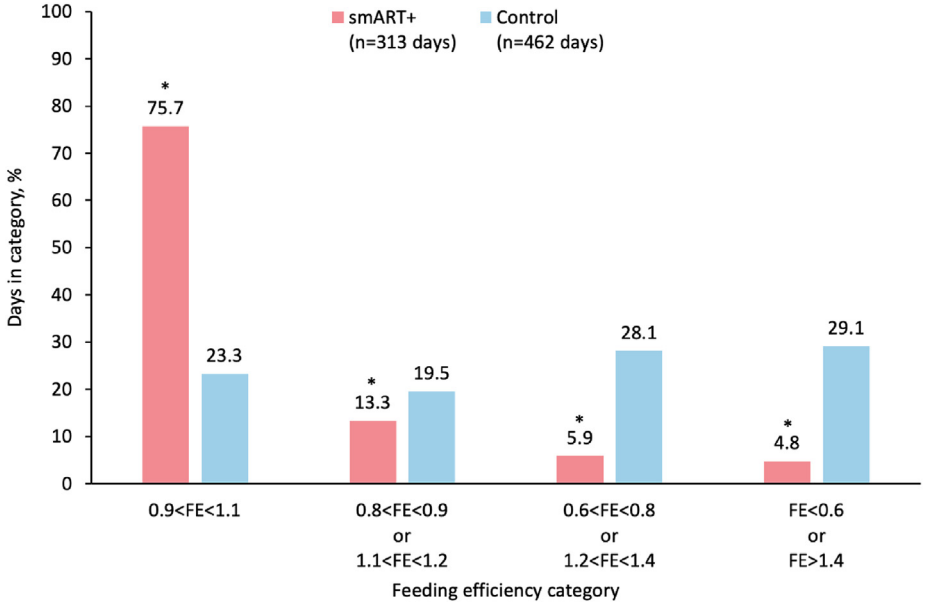

Fig. 1. Categorical analysis of daily feeding deviation from targeted nutrition. From left to right, categories represent increasing deviations below and above target FE; additional detail is provided in Supplemental Table 1. Percentages estimated from a random effects multinomial logistic regression model. *p < 0.0001 versus control; FE, feeding efficiency.

Table 3
Overfeeding and underfeeding in the treated (smart+) and control groups, expressed as average percent feeding deviation from feeding target.

Over/underfeeding	Deviation from 100% FE								
	Group	N	Mean	SD	LCL	UCL	Min	Median	Max
Overfeeding (average FE > 100%)	Treated	1	2.7	–	–	–	–	–	
	Control	13	33.7	17.0	24.4	42.9	10.1	32.1	72.8
	All	14	30.7	18.3	21.8	41.1	2.7	30.7	72.8
Underfeeding (average FE ≤ 100%)	Treated	47	10.6	13.1	6.9	14.4	0.0	6.3	70.7
	Control	37	34.5	18.6	28.5	40.5	16.0	34.3	119.3
	All	84	21.1	18.3	21.8	41.1	0.0	17.8	119.3
All	Treated	48	10.5	13.0	6.8	14.1	0.0	6.1	70.7
	Control	50	34.3	18.0	29.3	39.3	10.1	33.9	119.3
	All	98	22.6	19.7	18.7	26.5	0.0	18.9	119.3

FE, feeding efficiency; LCL, lower confidence level; Max, maximum; Min, minimum; SD, standard deviation; UCL, upper confidence level.

0.093, 95%CI 0.022–0.396; p < 0.002). Erythromycin and noradrenaline use were not significantly different between groups (data not shown).

Deployment of the balloon did not result in any instances of esophageal bleeding. Five patients developed a VAE in the control group (four during the study period and one after) and only one in the smART+ group (Fig. 3). ICU mortality was similar in the two treatment groups (9 of 50 patients [18%] smART+ group and 6 of 50 [12%] in the control group; p = 0.40). Mortality did not modify improvements in LOS and LOV. In the smART+ arm, LOS and LOV in

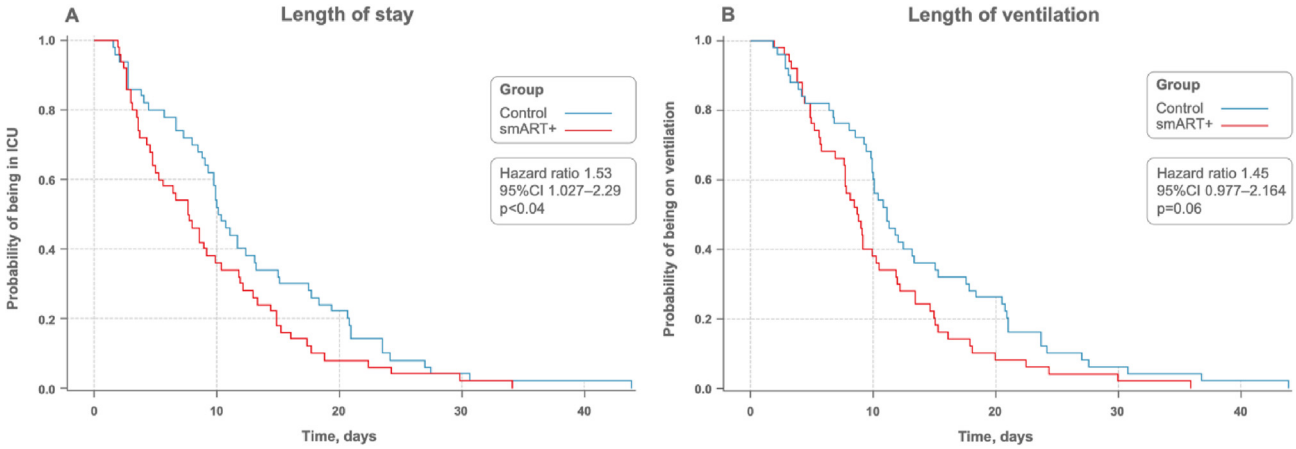

Fig. 2. Kaplan–Meier analysis of probability of being in the ICU (A) and being on ventilation (B) over time. Unadjusted data. CI, confidence interval; ICU, intensive care unit.

ICU were found to be very similar in patients who died versus those who did not. Therefore, the trend for shorter LOS and LOV in the treated arm compared to the control arm is not dependent on mortality.

4. Discussion

The present study shows that the smART+ Platform can significantly improve feeding efficiency versus standard-of-care ESPEN-based feeding protocols. Average feeding deviation over Days 2–14 of the ICU stay was around 10% for smART+ versus over 30% for control patients. Nutrition goals across the whole ICU stay were successfully reached in 75% of days on smART+ versus approximately 25% for control. The degree of difference between the two groups on the primary endpoint led to the study being stopped at 50% of planned enrollment.

The core principle of the smART+ Platform is to deliver maximal feeding efficiency by detecting and reacting to gastric intolerance in real time. The clinical implications of unmanaged gastric intolerance are widely documented. The incidence of feeding intolerance and large gastric residual volume has been estimated at greater than 60%, and inadequate enteral feeding may occur in more than 30% of cases [17]. A post hoc analysis of the TARGET study (n = 3876) showed that patients with any episode of GRV >250 mL had significantly more diarrhea and constipation, a lower energy intake but also more bacteremia, longer LOV, longer LOS and higher mortality compared with GRV <250 mL [6]. These results confirmed results of an earlier retrospective study in 3959 ICU patients whereby gastrointestinal failure had a similar impact on outcomes [18]. For the smART+ Platform, the combination of EE data, delivered volume reflux and GRV values (managed by a single system) may reveal the possibility that gastric intolerance occurs in

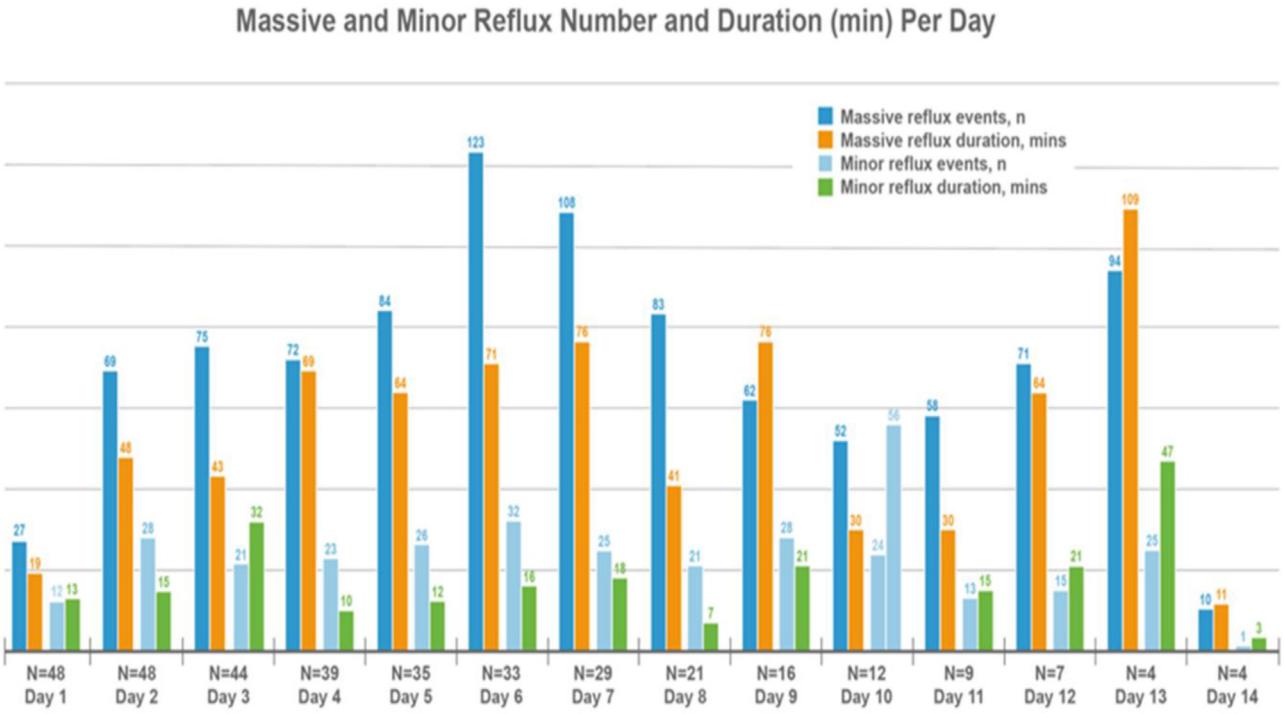

Fig. 3.

'windows' within which effective management can bring it under control. Manual management of GRV and reflux may miss these windows, and result in an overall decrease in nutritional delivery versus that achievable with a dynamic, controlled management ed system.

There are several causes and negative consequences of inadequate enteral intake. From a review of 30 published articles, Kim et al. found that factors causing inadequate enteral nutritional intake include delayed initiation of enteral feeding, slow increase of influx rate, under-prescription, incomplete delivery of planned nutrition, and frequent interruption of the feeding process [19]. Interruptions were caused by diagnostic testing, gastrointestinal intolerance, surgical procedures, issues with feeding tubes, and nursing tasks [19]. The smART+ Platform addresses many of these problems. Firstly, the system is designed to prevent delayed initiation of enteral feeding by assisting in tube positioning, continuously calculating an appropriate energy goal and supporting the physician in selecting the right feeding formula practice. As discussed, the smART+ Platform enables energy goals to be met in the majority of patients; but even with this system, some interruptions are unavoidable. However, when they do occur, the system calculates the resulting deficit and delivers gradual compensation so that planned nutrition is delivered close to 90%. There is also minimal need for manual feeding stops and manual assessment of GRV. Taken together, these features of the smART+ Platform have the potential to reduce nursing time consumed by management of under-performing feeding protocols.

Feeding intolerance is chiefly defined by large GRV (100 mL −>500 mL) or inability to reach nutritional goal [20]. However, GRV levels and outcomes do not appear to be related. In the NUTRIREA 1 study, Reignier et al. (2013) showed that monitoring GRV did not result in any clinical advantage over no monitoring at all [21]. Elke et al. (2015) summarized the pros and cons of measuring gastric residual volume, leaving us with the comment that "GRV should still be regarded as one piece in the puzzle of monitoring GI function" [22]. The smART+ Platform has the potential to offer new insight into the relevance of GRV by replacing manual assessment with a system that offers nutrition management of both minor and massive reflux events, while simultaneously recording event number, duration, and severity. This has the potential to turn the discussion on relevance of GRV on its head by offering an entirely new means of securing nutrition supply by micro-managing GRV in a way not previously possible.

The second major finding of the present study is the significant, approximately 3 days mean reduction in LOS and LOV in the smART+ group versus control. This was associated with decreases in the incidence of VAE for the system versus control. Micro-aspiration of gastric contents is a frequent consequence of reflux and may increase the risks of larger-scale aspiration and extend LOV [23]. A previous study using an early generation of the smART+ Platform demonstrated a high rate of minor and major refluxes mainly due to changes on tube position and tracheal suction [24]. In the present study, the number and duration of the massive and minor refluxes was comparable to the previous study, but evolution of the smART+ Platform to include the anti-reflux balloon deployed in instances of temporary blockage of the reflux backflow reduced risk of aspiration, released gastric pressure release and controlled reflux evacuation. Overall, this reduced the duration and severity of reflux events versus control.

The management of enteral feeding using a controlled management system may be beneficial to reduce the risks of aspiration. This may explain the reduction in LOS and LOV observed in the study group. The smART+ Platform improves gastric tolerance over control, and an association has been identified between feeding intolerance (FI) and increase LOS and LOV among 22 studies subject to a systematic review [20]. The pattern of findings was varied whereby four studies found associations for feeding intolerance (FI) with both LOS and LOV [25–28]; three with LOS alone [29–31]; and two with LOV only [32,33]. Four additional studies failed to identify any association between FI and either LOS or LOV [20].

The present study has some limitations. As a single-center study, the findings should be confirmed in larger, more diverse patient populations with differing nutrition goals. The smART+ Platform is a major, multi-factorial diversion from standard-of-care feeding, so it has not yet been possible to determine the individual contribution of each feature to the improved outcomes. Another major limitation is the fact that the devices used to determine EE were inherently different between the two feeding groups. Therefore, no comparison between the 2 devices (Q NRG+ and smART + EE measurements) was performed. In addition, the smART + device was using the measurement of VCO2 only. Many studies have concluded that EE derived from VCO2 only were less accurate than from VO2 and VCO2 [34–36]. However, even if EE derived from VCO2 alone has been found more accurate than predictive equation [37], inaccuracy can reach 15% of the measurement and lead to inaccurate determination of the target. In this study, a consequence could be a large difference between the energy administered in the study group and the control group that benefited from a "gold standard" indirect calorimeter. Prescription of enteral feeding was performed similarly in both groups as a percentage of the calculated energy expenditure derived from measurements. Regarding this prescription we observed that the progression of feeding to goal was faster than advocated in the ESPEN guidelines. In the control group, the patients received approximately 40% (804/2028) of the measured EE on day 1, 58% on day 2, 57% on day 3 and 62% on day 4. In the study group they received 29% (501/1725) of the measured EE on day 1, 62% on day 2, 65% on day 3 and 64% on day 4. These prescriptions do not follow strictly the ESPEN guidelines and are related to the decision of the physician when planning the nutritional regimen according to the patient condition, underlining the challenge to follow strictly the ESPEN recommendations. In addition, as written previously, two different devices were used to determine the feeding energy target and since the feeding energy target of the study group was lower, this may explain the differences in outcome that were observed. Different feeding energy targets may induce underfeeding in one group and explain improved feeding efficacy and reduced length of stay and length of ventilation. In general standard of care, most of the energy prescribed are based on predictive equations and not on energy expenditure (EE) calculated from VO2 and/or VCO2 measurements [38]. Studies have shown the advantages of measuring REE and planning the energy intake accordingly [10,39]. Improved survival is associated with a calorie intake is at 70%−100% of EE, and even over-feeding can may be associated with increased mortality [40]. This underscores the importance of EE [41]. Finally, the new studied platform will induce increased costs. We did not perform cost effectiveness studies comparing the price of the platform to the reduction in expenses related to shorter length of stay. However, when more studies on this device will be available and will confirm the findings, it will be possible to evaluate the financial burden or advantages of the use of smART+.

In conclusion, the use of an enteral nutrition management system was associated with a high feeding efficiency and a low rate of under or over feeding in comparison to standard-of-care feeding protocols. This was associated with significant comparative decreases in GRV, and LOS. There were no safety concerns associated with the system.

Take-home messages (2 sentences)

The robot-guided smART+ enteral feeding is capable of delivering nutrition with an average deviation of only 10.5% from the targeted daily amount, compared to 34.3% on standard feeding protocols, and substantially reduces length of ventilation time and length of stay for patients in ICUs. The smART+ system has the potential to improve ICU outcomes and reduce ICU resource use in patients requiring enteral feeding and ventilation.

140-Character social media post

Robot-guided smART+ enteral feeding can maximise nutritional delivery and improve ICU outcomes.

Trial funding

This study was funded by ART MEDICAL Ltd.

Data sharing statement

Tables, listings and figures can be made available on reasonable request to the author for correspondence from the time of publication and in perpetuity.

Conflicts of interest

IK: Supported via institutional research funds for the concoct of the present study, which was funded by ART MEDICAL Ltd.

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IB: None.

LS: None.

GF: None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clnu.2023.06.018.

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