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Original Research

A Randomized Trial of Cardiac Catheterization With Fasting Versus Liberal Oral Intake: The CALORI Trial

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ABSTRACT

Background: Routine preprocedural fasting before cardiac catheterization remains common practice, despite a lack of robust evidence to support this practice. We investigated the impact of a liberal nonfasting strategy vs a standardized nil per os (NPO) regimen prior to cardiac catheterization.

Methods: Adult inpatients undergoing elective or urgent cardiac catheterization were randomized (1:1 ratio) to either NPO past midnight or ad libitum intake of liquids and solids (without dietary constraints) until immediately prior to the procedure. Only patients at high risk of aspiration or undergoing complex interventions were excluded. The primary end point was preprocedural patient-reported well-being scores (scaled 0-5, with 0 signifying absence of ailment and 5 the most extreme form), for variables including hunger, fatigue, anxiety, and nausea. A composite score summed the individual scores for hunger and fatigue. Other end points were periprocedural adverse events including emesis, aspiration, or intubation, in addition to postprocedural satisfaction.

Results: A total of 198 patients (65% male and 42% Black) were included in the final analysis. There were no differences in baseline characteristics between groups. Time from most recent oral intake (liquid or solid) to the start of the procedure averaged 148 minutes for the nonfasting group and 970 minutes for the NPO strategy ($P < .001$). The composite preprocedural well-being score was significantly better in the nonfasting arm (2.4 ± 2.4 nonfasting vs 6.0 ± 2.5 NPO; $P < .001$), as were the individual components of hunger (0.9 ± 1.5 vs 3.7 ± 1.5; $P < .001$), fatigue (1.5 ± 1.6 vs 2.3 ± 1.8; $P < .001$), and nausea (0.1 ± 0.5 vs 0.5 ±1.2; $P = .006$). There were no significant differences in adverse events between groups. Overall postprocedural satisfaction scores were significantly better in the nonfasting vs NPO group (0.3 ± 0.7 vs 1.0 ± 1.3, respectively; $P < .001$).

Conclusions: In this single-center randomized trial, a liberal nonfasting strategy prior to cardiac catheterization significantly improved patient well-being and satisfaction without compromising safety. Given the findings of this and other studies, routine fasting prior to cardiac catheterization should be reconsidered.

Introduction

Requiring patients be kept nil per os (NPO) prior to cardiac catheterization procedures is a common practice. This tradition is rooted in the premise that preprocedural fasting allows time for gastric emptying, which lowers the volume and acidity of gastric contents, thereby reducing the risk of regurgitation and pulmonary aspiration.[1] Modern preprocedural fasting theories and standards were established among patients undergoing elective surgery with anesthesia, and later extrapolated and applied to minimally invasive cardiac procedures. However, contemporary data suggest that indiscriminate fasting requirements, and particularly prolonged regimens such as "NPO after midnight," are outdated and potentially harmful to patients.[2–4]

Contrary to foundational theories rationalizing fasting, fasting duration is not correlated with residual gastric fluid volume or gastric pH.[5–8] Further, in a meta-analysis of randomized clinical trials, longer fasting times were associated with higher residual gastric fluid volumes and higher rates of aspiration.[5]

Although conventional fasting standards may be reasonable for certain patient subsets undergoing general anesthesia, the overall incidence of aspiration remains exceedingly low.[9,10] This calls into question the applicability to modern cardiac catheterization and minimally invasive

Abbreviations: HFrEF, heart failure with reduced ejection fraction; NPO, nil per os; NRS, numeric rating scale; PCI, percutaneous coronary intervention; RHC, right heart catheterization.

Keywords: cardiac catheterization; fasting; patient-reported outcomes.

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cardiac procedures, which almost exclusively use conscious sedation rather than general anesthesia, making aspiration events even more uncommon.[3] Current hypo-osmolar contrast agents are significantly less likely to cause nausea or vomiting than historical formulations, further lowering the risk. Although aspiration events are more likely with emergency procedures, current rates for percutaneous coronary intervention (PCI) conversion to emergency surgery are less than 0.1%.[3] In studies involving both elective[11] and emergent cardiac catheterizations[12] with minimal or no fasting requirements, there were no differences in clinical outcomes. Moreover, prolonged fasting prior to elective cardiac procedures may increase the chances of contrast-induced nephropathy, hypoglycemia, dehydration, and reduced patient satisfaction.[2]

Society guideline recommendations have evolved to reflect this evidence more appropriately, with the 2017 American Society of Anesthesiology guidelines allowing clear liquids up to 2 hours prior to the start of the procedure, a "light" meal up to 6 hours prior, and a "heavy" meal up to 8 hours prior for healthy patients.[2] Despite these updated guidelines, mandatory prolonged preprocedural fasting requirements remain widely utilized, and fasting intervals often exceed the intended duration.[13,14]

Few studies have prospectively assessed the patient impact of a liberal nonfasting strategy vs a standardized NPO regimen prior to cardiac catheterization. Given the limited evidence to guide care, we conducted the Catheterization with Liberal ORal Intake (CALORI) trial, a randomized controlled trial comparing fasting after midnight vs ad libitum intake of liquids and solids immediately prior to cardiac catheterization.

Materials and methods

Study design and setting

This prospective randomized controlled trial was conducted at a single medical center in the United States between March and November 2023, following approval by the Virginia Commonwealth University Institutional Review Board (protocol HM20025962). The trial was registered at ClinicalTrials.gov (NCT05851872).

Participants

This study included inpatients aged 18 years and older who underwent elective or urgent cardiac catheterization (left heart catheterization, coronary angiography, PCI, right heart catheterization [RHC]) with planned conscious (moderate) sedation. Pregnant women, patients with body mass index greater than 45 kg/m^2, active gastrointestinal illness (including nausea), encephalopathy, dementia, or severe gastroesophageal reflux disease (requiring more than 1 medication for adequate gastroesophageal reflux disease control or requiring medical intervention within the past 1 year), as well as those scheduled for deep sedation, taking chronic pain medications at home, or on a current brief course of narcotics, were excluded. Patients requiring emergent procedures, all mechanical circulatory support–assisted procedures, hemodynamically unstable patients, and other high-risk procedures as identified by the operator were also excluded.

Potential eligible patients were screened for exclusion and inclusion criteria via the electronic medical record prior to the planned procedure. Once the eligible patient was identified, a member of the study group approached the patient regarding potential participation and provided a detailed description of the study. Written informed consent was then obtained from the patient prior to randomization.

Randomization and allocation

Patients were randomly allocated into 2 parallel groups (1:1 ratio), to either the NPO or nonfasting group. Each group was further stratified by arterial (± venous) vs venous-only procedure. Randomization occurred using blinded envelopes. Envelope contents were randomized using Research Randomizer version 4.0 (Geoffrey C. Urbaniak and Scott Plous) prior to initial enrollment. After signing the study consent form, the randomization envelope was opened and the patient and respective care team were informed about study arm allocation. Instructions were then provided based on group allocation. Patients in the NPO group followed our institution's standard protocol and were required to fast after midnight prior to the procedure for both solids and liquids, except for sips of water with essential medications. Patients in the nonfasting group were encouraged to ingest at least some amount of both solid and liquid at a minimum, with no maximum intake stipulated. There were no dietary restrictions. The type and amount of solid and liquid intake were at the patient's discretion, and participants were allowed to eat and drink up to the time immediately prior to transfer to the cardiac catheterization laboratory for the scheduled procedure. For those in the nonfasting arm, the previously prescribed diet was reordered, and therefore the selection of diet type was as per the judgment of the primary team.

Participants and staff members involved in direct patient care (nurses, primary team) were unblinded to group allocation, to ensure appropriate adherence to the allocation arm. For patients in the nonfasting arm, bedside nursing staff ensured drinks and foods were made available until the time of transfer for catheterization, and the primary team was informed so that the diet order could be changed appropriately. The coinvestigators conducting preprocedural screening, enrollment, and preprocedural and postprocedural standardized questionnaires were also not blinded to group allocation but were never responsible for primary decision-making. The primary operators (interventional cardiologists) and catheterization laboratory staff members were not provided with NPO status prior to the start of the procedure as a rule, and operators were asked that group allocation not influence management. However, operators were not strictly blinded to group allocation so that NPO status was readily available to support decision-making in case of emergency to maximize patient safety. Fasting time was calculated as the time from the last solid and/or liquid intake to the time of sedation or start of the procedure.

Catheterization procedure

The cardiac catheterization procedures were performed per current standards of care. Local anesthesia with lidocaine 1% was administered to the procedural access site. A combination of intravenous analgesic (fentanyl) and sedative (midazolam) was used to achieve moderate sedation, with initial dosage and as-needed additional dose(s) at the operator's discretion. The decision to perform procedures without sedation, or with only mild sedation, was at the operator's discretion, if deemed unnecessary or unsafe based on the patient's risk profile, or if by patient request. All coronary angiography procedures utilized iohexol (OMNIPAQUE; GE HealthCare) contrast media. Procedural duration was defined as the time from onset of sedation initiation to case end or, in cases where no sedation was given, from time-out to case end.

Data collection

Patient-reported and procedural-related parameters. Baseline patient characteristics were collected from the medical record, including demographics, clinical characteristics, laboratory values, and medications. Medications and dosages given during the procedure were collected, as well as total contrast volume, total doses of sedatives and analgesics, and any required antiemetics. All relevant periprocedural adverse events were recorded, including intraprocedural and

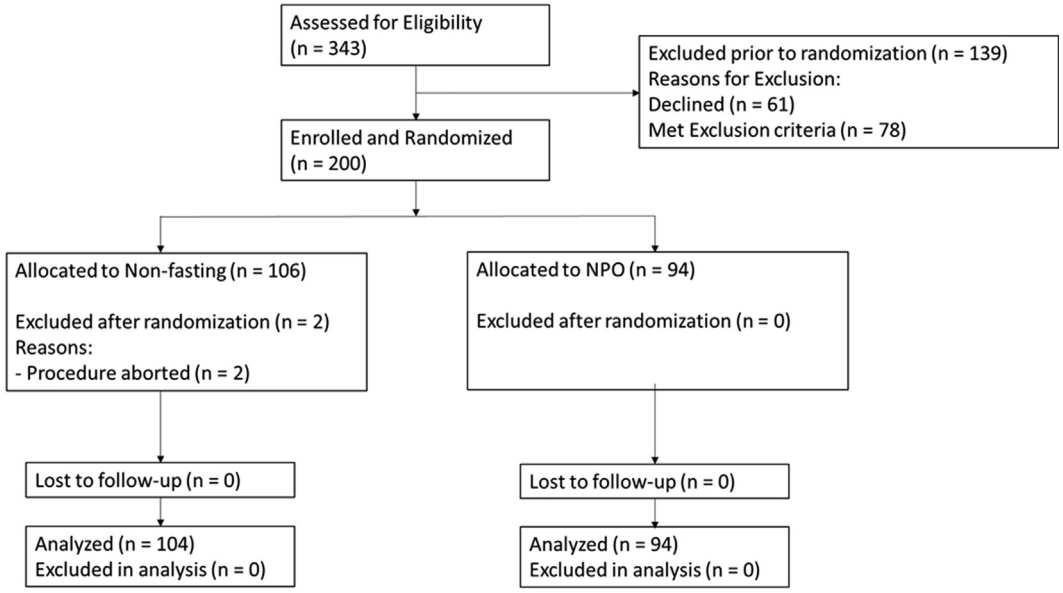


Figure 1.
CONSORT diagram. BMI, body mass index; GI, gastrointestinal; MCS, mechanical circulatory support; NPO, nil per os.

postprocedural nausea, emesis, aspiration events, emergency intubation, or hemodynamic instability.

Immediately prior to the start of the procedure, patients were asked to quantify several score items referencing their well-being and experience on a numeric rating scale (NRS) with values between 0 (variable not present) and 5 (variable in most extreme form). The score items collected immediately before the start of the procedure included hunger, fatigue, anxiety, and nausea.

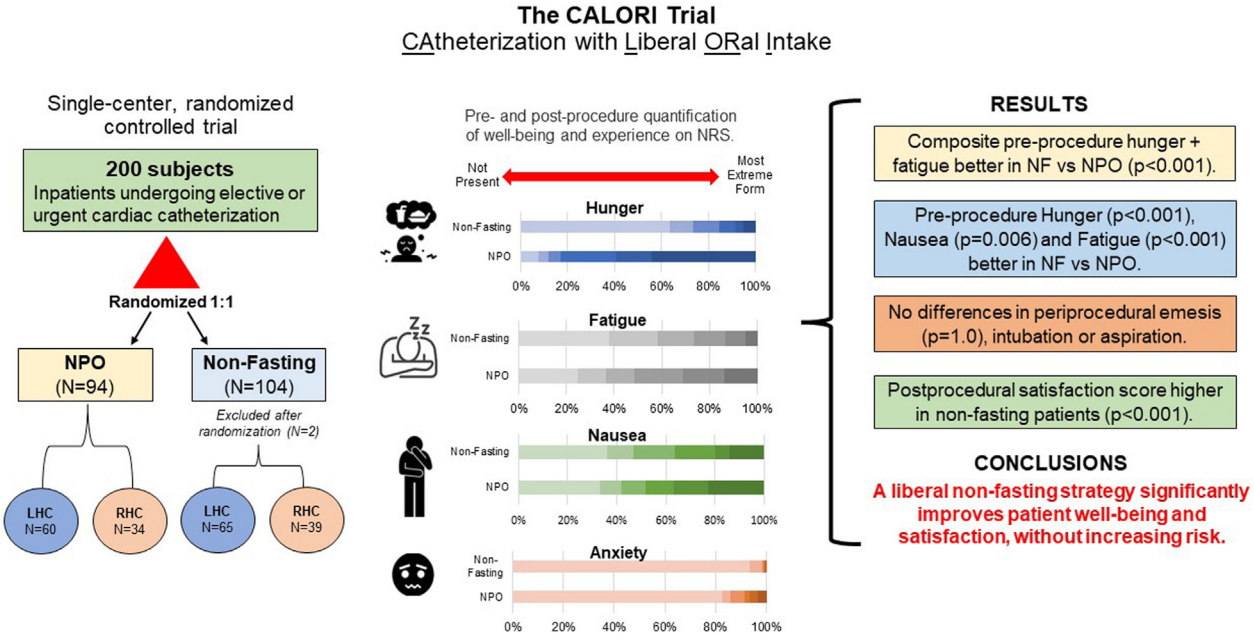
The day following the procedure, using an identical 0 to 5 NRS, participants were asked to rate procedure-site pain, sleep quality, postprocedure nausea, and overall satisfaction. The reported incidence of any relevant postprocedural symptoms or adverse events was also obtained.

Primary end points

The first primary end point was a composite preprocedural patient well-being score, calculated as the sum of the hunger and fatigue NRS.

The second primary end point was the incidence of intraprocedural and postprocedural adverse events, including emesis, aspiration, or need for urgent/emergent intubation. Adverse events were assessed via a combination of procedural record examination, medical record review, and patient interview.

Secondary outcomes were individual preprocedural well-being score variables, postprocedural patient experience scores, and changes in serum creatinine and glucose (defined as the change from



Central Illustration.
Study flow (left), distribution of individual well-being component scores (center), and summary of findings (right). LHC, left heart catheterization; NF, nonfasting; NPO, nil per os; NRS, numeric rating scale; RHC, right heart catheterization.

Table 1. Patient characteristics at baseline.

	NPO (n = 94)	Nonfasting (n = 104)	*P* value
Procedure type			.96
Coronary angiography ± LHC	60 (63.8%)	65 (62.5%)	
Right heart catheterization	34 (36.2%)	39 (37.5%)	
Age, y	61.5 ± 10.7	60.5 ± 12.8	.56
Male sex	60 (63.8%)	68 (65.4%)	.94
Race			.27
Black	35 (37.2%)	49 (47.1%)	
White	56 (59.6%)	51 (49.0%)	
Asian	1 (1.1%)	0 (0.0%)	
Other	2 (2.1%)	4 (3.9%)	
Body mass index, kg/m^2	28.8 ± 6.2	29.4 ± 6.7	.52
Diabetes mellitus			.74
Type 1	1 (1.1%)	3 (2.9%)	
Type 2	46 (48.9%)	48 (46.2%)	
Insulin-treated	19 (20.2%)	15 (14.4%)	.37
Prior CVA or TIA	16 (17.0%)	16 (15.4%)	.91
Chronic kidney disease[a]	52 (55.3%)	56 (53.8%)	.95
End-stage renal disease	6 (6.4%)	6 (5.8%)	>.99
LVEF, %	46.8 ± 17.2	45.3 ± 18.5	.57
LVEF categories			.72
Preserved LVEF (≥50%)	47 (50.5%)	52 (51.0%)	
Reduced LVEF (≤49%)	24 (25.8%)	22 (21.6%)	
Severely reduced LVEF (<30%)	22 (23.7%)	28 (27.5%)	
Coronary artery disease	49 (52.1%)	50 (48.1%)	.67
Arterial hypertension	75 (79.8%)	68 (65.4%)	.02
Preprocedural laboratory values			
Creatinine, mg/dL	1.61 ± 1.44	1.60 ± 1.48	.97
eGFR[b], mL/min/1.73^2	67.1 ± 31.4	67.8 ± 31.8	.89
Blood glucose, mg/dL	136 ± 55.0	136 ± 58.5	.91

Values are mean ± SD or n (%).
CVA, cerebrovascular attack; eGFR, estimated glomerular filtration rate; LHC, left heart catheterization; LVEF, left ventricular ejection fraction; NPO, nil per os.
[a] eGFR <60 mL/min/1.73 m^2. [b] Calculated using the Modification of Diet in Renal Disease (MDRD) equation.

the most recent preprocedural laboratory value to postprocedure value obtained on the day following the procedure).

Statistical analysis

The estimated sample size sufficient to detect a significant difference between the 2 groups for the primary outcome was based on a recent trial by Bode et al[15] which was conducted in a similar fashion to this trial, whose surveys contained similar questions and responses to our patient well-being and satisfaction surveys. We powered this trial to detect a mean between-group difference of 1, with a SD of 0.5 to 1.5. For 80% power, using an alpha of 0.05, the estimated number of patients needed to answer the primary clinical question was 200. There were no safety events in the Bode et al[15] trial; hence, we did not anticipate a significant difference in safety between groups.

For the first primary end point of summed well-being score, as well as the individual preprocedural well-being scales and postprocedural patient satisfaction scales, statistics are presented as mean ± SD. The mean difference between groups was compared using the *t* test. For the second primary end point, binary event rates were compared with the χ^2 test.

Statistical significance was set at $P < .05$, and all data analysis was conducted using R (The R Foundation).

Table 2. Procedural characteristics.

	NPO (n = 94)	Nonfasting (n = 104)	*P* value
Procedure duration, min	31.1 ± 19.3	35.2 ± 27.0	.219
LHC duration, min	34.5 ± 20.3	40.6 ± 31.7	.201
RHC duration, min	25.1 ± 15.9	26.2 ± 12.4	.747
Coronary angiography ± LHC			
PCI performed	13 (21.7%)	18 (27.7%)	.446
Contrast volume, mL	57.0 ± 39.1	62.4 ± 45.3	.462
Time from last solid intake to procedure, min	1109 ± 210	175 ± 157	<.001
Time from last liquid intake to procedure, min	970 ± 292	155 ± 100	<.001
Time from most recent oral intake (solid or liquid) to procedure, min	970 ± 291	148 ± 90.3	<.001
Medication			
Fentanyl dose, μg	30.6 ± 23.5	32.0 ± 24.7	.687
Fentanyl utilization	83 (88.3%)	89 (85.6%)	.722
Midazolam dose, mg	0.98 ± 0.58	0.97 ± 0.64	.886
Midazolam utilization	84 (89.4%)	90 (86.5%)	.697

Values are mean ± SD or n (%).
LHC, left heart catheterization; NPO, nil per os; PCI, percutaneous coronary intervention; RHC, right heart catheterization.

Results

Baseline characteristics

A total of 343 inpatients were screened for inclusion, with 200 enrolled and randomized between March and November 2023. Of these, 2 patients did not undergo catheterization and were excluded, resulting in 198 patients (NPO, n = 94; nonfasting, n = 104) included in the final analysis (Figure 1, Central Illustration, left).

There were no differences in baseline demographic and clinical characteristics between the NPO and nonfasting arms (Table 1). One hundred twenty-five (63%) patients underwent coronary angiography ± RHC, and 73 (37%) underwent RHC only. The distribution of procedure type was similar between study arms ($P = .96$).

Procedural characteristics are summarized in Table 2. There was no difference in average procedure duration between the study groups. PCI was performed in 22% of cases in the NPO arm, and 28% within the nonfasting arm ($P = .45$). Average contrast volume was similar between groups. Utilization and mean doses of fentanyl and midazolam were not significantly different. Overall, 21 patients received no conscious sedation (neither fentanyl nor midazolam), the majority of whom underwent RHC (18/21, 85.7%). The mean duration from the last oral intake (solid or liquid) was 970 minutes in the NPO arm compared with 148 minutes in the nonfasting arm ($P < .001$).

Primary analysis

The summed patient well-being score of hunger plus fatigue was 6.0 ± 2.5 for NPO vs 2.4 ± 2.4 for the nonfasting group, $P < .001$. (Figure 2A, Table 3). The NPO group reported worse scores for each individual component of the well-being score, with statistically significant differences for hunger, tiredness, and nausea (Figure 2B, Table 3, Central Illustration, center). A linear relationship was observed between fasting duration and the summed hunger + tiredness score, such that time since the last solid/liquid intake was associated with the preprocedural discomfort score, regardless of the randomization arm (Figure 3).

There was no difference between periprocedural adverse events between the 2 groups (Table 4). There were 2 instances of intraprocedural emesis. One patient allocated to the NPO arm vomited during intraaortic balloon pump insertion, although there was no need for urgent intubation, no aspiration, and no development of pneumonia. Another patient randomized to the nonfasting arm had intraprocedural emesis, and the procedure was aborted. This patient had heart failure with reduced ejection fraction (HFrEF), end-stage renal disease, and underwent PCI. Despite emesis, intubation was not required, and chart interrogation revealed no evidence of aspiration,

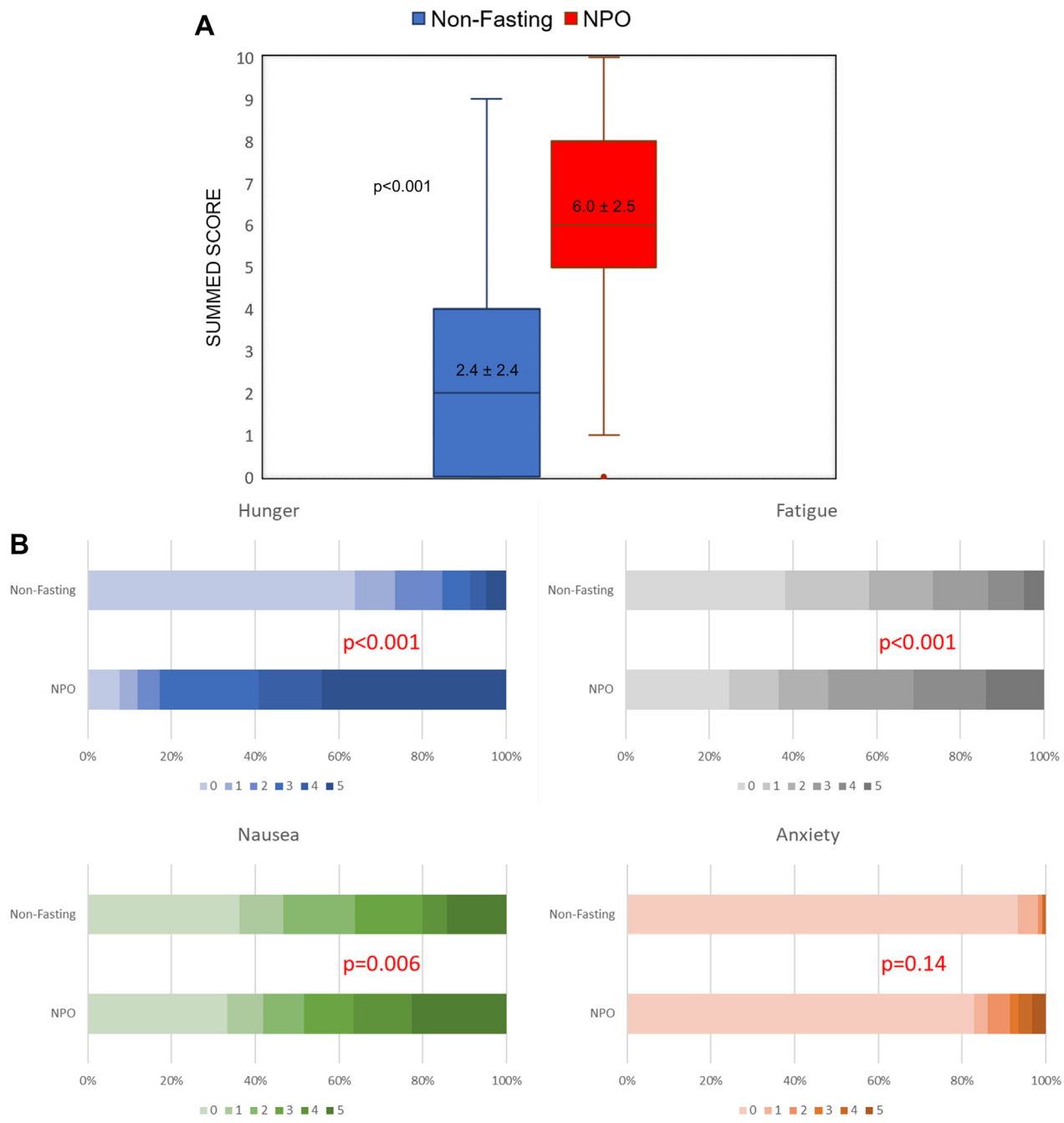


Figure 2.
Preprocedural summed hunger + tiredness scale (A) and distribution of individual well-being component scores (B). NPO, nil per os.

Table 3. Patient-reported well-being scores preprocedure.

	NPO (n = 94)	Nonfasting (n = 104)	*P* value
Summed well-being score (hunger + tiredness)	6.0 ± 2.5	2.4 ± 2.4	<.001
Hunger	3.7 ± 1.5	0.9 ± 1.5	<.001
Tiredness	2.3 ± 1.8	1.5 ± 1.6	<.001
Anxiety	2.3 ± 2.0	1.9 ± 1.8	.14
Nausea	0.5 ± 1.2	0.1 ± 0.5	.006

Values are mean ± SD. Scores range from 0 to 5, with 0 representing absence and 5 representing the most severe form of the symptom.
NPO, nil per os.

pneumonia, or other respiratory distress. This patient's death 2 days later was attributed to ventricular fibrillation and cardiac arrest.

Secondary analyses

Patients in the NPO arm reported worse postprocedural overall satisfaction than those in the nonfasting arm (1.0 ± 1.3 vs 0.3 ± 0.7, $P <$ .001), but there were no statistically significant differences between groups for the individual components of the surgical site or other pain, sleep quality, or nausea. (Table 4) and no between-group differences were observed in preprocedural or postprocedural creatinine or glucose.

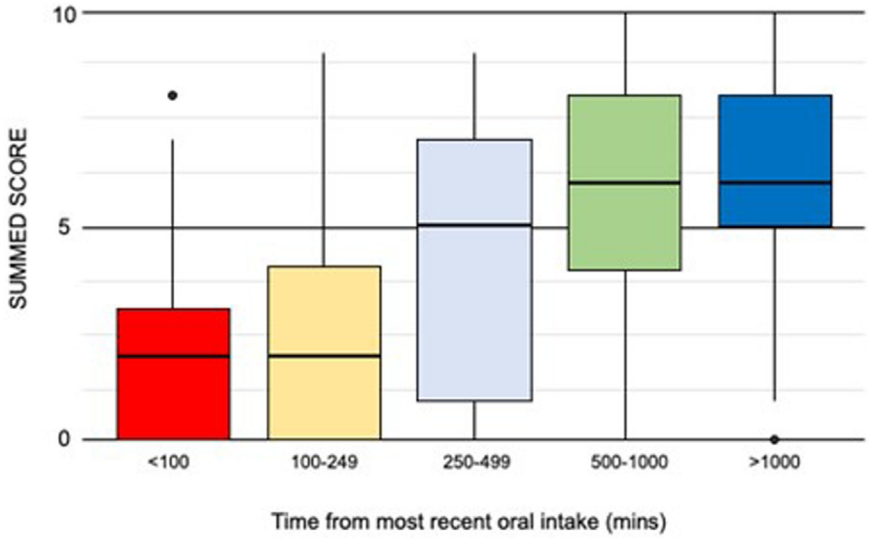


Figure 3.
Association of fasting duration with preprocedural patient-reported hunger + tiredness score.

Discussion

This trial found that for patients undergoing elective or urgent inpatient cardiac catheterization, a liberal nonfasting strategy was associated with significantly improved patient well-being compared to a traditional fasting strategy, with no differences in patient outcomes or periprocedural adverse events (Central Illustration, right). The preprocedural summed well-being score (hunger + fatigue) was significantly lower (ie, better) in the nonfasting group, as were the individual measures of hunger, fatigue, and nausea. There was no difference in the incidence of intraprocedural emesis, aspiration, or emergent intubation. Similarly, postprocedure blood glucose and renal function were not influenced by group allocation. Overall postprocedural satisfaction scores were significantly better in the nonfasting group compared to the standard NPO arm.

Our findings of significantly better preprocedural patient well-being scores and postprocedural satisfaction, as well as the observed linear "dose-response" relationship between fasting duration and negative patient experience, are consistent with other studies examining the effects of reduced fasting duration on patient well-being and outcomes.

Table 4. Periprocedural and postprocedural outcomes and postprocedural patient experience scores.

	NPO (n = 94)	Nonfasting (n = 104)	*P* value
Periprocedural and postprocedural outcomes			
Emesis	1 (1.1%)	1 (1.0%)	>.99
Aspiration	0	0	—
Intubation	0	0	—
Postprocedural laboratory values			
Creatinine, mg/dL	1.54 ± 1.27	1.54 ± 1.30	.99
eGFR postprocedure, mL/min/1.73 m^2	67.6 ± 31.4	68.5 ± 31.7	.86
Blood glucose post, mg/dL	130 ± 52.5	144 ± 64.9	.10
Postprocedural patient experience scores			
Surgical site or other pain	1.0 ± 1.3	0.6 ± 1.1	.05
Sleep quality	1.6 ± 1.4	1.6 ± 1.5	.97
Nausea	0.4 ± 0.8	0.2 ± 0.8	.12
Overall satisfaction	1.0 ± 1.3	0.3 ± 0.7	<.001

Values are mean ± SD or n (%).
NPO, nil per os.

A meta-analysis by Brady et al[5] found that shorter fasting periods had lower rates of aspiration with reduced thirst and hunger. Another meta-analysis by Cheng et al[16] demonstrated a significant improvement in preoperative thirst, hunger, and pain vs strict fasting, with no difference in perioperative nausea, vomiting, or aspiration. Fewer dedicated studies have prospectively examined alternative fasting protocols in cardiac procedures. One study found no differences in patient satisfaction or clinical outcomes, including aspiration pneumonitis, in 599 patients randomized to either an overnight fasting (with liquids up to 2 hours prior) or a nonfasting protocol prior to nonemergent cardiac catheterization.[11] Another found that in cardiac implantable electronic device procedures, a nonfasting strategy was associated with significantly improved patient well-being scores, with no difference in periprocedural adverse outcomes.[15] Most recently, Atkinson et al[17] demonstrated no difference in satisfaction or adverse events among patients randomized to a liberal fasting protocol prior to transcatheter aortic valve replacement or arrhythmia ablation.

There were few incidences of intraprocedural emesis, aspiration, or intubation in our study and no difference between study groups. This is unsurprising, given that perioperative aspiration and emergent intubation events are rare. A retrospective study by Warner et al[9] found the overall incidence of aspiration was 0.02% (52 events among 202,061 cases) in a large cohort of patients undergoing elective surgery with general anesthesia. Two additional large studies reported even less frequent event rates. Sakai et al[18] described an aspiration incidence of 0.01% for patients receiving general or monitored anesthesia care, while Sun et al[10] noted that pulmonary aspiration occurred in 0.01% of all anesthesia cases (20 events in 166,491 cases) and in 0.004% of elective cases. Specific to cardiac interventions, a retrospective analysis of 1916 patients who did not fast prior to elective or emergent PCI, 61.5% of whom had ACS, found no episodes of aspiration pneumonia, or need for emergent intubation.[12] Similarly, among nonfasting patients undergoing coronary angiography with or without PCI, there were no instances of aspiration, and urgent intubation was required in only 0.08% of cases.[19] Finally, although there was a trend toward less nausea in the nonfasting group, this was not statistically significant. This is consistent with the meta-analyses mentioned earlier which noted a relatively low incidence of nausea overall, and minimal difference between groups.[5,16] Appropriate exclusion of high-risk individuals, in addition to well-matched baseline parameters, may also help explain this finding.

Importantly, there were no differences between groups in terms of fentanyl or midazolam utilization or dosage. This is notable, as it suggests a lack of operator bias despite the unblinded study design. Further, it may reassure providers that the use of routine sedation in a nonfasting population does not compromise safety.

Our study found that patients in the liberal intake group still fasted for 148 minutes on average, despite being encouraged to eat and drink prior to their procedure. This is not entirely surprising, considering the patients were likely limited to hospital food which is delivered on a set schedule, resulting in gaps in eating between meals. Our results are consistent with those of multiple other studies that have shown that patients fast for longer than the required duration.[13–15,17] Bacus et al[14] found that 80% of patients fasted longer than the recommended 6 hours, with an average fasting duration of 11.6 hours. Chon et al[13] found that procedural delays leading to increased fasting duration are common, with the average fasting time of 12.8 hours increasing to an average of 13.5 hours in significantly delayed cases.

Although our trial shares some similarities with previous studies, it differs in many key aspects. Most studies have mandated that the abbreviated fasting arm intake either a specific type of liquid (eg, clear liquid, carbohydrate beverage) or a specific diet type, and intake was frequently allowed until 2 hours prior to the start of the procedure. Conversely, our nonfasting patients were allowed near complete autonomy on the type and amount of liquid and solid intake, within the parameters of their preexisting diet orders. This strategy has the advantages of being simple to implement and widely generalizable while testing the most liberal iteration of the nonfasting strategy. We enrolled inpatients because their diets would be easy to monitor and because inpatient procedures are typically performed after outpatients, and therefore would result in longer fasts, making between-group differences easier to detect. Further, there was a high comorbidity burden among our trial participants: 25% had severely reduced left ventricular ejection fraction (<30%), 49% had diabetes mellitus, 50% had coronary artery disease, and 60% had chronic kidney disease or end-stage renal disease.

Limitations

Limitations of our study include the unblinded design. Despite physician awareness of the protocol, there were no significant differences in utilization or dosage of midazolam or fentanyl between study arms. We cannot ensure that all patients prescribed to fast past midnight comply, despite the care team's diligence and the presence of appropriate diet orders. Nonfasting adherence could reliably be corroborated by nursing staff who assisted with meals; we still relied on patient recall to determine the timing of the last liquid and solid intake, which may have been biased. RHC procedures were on average shorter in duration and less complex overall, potentially impacting risk. Approximately 25% (18/73) of RHC-only procedures were performed without sedation, which was at the discretion of the operator and/or patient and influenced by perceived patient risk. Lack of sedation might impact risk, yet this was likely balanced by the significant proportion of moderate to severe HFrEF among patients undergoing RHC in this study. Sedation in the presence of moderate to severe HFrEF may confer elevated risk given relative hypotension, lower thresholds for respiratory distress in the setting of elevated filling pressures, reduced gastrointestinal motility, and concern for sedative accumulation due to renal and/or hepatic dysfunction. Due to the very low rates of periprocedural adverse events including aspiration and emergent intubation (after excluding high-risk patients we would estimate an event rate of <1%), it is not feasible to power our study to assess for these safety end points, which presumably explains why similar studies have used patient experience variables as primary end points.

Conclusions

This study found that in patients undergoing cardiac catheterization, a liberal nonfasting strategy significantly improved patient well-being without compromising safety. We included a demographically and clinically diverse patient population, in both urgent and elective procedures, and with liberal nonfasting allowances, which should allow for easy generalizability. Routine fasting prior to cardiac catheterization should be reconsidered.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding sources

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Ethics statement and patient consent

This prospective randomized controlled trial was conducted according to all relevant ethical guidelines following approval by the Virginia Commonwealth University Institutional Review Board (protocol HM20025962). All patients provided written informed consent prior to randomization.

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