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A controlled rapid-sequence induction technique for infants may reduce unsafe actions and stress

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Background: Classic rapid-sequence induction of anaesthesia (RSI-classic) in infants and small children presents a time-critical procedure, regularly associated with hypoxia. This results in high stress levels for the provider and may trigger unsafe actions. Hence, a controlled induction technique (RSI-controlled) that involves gentle mask ventilation until full non-depolarizing muscular blockade has become increasingly popular. Clinical observation suggests that RSI-controlled may reduce the adverse effects noted above. We aimed to evaluate both techniques with respect to unsafe actions and stress.
Methods: In this controlled, randomized simulator-based study, 30 male trainees and specialists in anaesthesiology performed a simulated anaesthesia induction in a 4-week-old infant with pyloric stenosis. Two different RSI techniques, classic and controlled, were applied to 15 candidates each. We recorded the incidence of hypoxaemia, forced mask ventilation, and intubation difficulties. In addition, we measured individual stress levels by ergospirometry, salivary cortisol, and α-amylase, as well as a post-trial questionnaire.
Results: Hypoxaemia always occurred in RSI-classic but not in RSI-controlled, repeatedly resulting in unsafe actions. Subjective stress perception and some objective stress levels were lower in the volunteers performing RSI-controlled.
Conclusions: Our data suggest that RSI-controlled, as compared with RSI-classic, leads to fewer unsafe actions and may reduce individual stress levels.

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Anaesthesia induction and intubation in patients with a full stomach is a prime example of a time-critical high-risk procedure. To minimize the likelihood of pulmonary aspiration, a classic rapid-sequence induction (RSI-classic) technique has traditionally been used, comprised of pre-oxygenation, application of predetermined doses of hypnotics and suxamethonium, cricoid pressure, and apnoea until intubation.[1] In infants and small children with a low tolerance for apnoea, this procedure is associated with hypoxaemia, which leads to pressure for time and a high stress level for the provider.[1,2] This potentially results in a higher incidence of unsafe actions, such as hypoxaemia, forced mask ventilation, and unsuccessful intubation attempts.[3] In addition, the efficacy of cricoid pressure for the prevention of gastric regurgitation has not been conclusively validated in children but impairs visualization of the glottis.[4–7] Furthermore, RSI-classic relies on the use of suxamethonium, which is debated for its rare but detrimental side effects.[8–11]

A controlled RSI technique (RSI-controlled) has become increasingly accepted by many paediatric anaesthetists and professional bodies.[4,8,12] Balancing the risk of pulmonary aspiration with the much more prevalent risk of hypoxaemia, the new German recommendations for RSI-controlled in children acknowledge the following principles: pre-oxygenation, rapid induction of adequate hypnosis and profound muscle paralysis using a non-depolarizing muscle relaxant, gentle mask ventilation with a maximum airway pressure of 12 cmH_2O, laryngoscopy, and finally intubation when deep anaesthesia and full muscular blockade are present.[8] This should suffice to provide adequate oxygenation but is unlikely to cause relevant gastric inflation.[13,14]

The work was carried out at the Department of Anaesthesiology, Emergency and Intensive Care Medicine, University Medical Centre Göttingen, Göttingen, Germany.

RSI-controlled is aimed to prevent hypoxaemia and to reduce time pressure, subsequently leading to fewer unsafe actions and less stress for the provider.[4,8,12] These assumptions are based on common sense and clinical perception but have not yet been evaluated in a controlled comparative study. Because of ethical considerations it is regarded inappropriate to subject this protocol to clinical testing in children. As a result, we have established an infant-simulator model for the evaluation of clinical guidelines.[15]

In this controlled, randomized simulator-based study with trainees and specialists in anaesthesiology, we aimed to prove the hypotheses that RSI-controlled reduces the incidence of unsafe actions as compared with RSI-classic, and that RSI-controlled produces less stress for the provider.

Methods

After approval by our institutional Medical Research Ethics Committee, we conducted a controlled randomized study in an operating theatre at our clinical simulation centre. Thirty male residents and anaesthetists from the Department of Anaesthesiology, Emergency and Intensive Care Medicine at University Medical Centre Göttingen, participated. The two RSI-protocols, classic and controlled, were assigned randomly and each performed by 15 candidates (Table 1).

Table 1

Flow chart of the simulated scenario and the stress measurements.

Time (min)	RSI-classic	RSI-controlled
−10	First saliva specimen (pre-stress value)	
−5	Start of ergospirometry 5-min rest	
0	Briefing and start of scenario Pre-oxygenation Thiopentone (7 mg/kg) and suxamethonium (2 mg/kg) Cricoid pressure No mask ventilation	 Thiopentone (7 mg/kg) and rocuronium (0.6 mg/kg) No cricoid pressure Mask ventilation ($P_{max} \leq 12\,cmH_2O$)
(t_i)	Intubation attempt after 60 s Further course of scenario until successful intubation and ventilation	Intubation attempt after 120 s
+10	Second saliva specimen (first stress value) 5-min rest End of ergospirometry	
+20	Third saliva specimen (second stress value)	
+40	Fourth saliva specimen (post-stress value) Post-stress questionnaire End of trial	

RSI, rapid-sequence induction.

Controlled variables

The protocols for RSI were standardized, based on the German recommendations from 2007 on RSI in children.[8] The same anaesthetic nurse assisted in all procedures strictly following the study protocol (Table 1). Thiopentone (7 mg/kg), suxamethonium (2 mg/kg), or rocuronium (0.6 mg/kg), respectively, were pre-prepared and administered by the anaesthetic nurse when prompted by the candidate. As the simulator manikin is not capable of reproducing muscle relaxation, the anaesthetic nurse indicated the exact timing for the first intubation attempt, 60 s after the application of suxamethonium and 120 s after rocuronium. Candidates using RSI-classic had to begin without mask ventilation after onset of apnoea but were explicitly free to modify or change their technique when felt to be indicated.

We used a SimBaby™ high-fidelity infant simulator (Laerdal Medical, Stavanger, Norway). Two days before the study, all candidates were familiarized with the simulator manikin, the vital signs monitor, and the anaesthetic work station (Dräger Fabius Tiro™, Dräger Medical, Lübeck, Germany).

We scripted a standardized scenario of anaesthesia induction in a 4-week-old baby boy with a body weight of 4000 g suffering from pyloric stenosis. An intravenous line and nasogastric tube were *in situ*. The initial respiratory rate (RR), SpO_2, heart rate (HR), blood pressure (BP), and torso movement were defined. Additionally, three trends for RR, HR, and SpO_2 were programmed: 'RSI-classic', 'RSI-controlled', and 'recovery from hypoxaemia'. Hence, all candidates were presented with the same standardized conditions.

The trends for SpO_2 were based on data derived from the Nottingham physiology simulator as determined for a 1-month-old infant by Hardman and Wills.[2] Under the assumption that in a wiggling child effective pre-oxygenation is not feasible but the airway is open, this allows SpO_2 to fall below 90% after 18 s and to fall to 40% after another 101 s.

Measured variables

Using a checklist two observers recorded unsafe actions or signs, defined as follows: $SpO_2 < 90\%$,

forced mask ventilation with $P_{Airway} > 20\,cmH_2O$ (measured by the anaesthetic machine), a prolonged intubation attempt (>30 s), oesophageal or endobronchial intubation, and more than one intubation attempt. The providers' physical and mental stress was assessed by continuous ergospirometry, analyses of salivary cortisol and α-amylase, and by a brief post-trial questionnaire.

Ergospirometric measurements were performed with a mobile breath-by-breath ergospirometry device (Cortex Metamax 3 B™, Cortex Biophysik, Leipzig, Germany), combined with a chest belt heart rate meter (Polar T 41™, Polar Electro, Büttelborn, Germany). We recorded RR, respiratory minute volume (MV), oxygen consumption (VO_2), carbon dioxide production (VCO_2), and HR. All parameters were transmitted wireless to a Windows™-based PC and recorded using MetaSoft 3.3™ software (Cortex Biophysik). Before and after the scenario, all candidates were asked to relax for 5 minutes to reach their individual cardiorespiratory baseline values (Table 1).

As cortisol levels follow a circadian rhythm all trials were executed between 14:00 and 18:00 hours. All candidates fasted for at least 2 h. Based on the salivary kinetics of α-amylase and cortisol, four saliva samples were obtained for each trial.[16,17] 10 min before as well as 10, 20, and 40 min from the start of the scenario (Table 1). Saliva specimens were obtained with cotton rolls to chew on (Salivette™, Sarstedt AG & Co., Nürmbrecht, Germany), centrifuged, and then cooled to 5 °C. All analyses were performed within 24 h of collection. For α-amylase we used a Cobas Integra 800™ kit and for cortisol a Cobas Modular Analytics E 170™ system (both Roche Diagnostics, Mannheim, Germany).

At the end of the trial, all candidates completed a brief questionnaire that consisted of two ratings and one open question related to the RSI technique used: perception of subjective stress and safety levels, using interval scales from 1 (very low/safe) to 10 (very high/unsafe). They were also asked to specify any unsafe actions that may have occurred during the scenario.

Statistical analyses

Statistical analyses were performed with SPSS Version 14 (SPSS GmbH, Munich, Germany). We analysed all nine dependent variables (five from ergospirometry, two from saliva analyses, and two self-assessments) separately. Ergospirometry measurements were categorized into segments of 30 s, starting 2 min before the beginning of the scenario. As dependent variables, we defined ergospirometry values at the time of intubation (t_i), and the mean of salivary measures at 10 and 20 min after the beginning of the scenario.

The hypotheses were tested by stepwise regression. In the first step the dependent variables were regressed to the individual baseline values of each candidate to control the absolute high of measures (ergospirometry at t_i, and salivary measures at $t - 10$ min). The constant of this first equation is informative with regard to induced stress. In the second step we included the experience of the candidates as stress levels may vary with experience. The experience of candidates was square root transformed to compensate skewness. In the third step of the regression analysis, the experimental RSI technique was included in the form of a code (−1 for RSI-classic, +1 for RSI-controlled). The β-coefficient of this third step tests the main hypothesis of method differences in relative stress parameters, controlled for experience. Finally, the interaction between experience and method was included in the regression. The analysis of the subjective measures was performed by the same procedure but used the transformed experience of the participants in the first step.

Stepwise regression enables to assess the amount of variance declared by each source looking at the R^2 change (abridged $+R^2$), and it enables to use one-tailed tests to compensate for the small sample size in terms of design. One-tailed P-values <0.05 were regarded as significant.

With 30 participating candidates a factor needed to reach at least 3% of the variance of a stress measure to be significant ($+R^2 \geq 0.03$). A β-coefficient below zero indicated a reduced stress level. β-coefficients of 0.10, 0.30, and 0.50 represent a weak, medium, and strong effect, respectively.

Results

All 30 candidates completed the study. They had a median age of 36.5 (range 29–53) years and a median of experience in clinical anaesthesia of 8.0 (range 1.5–26) years. Professional experience did not differ between the two groups [$t(28) = 0.36$; $P = 0.72$]. Marked physical and mental stress was induced in all candidates in the course of all scenarios, which lasted between 4 and 7 minutes. The main increase in HR, RR, MV, VO_2, and VCO_2 occurred near the time of intubation (t_i). Salivary

cortisol and α-amylase peaked at 10 or 20 min after the start of the scenario.

Hypoxaemia ($SpO_2 < 90\%$), being part of the protocol, always occurred during RSI-classic, which resulted in forced mask ventilation with $P_{Airway} > 20$ mbar in two cases. In contrast, hypoxaemia and forced mask ventilation were not observed during the RSI-controlled trials. The incidence of prolonged or unsuccessful intubation attempts, endobronchial, and oesophageal intubation did not differ between the methods (Table 2).

RSI-controlled significantly reduced the providers' stress levels as measured by carbon dioxide production and subjective stress rating. In addition, respiratory MV and cortisol tended to be lower in the RSI-controlled trials than in the RSI-classic trials (Table 3). A significant effect of professional experience was shown in a lower rating of stress and tended to also occur as lower HR and cortisol level as well as higher perceived safety rating. The effects of professional experience on stress applied to both RSI-protocols. For three of the nine dependent variables (i.e., RR, VO_2, and α-amylase), no significant correlations were observed with respect to RSI technique, professional experience, or their interaction (Table 3).

Analysis of the post-stress questionnaire revealed that 10 out of 15 candidates performing RSI-classic found it difficult to decide whether or not to begin mask ventilation when hypoxaemia developed. Three candidates in the RSI-controlled group perceived high subjective stress levels, as they felt unfamiliar with that technique (i.e., mask ventilation on a non-fasted patient). Table 3 provides all the analysed objective and subjective stress measurements (dependent variables).

Table 2

Observational features of rapid-sequence induction (RSI)-classic and RSI-controlled trials.

	RSI-classic ($n = 15$)	RSI-controlled ($n = 15$)	Fisher's exact test
Hypoxaemia ($SpO_2 < 90\%$)*	15	0	$P < 0.001$
Unplanned mask-ventilation	4	0	$P = 0.05$
Forced mask-ventilation ($p_{AW} > 20$ mbar)*	2	0	$P = 0.24$
More than one intubation attempt*	1	1	–
Prolonged duration of intubation (>30 s)*	3	4	–
Endobronchial intubation*	3	3	–
Oesophageal intubation*	1	1	–

*Unsafe actions and signs.

Discussion

In this infant simulator-based evaluation RSI-controlled caused a lower incidence of unsafe actions and signs as compared with RSI-classic. Some dependent variables also indicated that RSI-controlled produced lower stress levels in the provider.

In the search for greater patient safety, the classic RSI technique has been revisited repeatedly, without resolving its controversial aspects.[4] Clinical data suggest that regurgitation and pulmonary aspiration of gastric content occurs almost exclusively when the depth of anaesthesia and muscle relaxation are inappropriate.[18] As compared with the low incidence of aspiration, hypoxaemia almost always occurs during RSI-classic in infants and small children and is potentially associated with unsafe actions.[4,8,12] Our results support this clinical observation as we found a higher incidence of unsafe actions and signs in RSI-classic, i.e. hypoxaemia and forced mask ventilation. We regard the latter as an expression of stress related to time criticalness when hypoxaemia rapidly develops. Hence, the prevention of hypoxaemia and the provision of optimal intubation conditions is the essential characteristic of a safer RSI technique.

In clinical reality, untimely and hasty laryngoscopy frequently occurs in RSI-classic when hypoxaemia evolves, which induces bucking and coughing in the child. This frequently impedes laryngoscopy and intubation and may induce regurgitation and aspiration.[4,12] We replaced the manikin's lack to exhibit muscle relaxation by the anaesthetic nurse's strictly clocked clearance for the first intubation attempt. Consequently, hypoxaemia was inevitable following the protocol for RSI-classic. As the simulator trend was based on validated data from the Nottingham Physiology Simulator, this reflects the clinical condition realistically.[2]

The overall incidences of unsafe actions were relatively low in both techniques. This may be result of a combination of good skills and omission of difficult airway features in the simulator manikin as well as high mental concentration and a particular anticipation under the study conditions (Hawthorne effect).[19] Furthermore, the study protocol excluded medication errors and application difficulties.

Table 3

Analyses of the measured and self-reported stress levels (dependent variables) in correlation to professional experience, RSI-technique, and their interaction effect (stepwise regression).

Dependent variable	Step	$+R^2$	Professional experience			RSI-technique		
			β	*t*	$p_{one\text{-}t}$	β	*t*	$p_{one\text{-}t}$
RR	2 Experience	0.025						
	3 RSI	0.000						
	4 Interaction	0.005						
MV	2 Experience	0.005						
	3 RSI	0.039	−0.091	−0.55	0.30	−0.199	−1.217	0.12
	4 Interaction	0.021						
VO_2	2 Experience	0.010						
	3 RSI	0.007						
	4 Interaction	0.015						
VCO_2	2 Experience	0.001						
	3 RSI	0.139	−0.067	−0.37	0.36	−0.387	−2.086	0.03
	4 Interaction	0.005						
HR	2 Experience	0.041	−0.210	1.41	0.07			
	3 RSI	0.013						
	4 Interaction	0.000						
Cortisol	2 Experience	0.028						
	3 RSI	0.038	−0.180	−1.26	0.11	−0.205	−1.363	0.10
	4 Interaction	0.002						
α-amylase	2 Experience	0.001						
	3 RSI	0.000						
	4 Interaction	0.001						
Stress rating	1 Experience	0.218						
	2 RSI	0.157	−0.494	−3.24	0.002	−0.397	−2.605	0.01
	3 Interaction	0.003						
Safety rating	1 Experience	0.049	−0.220	−1.20	0.13			
	2 RSI	0.002						
	3 Interaction	0.000						

For ergospirometry and salivary measures step 1 represents baseline; professional experience = square root of years; RSI-technique as dummy code: +1, RSI-classic; −1 RSI-controlled. If incrementally declared variance was low ($+R^2 < 0.03$), β-coefficients are not reported. The standardized regression coefficient β shows effect sizes of 0.10, 0.30, and 0.50 for weak, medium, and strong effects. *t*-coefficient and $p_{one\text{-}t} = p_{one\text{-}tailed}$ prove the significance of β.
RR, respiratory rate; MV, respiratory minute volume; VO_2, oxygen consumption; VCO_2, carbon dioxide production; HR, heart rate; $+R^2$, variance; β, regression coefficient; *t*, significance; $p_{one\text{-}t}$, $p_{one\text{-}tailed}$; RSI, rapid-sequence induction.

High stress levels are likely to trigger unsafe actions.[20–22] Therefore, clinical guidelines aim to reduce stress in order to increase patient safety. However, stress levels and their perception vary interpersonally and there is no linear correlation between stress levels.[17,22] We addressed stress by ergospirometry, biochemical analysis of salivary cortisol and α-amylase as well as by self-assessment. The combination of objective stress measurement with observation and self-perception is thought to be a powerful tool for the evaluation of clinical guidelines.

Salivary cortisol and α-amylase do not allow measurements of rapid changes in stress levels.[16,17,23] Therefore, we used mobile ergospirometry in order to gain a more dynamic picture of instantaneous stress. Self-assessment helps to identify individually perceived attitudes and behaviour.[21] In our study, most candidates found it stressful to decide whether or not to begin mask ventilation when hypoxaemia developed in RSI-classic. Although self-assessed stress levels for RSI-classic were significantly higher as compared with RSI-controlled, perceived safety levels remained identically high in both groups. Additionally, we did not find an interaction of stress reduction and experience.

All our candidates were unfamiliar with the protocol of RSI-controlled before their participation in this study. Some reported distinct stress with this technique because deliberate mask-ventilation in RSI breaches a strong anaesthetic dogma. This emphasizes the importance of educational strategies before the establishment of a clinical guideline in order to achieve its intended benefit.

Some limitation of simulator-based studies is related to their clinical authenticity, including distinct technical features of the manikin. However, reproducible stress progression was generated in the course of all scenarios in all candidates, also

revealing distinct differences between the two RSI techniques. In concordance with other investigators our results support the assumption that essential clinical features of an evaluated protocol can be validly reproduced in a simulator setting.[20,21,24]

In conclusion, we found that the reduction of haste in RSI-controlled compared with RSI-classic reduces the incidences of unsafe actions as well as the providers' stress levels. Some stress measurements correlated positively with professional experience without differences between the two RSI techniques.

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