

## Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

**eTable 1: Adverse event definitions (Quebec Guidelines)**

Adverse Event	Definition
Oxygen Desaturation	Oxygen desaturation occurs <b>AND</b> one or more interventions are performed with the intention of improving the saturation. The interventions include: (a) Verbal cues (b) Tactile stimulation (c) Airway repositioning (d) Suctioning (e) Supplementing or increasing oxygen delivery (f) Oral or nasal airway (g) Application of positive pressure with bag mask but <i>without</i> assisted ventilation (h) Application of bag mask <i>with</i> assisted ventilation (i) Tracheal intubation
Vomiting	The expulsion of gastric contents through the mouth or nose that occurs during either the Sedation phase (to include Induction and Maintenance) or the ED Recovery phase of sedation. If the timing and extent of vomiting presents a suspicion or confirmation of clinically apparent pulmonary aspiration, this adverse event must also be documented
Apnea	Cessation or pause of ventilatory effort <b>AND</b> one or more interventions are performed with the intention of stimulating or assisting ventilation. The interventions include: (a) Verbal cues (b) Tactile stimulation (c) Airway repositioning (d) Application of bag mask <i>with</i> assisted ventilation (e) Tracheal intubation
Partial Airway Obstruction	Manifested by the presence of one or more of the following: a) Stridor b) Snoring and/or c) Chest wall and suprasternal retractions <b>AND</b> one or more of the following interventions are performed with the intention of relieving partial airway obstruction (a) Airway repositioning (b) Suctioning (c) Oral or nasal airway (d) Application of positive pressure with bag mask but <i>without</i> assisted ventilation
Myoclonus	Involuntary, short contraction of some muscle fibers, of a whole muscle, or of different muscles of one group, leading to short observable movements of the corresponding body parts, usually not longer than 1/10 <sup>th</sup> of a second (100 milliseconds) <b>AND</b> required an intervention, administration of medications or interfered with the procedure
Paradoxical Response	Unanticipated restlessness or agitation in response to the administration of sedation drugs occurring during the Sedation phase <b>AND</b> results in the unplanned administration of reversal agents or alternative sedation drug(s), or results in a delay in the completion or discontinuation of the procedure
Hypotension	Systolic blood pressure less than the 5 <sup>th</sup> percentile for age as defined by the American Heart Association for Pediatric Advanced Life Support <b>AND</b> one or more intervention is performed with the intention of improving the blood pressure. These interventions include administration of: (a) IV Fluid (b) Chest compressions (c) Administration of medications
Seizure	Temporary abnormal electro-physiologic phenomenon of the brain that manifests as involuntary contractions or series of contractions of the voluntary muscles. The contraction can be prolonged (tonic) or repeated (tonic-clonic). An extreme form of muscle rigidity with shaking can resemble seizure activity but confirming this would require the use of electroencephalography (EEG).
Laryngospasm	Complete airway obstruction <b>WITH</b> oxygen desaturation due to involuntary and sustained closure of the vocal cords preventing effective ventilation that <b>REQUIRES</b> positive pressure ventilation with or without neuromuscular blockade to overcome the symptom.
Clinically Apparent Pulmonary Aspiration	Suspicion <b>OR</b> confirmation of oropharyngeal or gastric contents in the trachea during the sedation or immediate post-Sedation phase <b>AND</b> the

Adverse Event	Definition
	<p>appearance of respiratory signs and symptoms that were not present prior to the sedation. The new signs and symptoms must present before the end of the ED Recovery phase (see Figure 1 for Sedation Time Intervals).</p> <p>The patient must have <u>one or more</u> sign or symptom in <u>any</u> of the following three categories: (i) <u>Physical Signs:</u> Cough, crackles/rales, decreased breath sounds, tachypnea, wheezing, ronchi, respiratory distress (ii) <u>Oxygen Requirement:</u> Decrease in oxygen saturation from baseline requiring supplemental oxygen (iii) <u>Chest X-ray Findings:</u> Focal infiltrate or consolidation</p>
Bradycardia	<p>Heart rate less than 2 standard deviations below normal for age as described by the American Heart Association during the Sedation phase (includes Induction and Maintenance) or Physiologic Recovery phase. <u>AND</u> One or more intervention is performed with the intention of improving heart rate and cardiac output. The interventions include: (a) Tactile stimulation (b) Supplemental oxygen (c) Application of positive pressure with bag mask but <i>without</i> ventilation (CPAP) (d) Tracheal intubation (e) Chest compressions (f) Administration of medications</p>
Complete Airway Obstruction	<p>Ventilatory effort with NO air exchange manifested by ALL of the following: a) Absence of upper airway (e.g. stridor or snoring) and breath sounds on auscultation b) Loss of CO<sub>2</sub> waveform (when capnography is used) <b>AND</b> one or more of the following interventions are performed with the intention of relieving complete airway obstruction (a) Airway repositioning (b) Suctioning (c) Oral or nasal airway placement (d) Application of positive pressure with bag mask but <i>without</i> assisted ventilation (CPAP) (e) Application of bag mask <i>with</i> assisted ventilation (f) Tracheal intubation (g) Administration of additional sedation agents (h) Administration of neuromuscular blockade agents</p>
Muscle Rigidity	<p>Involuntary muscle stiffening in extension that can be associated with shaking <u>AND</u> interferes with the procedure, requiring an intervention or administration of medications.</p>
Permanent Neurological Injury	<p>A neurologic deficit that was not present prior to sedation and does not resolve</p>
Death	<p>The irreversible cessation of cerebral function, spontaneous function of the respiratory system and spontaneous function of the circulatory system</p>

**eTable 2: Multivariable penalized logistic regression analyses examining risk factors for sedation-related adverse events**

Variables	Odds Ratio	95% Confidence Interval	P value
<b>Dependent variable: any adverse events (number of events=717)<sup>a</sup></b>			
Fasting duration for solids (hours)	1.0	0.98 to 1.02	0.91
Sedation medication			<0.0001
- Ketamine	REF		
- Ketamine + Fentanyl	2.51	1.78 to 3.49	
- Ketamine + Midazolam	1.57	1.10 to 2.19	
- Ketamine + Propofol	1.02	0.81 to 1.28	
- Others	0.72	0.35 to 1.33	
- Propofol + Fentanyl	0.30	0.21 to 0.43	
- Propofol	0.4	0.24 to 0.63	
Age in years	1.08	1.05 to 1.10	<0.0001
Male	1.08	0.91 to 1.29	0.37
Pre-procedural opioid	1.66	1.39 to 1.99	<0.0001
Procedure type			0.0002
- Orthopedic reduction	REF		
- Foreign body removal	1.31	0.80 to 2.06	
- Abscess incision + drainage	1.07	0.67 to 1.63	
- Laceration repair	1.66	1.29 to 2.13	
- Lumbar puncture	2.32	1.42 to 3.67	
- Other	1.32	0.94 to 1.82	
<b>Dependent variable: serious adverse events (number of events=68)<sup>b</sup></b>			
Fasting duration for solids (hours)	1.01	0.95 to 1.07	0.64
Sedation medication			<0.001

Variables	Odds Ratio	95% Confidence Interval	P value
- Ketamine	Ref		
- Ketamine + Fentanyl	5.90	2.15 to 14.41	
- Ketamine + Midazolam	3.64	1.12 to 9.60	
- Ketamine + Propofol	4.33	2.20 to 8.57	
- Others	2.64	0.29 to 10.82	
- Propofol + Fentanyl	3.16	1.45 to 6.76	
- Propofol	5.68	2.30 to 13.33	
Age in years	1.05	0.98 to 1.12	<0.0001
Male	1.38	0.79 to 2.54	0.26
Pre-procedural opioid	1.57	0.93 to 2.65	0.08
Procedure type			0.35
- Orthopedic reduction	REF		
- Foreign body removal	0.45	0.004 to 3.35	
- Abscess incision + drainage	0.69	0.08 to 2.69	
- Laceration repair	1.46	0.57 to 3.36	
- Lumbar puncture	3.42	0.86 to 10.12	
- Other	1.30	0.41 to 3.20	
Fasting duration for liquids (hours)	1.01	0.94 to 1.07	0.69
Sedation medication			<0.0001
- Ketamine	REF		
- Ketamine + Fentanyl	5.90	2.15 to 14.42	
- Ketamine + Midazolam	3.64	1.12 to 9.59	
- Ketamine + Propofol	4.32	2.19 to 8.57	
- Others	2.63	0.29 to 10.80	
- Propofol ± Fentanyl	3.16	1.45 to 6.76	
- Propofol	5.68	2.30 to 13.33	
Age years	1.05	0.99 to 1.12	0.11
Male	1.38	0.79 to 2.55	0.25
Pre-procedural opioid	1.57	0.93 to 2.65	0.08
Procedure type			0.31
- Orthopedic reduction	REF		
- Foreign body removal	0.45	0.004 to 3.34	
- Abscess incision + drainage	0.70	0.08 to 2.71	
- Laceration repair	1.46	0.57 to 3.36	
- Lumbar puncture	3.54	0.91 to 10.22	
- Other	1.31	0.42 to 3.22	
<b>Dependent variable: vomiting (number of events=315)<sup>c</sup></b>			
Fasting duration for solids (hours)	1.00	0.97 to 1.02	0.79
Sedation medication			<0.001
- Ketamine	Ref		
- Ketamine + Fentanyl	1.93	1.25 to 2.91	
- Ketamine + Midazolam	0.91	0.54 to 1.46	
- Ketamine + Propofol	0.26	0.16 to 0.40	
- Others	0.15	0.02 to 0.55	

<b>Variables</b>	<b>Odds Ratio</b>	<b>95% Confidence Interval</b>	<b>P value</b>
- Propofol + Fentanyl	0.01	<0.001 to 0.04	
- Propofol	0.01	<0.001 to 0.09	
Age in years	1.12	1.09 to 1.15	<0.0001
Male	1.01	0.79 to 1.30	0.93
Pre-procedural opioid	1.42	1.09 to 1.85	0.01
Pre-procedural ondasetron	0.54	0.41 to 0.71	<0.0001
Procedure type			<0.001
- Orthopedic reduction	REF		
- Foreign body removal	1.82	0.96 to 3.22	
- Abscess incision + drainage	1.32	0.68 to 2.34	
- Laceration repair	1.72	1.19 to 2.46	
- Lumbar puncture	0.94	0.30 to 2.23	
- Other	0.95	0.54 to 1.56	
Fasting duration for liquids (hours)	1.00	0.96 to 1.03	0.81
Sedation medication			<0.001
- Ketamine	REF		
- Ketamine + Fentanyl	1.93	1.25 to 2.91	
- Ketamine + Midazolam	0.91	0.54 to 1.45	
- Ketamine + Propofol	0.26	0.16 to 0.40	
- Others	0.15	0.02 to 0.55	
- Propofol ± Fentanyl	0.01	<0.001 to 0.03	
- Propofol	0.01	<0.001 to 0.09	
Age years	1.12	1.09 to 1.15	<0.0001
Male	1.01	0.79 to 1.30	0.93
Pre-procedural opioid	1.42	1.09 to 1.85	0.01
Pre-procedural ondansetron	0.54	0.41 to 0.71	<0.0001
Procedure type			0.05
- Orthopedic reduction	REF		
- Foreign body removal	1.82	0.96 to 3.22	
- Abscess incision + drainage	1.31	0.68 to 2.33	
- Laceration repair	1.72	1.19 to 2.46	
- Lumbar puncture	0.93	0.30 to 2.20	
- Other	0.94	0.54 to 1.56	

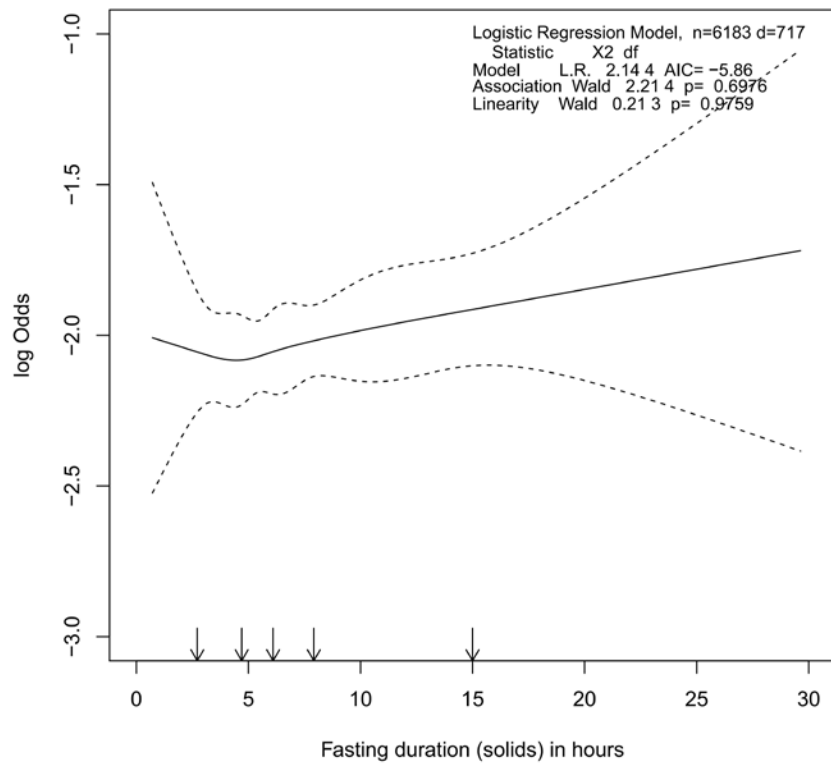
<sup>a</sup>solid model: Hosmer Lemeshow test: P-value=0.83; fluid model: Hosmer Lemeshow test: P-value=0.88

<sup>b</sup>solid model: Hosmer Lemeshow test: P-value=0.75; fluid model: Hosmer Lemeshow test: P-value=0.82

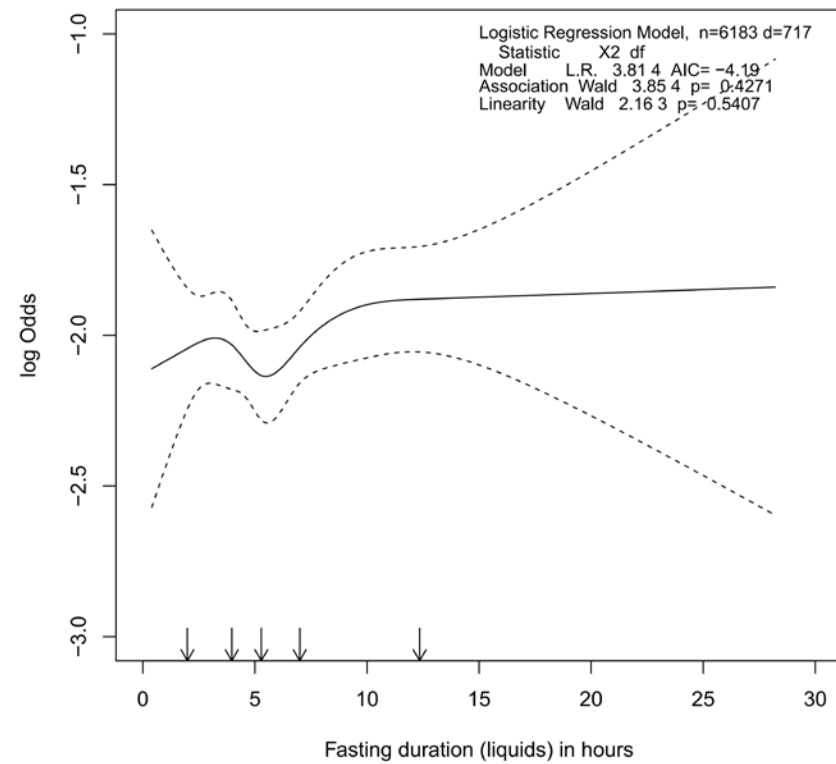
<sup>c</sup>solid model: Hosmer Lemeshow test: P-value=0.27; fluid model: Hosmer Lemeshow test: P-value=0.31

**eFigure 1: Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “any adverse event” and fasting duration for (i) solids and (ii) liquids**

**eFigure 1.1: Any adverse event and NPO solid with 5 knots**

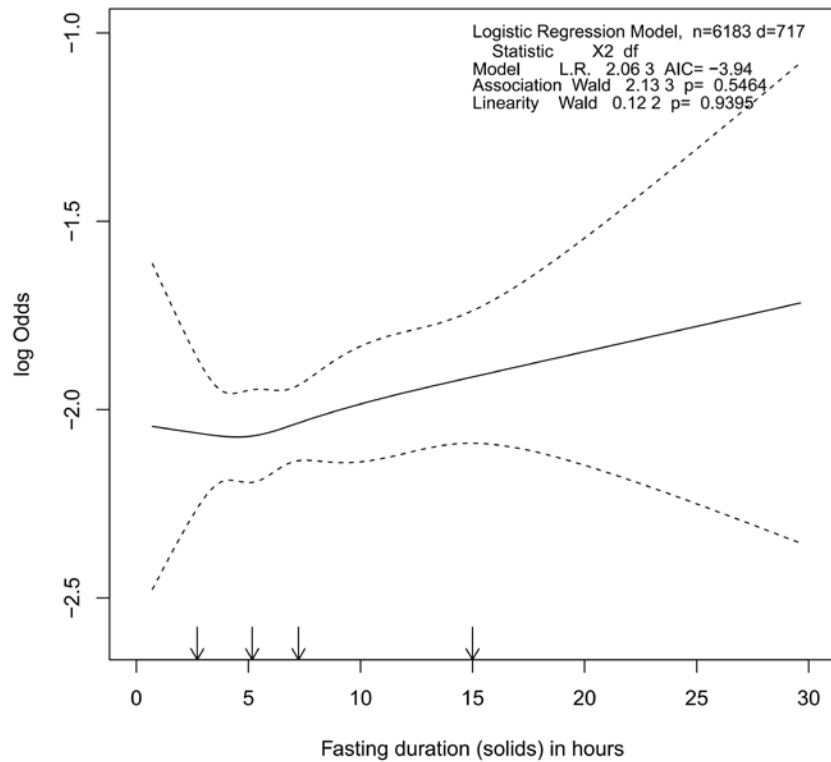


**eFigure 1.2: Any adverse event and NPO fluid with 5 knots**

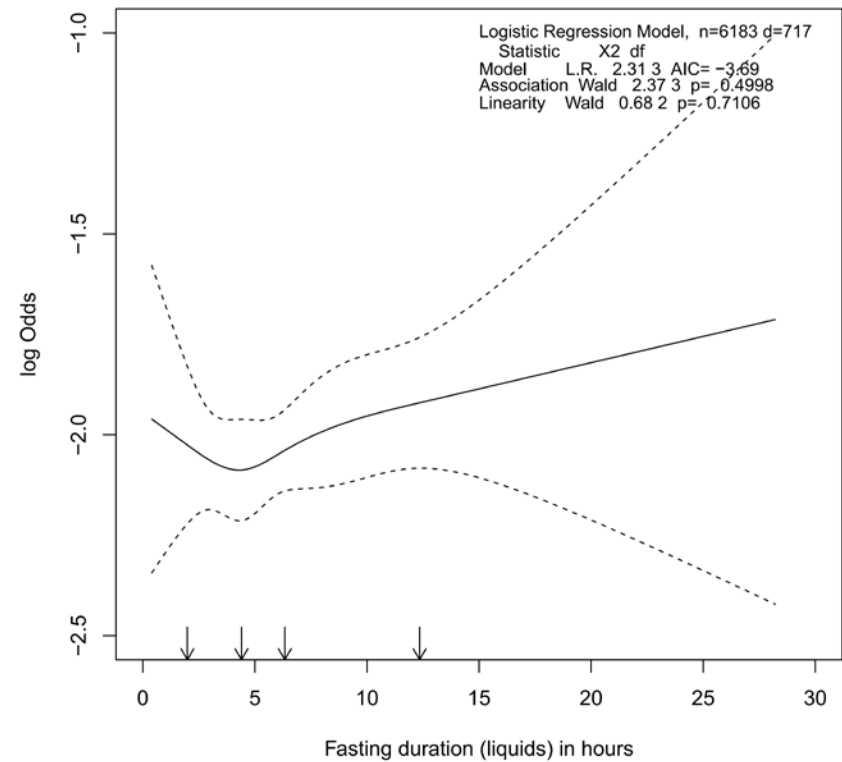


**eFigure 1 (continued): Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “any adverse event” and fasting duration for (i) solids and (ii) liquids**

**eFigure 1.3: Any adverse event and NPO solid with 4 knots**



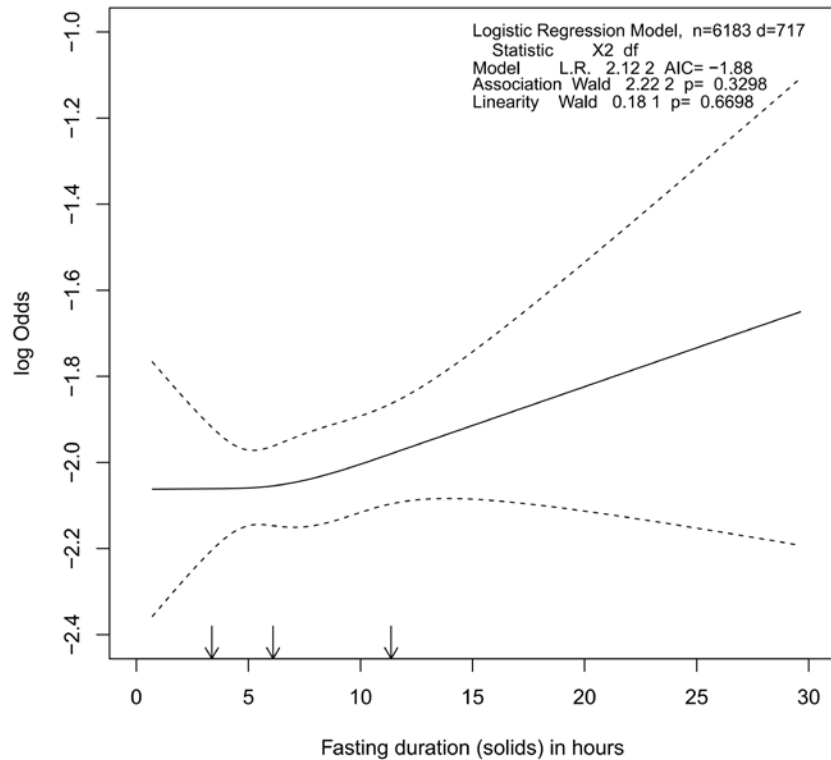
**eFigure 1.4: Any adverse event and NPO fluid with 4 knots**



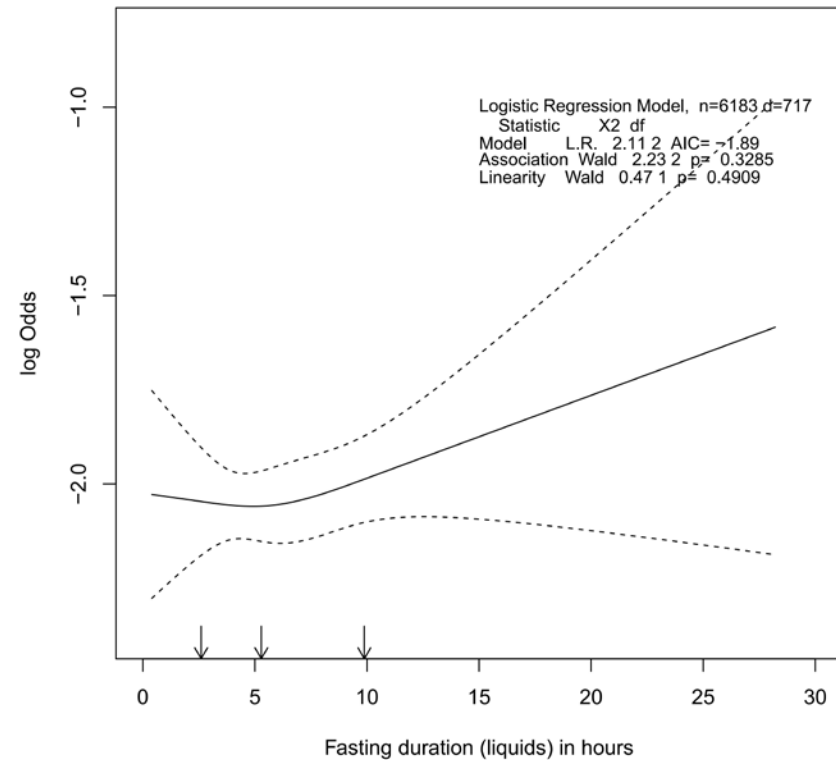


**eFigure 1 (continued): Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “any adverse event” and fasting duration for (i) solids and (ii) liquids**

**eFigure 1.5: Any adverse event and NPO solid with 3 knots**

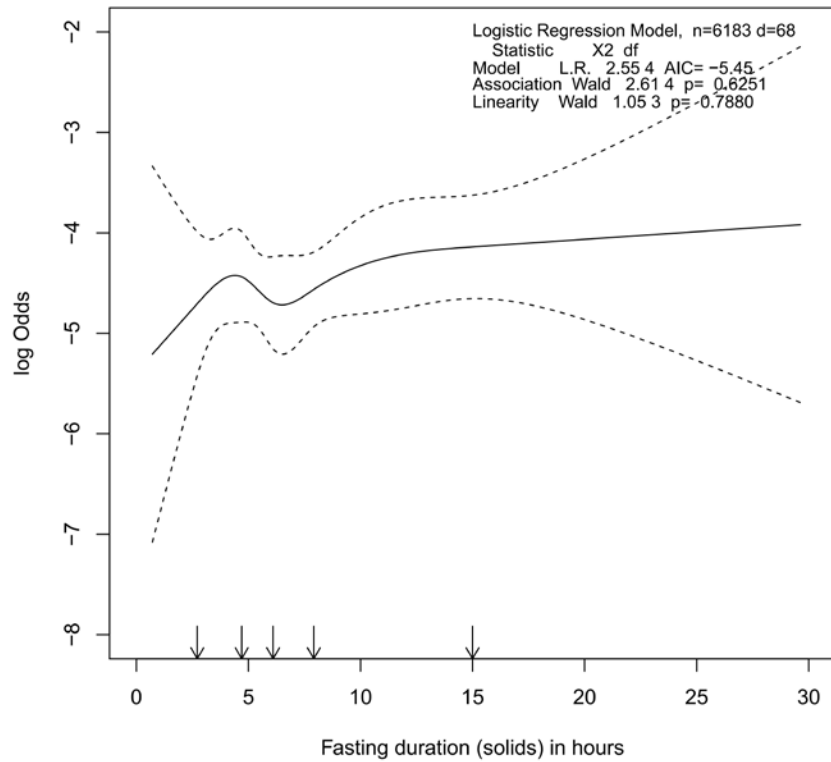


**eFigure 1.6: Any adverse event and NPO fluid with 3 knots**

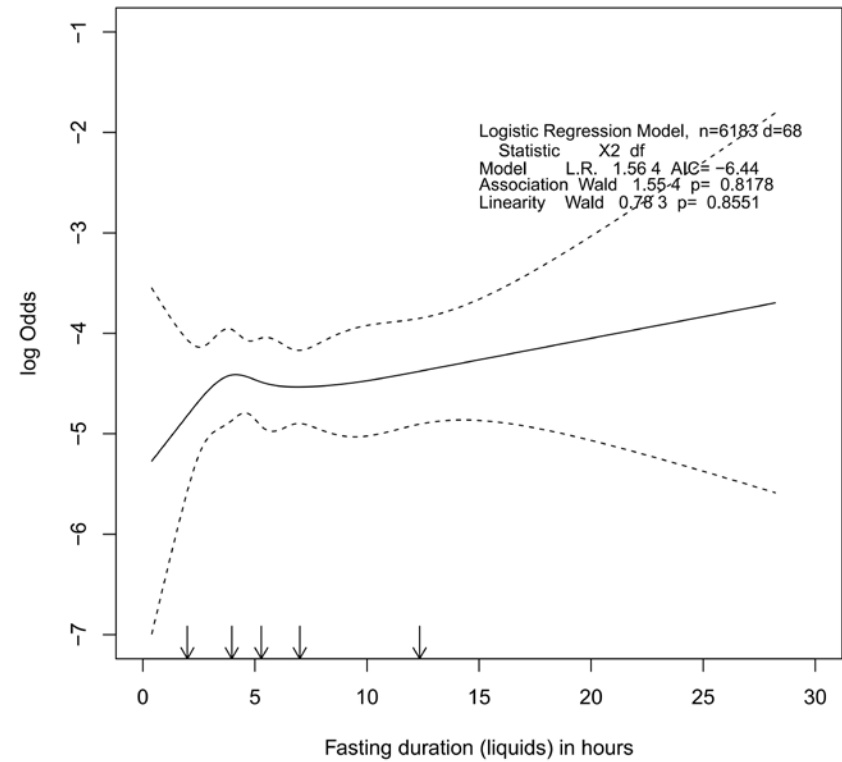


**eFigure 2: Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “serious adverse events” and fasting duration for (i) solids and (ii) liquids**

**eFigure 2.1: Serious event and NPO solid with 5 knots**

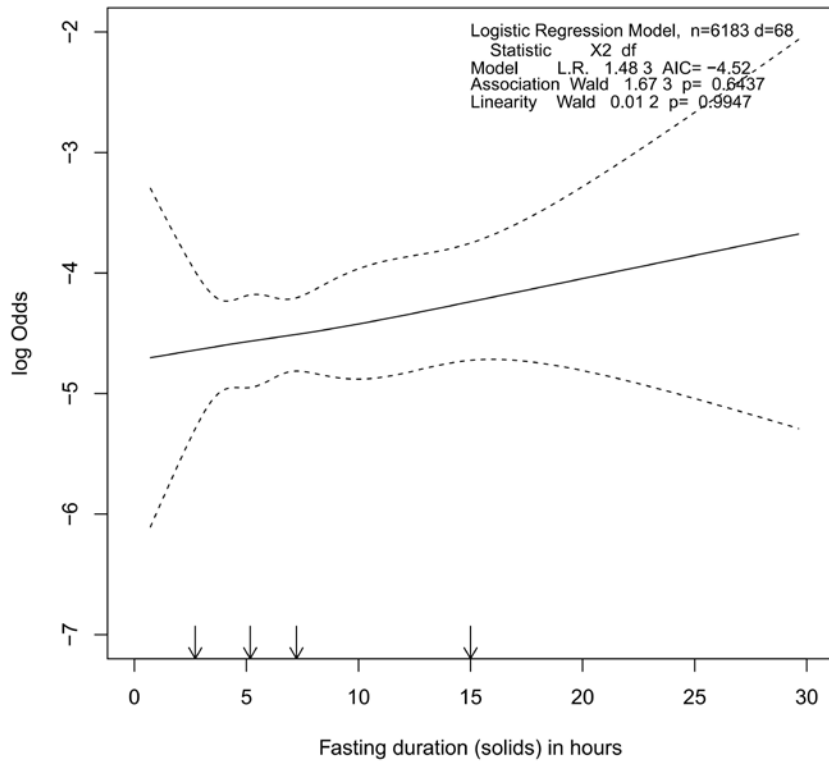


**eFigure 2.2: Serious event and NPO fluid with 5 knots**

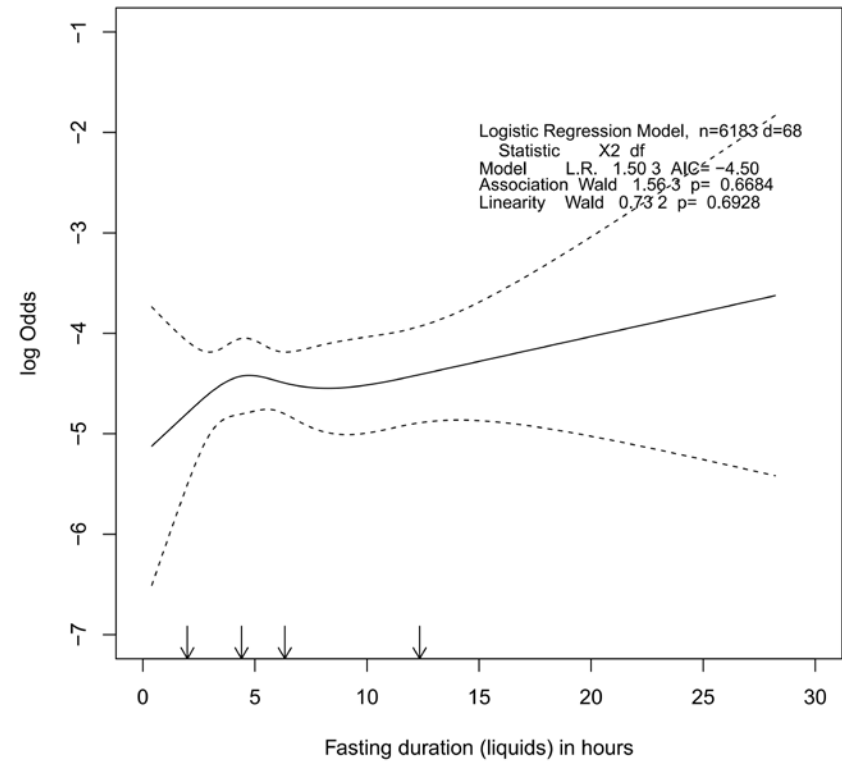


**eFigure 2 (continued): Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “serious adverse events” and fasting duration for (i) solids and (ii) liquids**

**eFigure 2.3: Serious event and NPO solid with 4 knots**

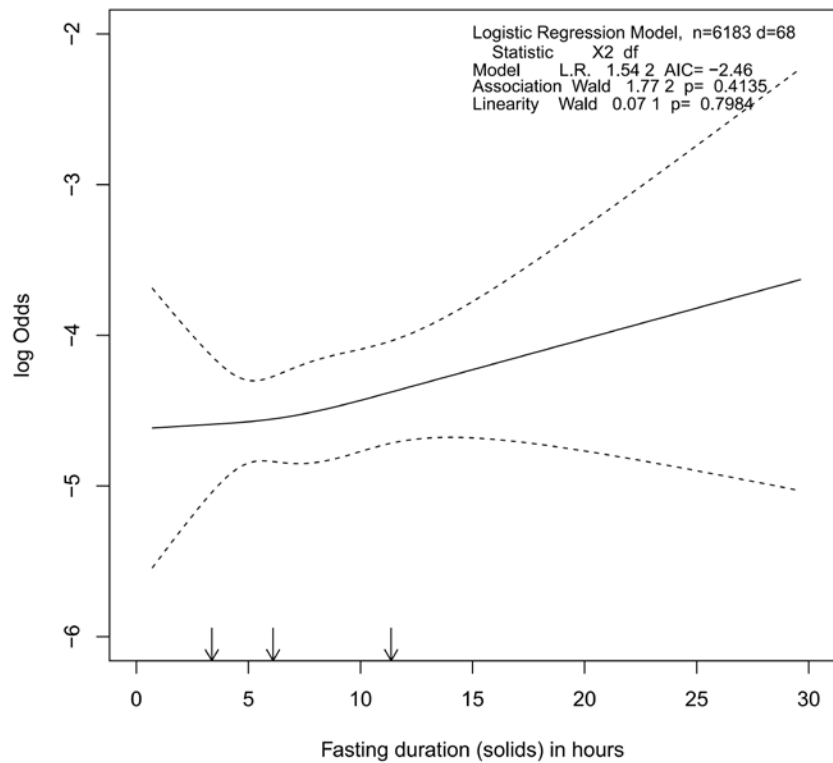


**eFigure 2.4: Serious event and NPO fluid with 4 knots**

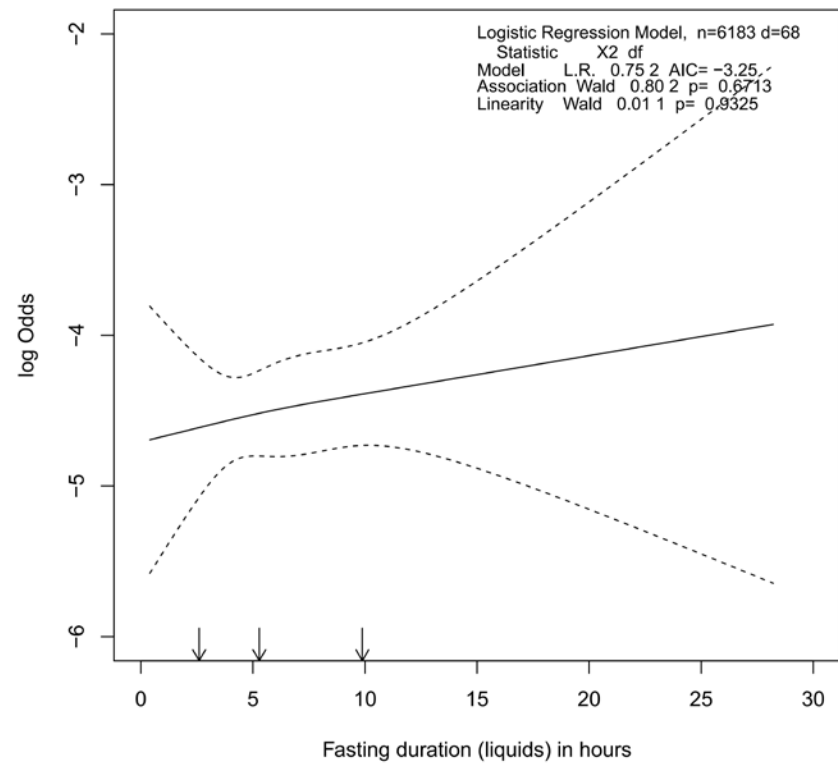


**eFigure 2 (continued): Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “serious adverse events” and fasting duration for (i) solids and (ii) liquids**

**eFigure 2.5: Serious event and NPO solid with 3 knots**

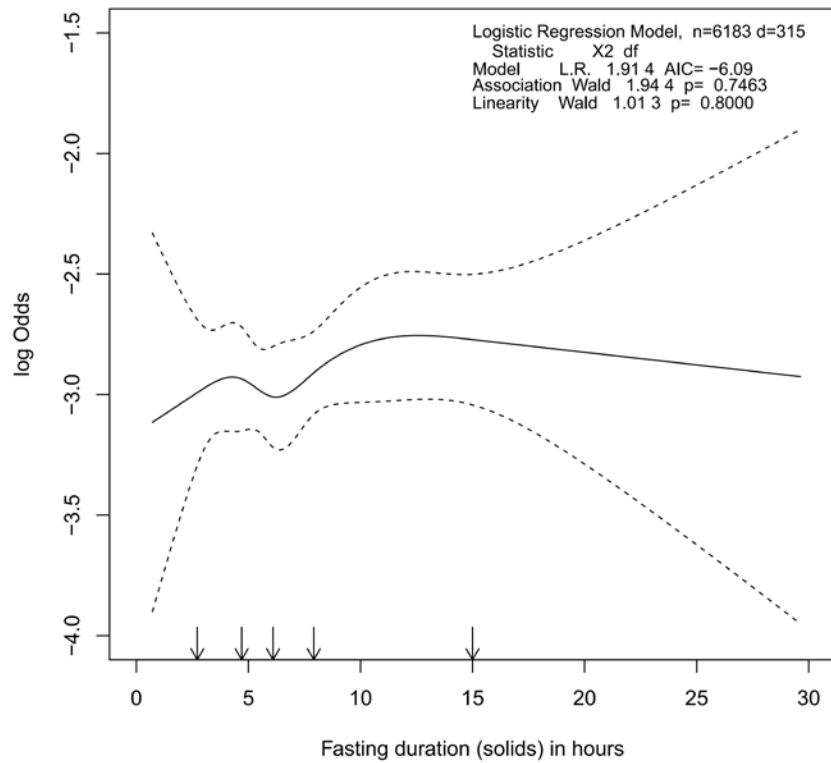


**eFigure 2.6: Serious event and NPO fluid with 3 knots**

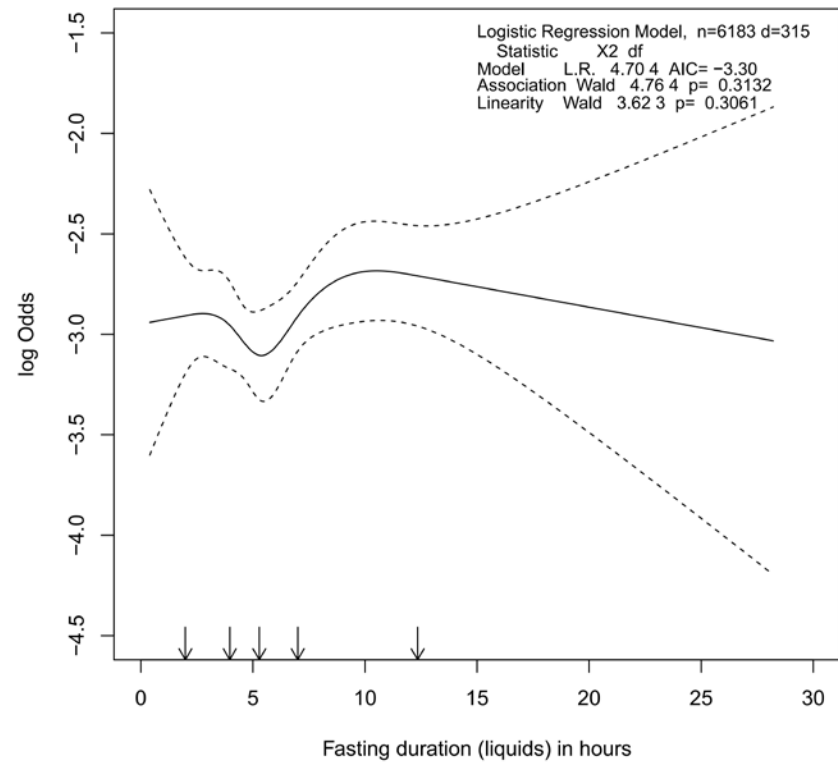


**eFigure 3: Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “vomiting” and fasting duration for (i) solids and (ii) liquids**

**eFigure 3.1: Vomiting and NPO solid with 5 knots**

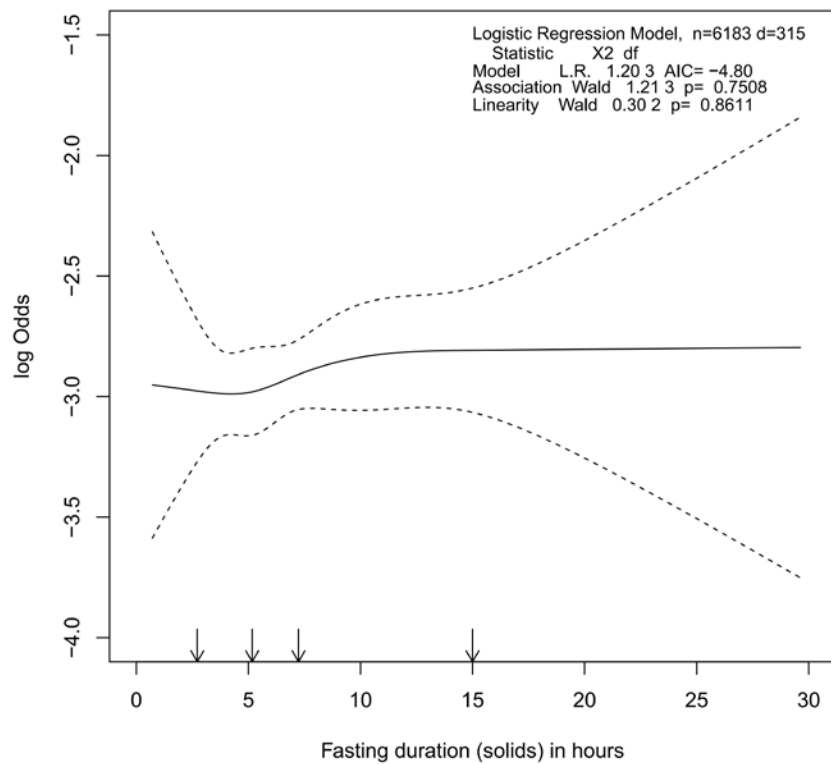


**eFigure 3.2: Vomiting and NPO fluid with 5 knots**

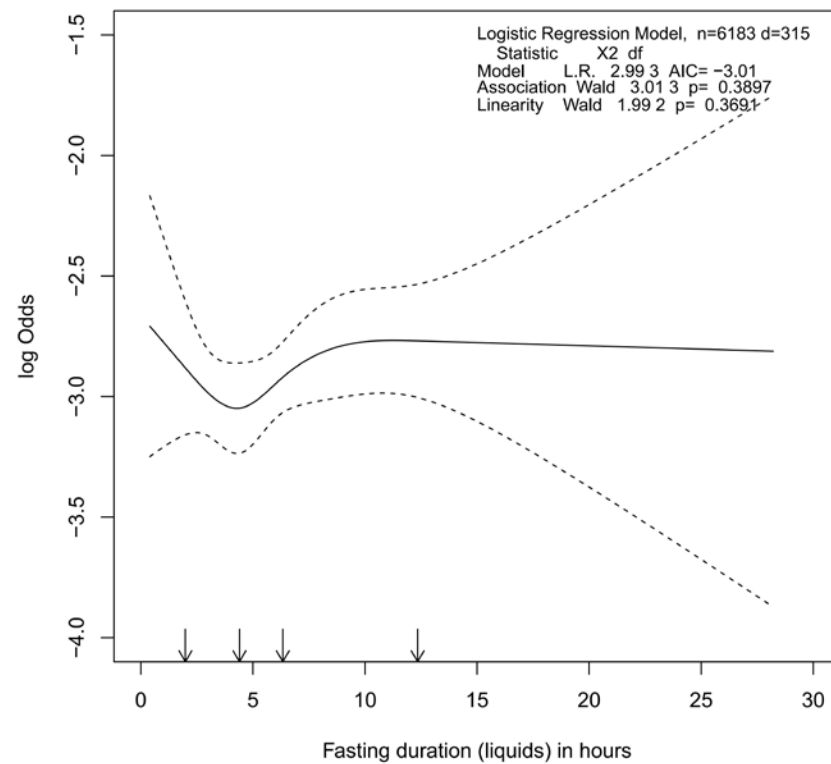


**eFigure 3 (continued): Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “vomiting” and fasting duration for (i) solids and (ii) liquids**

**eFigure 3.3: Vomiting and NPO solid with 4 knots**

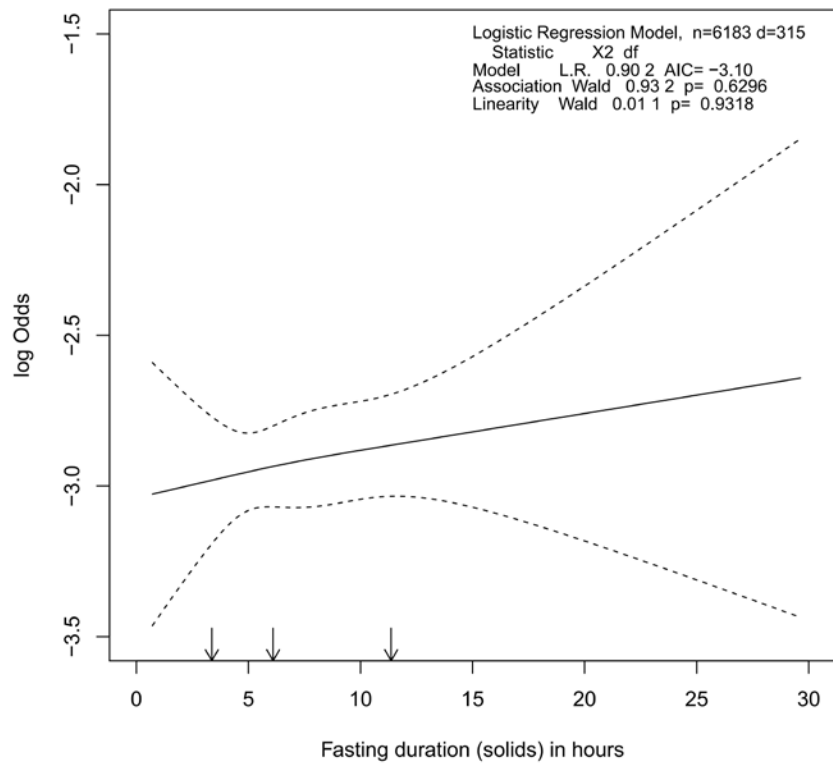


**eFigure 3.4: Vomiting and NPO fluid with 4 knots**



**eFigure 3 (continued): Restricted cubic spline plots with a) 5 knots b) 4 knots and c) 3 knots to examine the relationship between “vomiting” and fasting duration for (i) solids and (ii) liquids**

**eFigure 3.5: Vomiting and NPO solid with 3 knots**



**eFigure 3.6: Vomiting and NPO fluid with 3 knots**

