Introduction of a rapid sequence induction checklist and its effect on compliance to guidelines and complications

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Background: Current evidence for the conduct of rapid sequence induction (RSI) is weak. This increases the risk of clinicians modifying the RSI procedure according to personal preferences. Checklists may help increase compliance to best practice guidelines and reduce complication rates. Their value during RSI, a critical procedure in anaesthesia, is unknown. The aim of this study was to investigate compliance to local guidelines and frequency of RSI-related complications before and after introduction of an RSI checklist.

Methods: This was a prospective, observational, pre- and post-intervention study conducted at two hospitals. There were two interventions: the first was a standardized educational lecture to all staff at both hospitals, consisting of an educational instruction of the checklist and general information about RSI, and the second intervention was the introduction of a RSI checklist. The checklist consisted of 16 items. Compliance to guidelines was categorized as high, moderate and low, and was assessed pre- and post-intervention. The frequency of RSI-related complications was also measured.

Results: We registered 811 RSI procedures of which 412 were pre-intervention. After intervention, the proportion of procedures with high compliance to RSI guidelines increased from 49% to 70% (P < .001). The proportion with partial and low compliance decreased from 37% to 26% (P < .001) and 13% to 3.3% (P < .001) respectively. No change in RSI-related complication rates was detectable post-intervention (16.6%-16.7% P = .56).

Conclusion: The introduction of a structured RSI checklist significantly increased compliance to RSI guidelines. A change in RSI-related complications could not be detected due to the size of the study. A checklist may be a useful tool to reduce variance during the RSI procedure.
1 | INTRODUCTION

The concept of rapid sequence induction (RSI) of anaesthesia was introduced during the 1970's by Stept and Safar, as a 15-step procedure to reduce the risk of aspiration of foreign material to the lungs during induction of anaesthesia. Today the main differences between RSI and non-RSI induction are (1) pre-determined drug doses; (2) pre-oxygenation with 100% inspired oxygen (FiO₂), fresh gas flow (FGF) of ≥10 L/min for ≥3 minutes and the absence of manual lung ventilation before administering neuromuscular blockers prior to tracheal intubation.

Despite being introduced almost 50 years ago, this perioperative procedure has hardly changed to this day. Although the Scandinavian Society of Anaesthesia and Intensive Care has published guidelines on general anaesthesia for emergency situations that encompass the use of RSI, these guidelines have not been updated since their publication in 2010. We could find only one study that examined the effectiveness of RSI in preventing aspiration and decreasing direct complications of induction. Other available publications are mainly comparative studies on intubating conditions in emergency departments, usage of various analgesics, hypnotics and neuromuscular blockers. Only a few clinician-reported surveys exist regarding current practice, all of which have limitations, particularly bias in reporting. There are no European guidelines for RSI and few countries in Europe have national guidelines. RSI as a structured intervention is difficult to study in randomized controlled studies due to concerns regarding exposure of patients at high risk to potentially serious complications such as aspiration. The lack of evidence-based guidelines may lead clinicians to conduct the procedure according to experience and expert opinion despite the availability of local guidelines.

The use of checklists within perioperative medicine may decrease variation and improve safety in perioperative care. For example, the World Health Organization (WHO) Surgical Safety Checklist (SSC) has been associated with a decrease in post-operative complications and mortality. To our knowledge, there are no studies investigating whether a checklist for RSI may affect compliance to guidelines and complications during induction of anaesthesia. We designed a checklist for RSI based on evidence in current literature and local guidelines and introduced it at the anaesthetic departments of two hospitals in Sweden.

The aim of this study was to investigate compliance to local guidelines and its effect on six RSI-related complications, before and after structured introduction of the RSI checklist.

Our hypothesis was that an RSI checklist would affect staff compliance to local guidelines and decrease RSI-related complications.

2 | METHODS

2.1 | Study design

This prospective observational study of staff compliance to local RSI guidelines was performed at two hospitals in Region Östergötland and local guidelines and introduced it at the anaesthetic departments of two hospitals in Sweden.

The Ethics Committee of Linköping (D.nr 2017/393-31, 18/10 2017). All staff members (specialist anaesthetist, nurse-anaesthetist and resident) performing RSI in adult patients ≥18 years of age were eligible for inclusion. Exclusion criteria were refusal to participate, or RSI performed in patients <18 years old (Figure 1). All members of the staff at the participating centres were given oral and written information about the study, and consent was implied by completion of the questionnaire.

2.2 | Checklist design and content

The checklist is a 16-item document consisting of statements requiring binary yes/no and 'check' answers (Appendix S1). The statements were based on prior data in literature regarding the RSI procedure. Although we acknowledge that there is no evidence base for many of these items, they were found to be generally acceptable among clinicians and in line with current local guidelines at each hospital. The RSI checklist was designed to encourage consistency and completeness in RSI preparations and execution.

2.3 | Intervention

Pre-interventional observations were conducted from February 2016 to August 2017, the intervention was conducted during October to December 2017 and post-interventional observations were conducted from January to August 2018.

The interventional part of the study consisted of the introduction of an RSI checklist (Appendix S2). An educational lecture on its use was attended by all staff, which included 71 nurse anaesthetists (NA) and anaesthetists (A) at hospital 1 and 218 at hospital 2. To ensure conveyance of uniform information, one person (J.Z.) held the lectures on two separate occasions at both hospitals. The lectures were held during October 2017 at hospital 1 and December 2017 at hospital 2. The lectures covered local RSI guidelines, understanding the importance of a properly conducted

Editorial Comment

Rapid sequence induction (RSI) is used every day in anaesthesia practices, and personal preferences for how to implement this can vary. There is limited evidence for one uniform standardized procedure, so this 811 patients observational study tested compliance and complications with implementation of a single hospital system-chosen 16-step RSI checklist. Overall compliance was increased after instruction with this, although complications such as desaturation, hypotension, aspiration and dental injury rates did not appear to change.
RSI procedure, presentation of the RSI checklist and how to use it in practise.

NAs or As attending the patient during RSI completed a predefined questionnaire (Appendix S2) about the conduct of RSI and RSI-related complications. The questionnaire was completed immediately after induction and the same questionnaires were used pre- and post-intervention. Data were entered manually into the questionnaire that were collected at the end of each day. No data were collected from the patients’ medical records.

To mitigate possible bias due to self-reporting, 5% of observation questionnaires were doublets completed by both the NA/A and an independent assessor observing the RSI procedure.

2.4 | Definition of outcome parameters

The primary outcome was the compliance to local guidelines at the two hospitals (Appendices S3 and S4) before and after the intervention. Compliance was measured as a 7-point score, defined as the fulfilment of each seven parameters: (1) 100% FiO\textsubscript{2} with FGF ≥10 L/min for ≥3 minutes, (2) use of thiopentone or ketamine, (3) use of succinylocholine, (4) use of an orogastric tube, (5) use of a stylet in the endotracheal tube, (6) administration of sodium citrate and (7) reverse Trendelenburg or supine patient position. Each fulfilled requirement yielded 1 point. The degree of compliance to guidelines was categorized into low compliance (1-3 points), partial compliance (4-5 points) and high compliance (6-7 points). The categories were defined by consensus of the authors and individual parameters were not weighted.

The secondary outcome was the frequency of predefined RSI-related complications measured during induction of anaesthesia. The main complications were defined according to the Swedish Perioperative Registry (Appendix S5):

- Hypotension: If continuous vasopressor support was needed to counteract induction.
- Desaturation: Hypoxia: with Sp\textsubscript{O}\textsubscript{2} < 90% that required specific intervention to correct, for example lung recruitment.
- Bradycardia: Bradycardia that required administration of drugs to ameliorate.

The following complications were also registered in the questionnaire:

- Any complication: If any complications was detected during induction.
- Difficult airway: If unexpected difficult airway was detected.
- Regurgitation: If there was suspected or verified regurgitation of foreign material to the lungs.
- Dental injury: Injury to teeth during intubation.

The study results were reported according to the STROBE checklist for observational studies.

2.5 | Hospital characteristics

The two included hospitals are a university hospital and a regional emergency hospital in Östergötland County, Sweden. Both hospitals provide general-, orthopaedic-, gynaecological- and otolaryngology / head and neck surgery. Neuro- and plastic surgeries are exclusive to the university hospital (Table 1). Even if they have similar surgical departments, their profiles differ. The university hospital is more aligned towards malignant and elective surgery while the regional emergency hospital provides more non-malignant and emergency surgery as well as most elective caesarean sections in the region. Their volumes differ and reflect their assignments, the university hospital performs around 14 700 surgeries annually, and RSI is used in approximately 10% of the cases. At the regional emergency hospital, approx. 8300 surgeries are performed annually; RSI is used in 20% of the cases.

2.6 | Statistical analysis

Assuming a 20% pre-intervention compliance, we calculated that 294 observations at each time point would be required to detect a 10% absolute change in compliance using a two-sample proportions test, with a power of 80% and α = 0.05. In order to account for incomplete and missing data, we arbitrarily increased the sample size to around 400 observations for each of the pre- and post-intervention time points.
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<th>Post-intervention</th>
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<td>53 ± 19</td>
<td>53 ± 20</td>
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<td><strong>BMI (kg/m²), mean ± SD</strong></td>
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<td>27 ± 6</td>
<td>27 ± 6</td>
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<td>161 (40)</td>
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<td>124 (33)</td>
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<td>ASA 2</td>
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<td>333 (42)</td>
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<td>90 (24)</td>
<td>184 (23)</td>
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<td>8 (2)</td>
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<tr>
<td><strong>Neuromuscular blockade, n (%)</strong></td>
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<td>Succinylcholine</td>
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<td>384 (97)</td>
<td>788 (96)</td>
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<td>Rocuronium</td>
<td>17 (4)</td>
<td>11 (3)</td>
<td>29 (4)</td>
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</table>

**Note:** Patient characteristics and procedural data of the study cohort presented as number and per cent of total.

**Abbreviations:** BMI, body mass index; SD, standard deviation.

²Urology, neurosurgery, vascular catheter intervention, orofacial surgery, ent-surgery, radiological intervention, procedural anaesthesia.

²Ventricular retention, bleeding, non-fasting, airway protection.
Data were manually entered into MS excel and imported into IBM SPSS Statistics version 25 (SPSS) for statistical analysis. The Shapiro-Wilk test was used to control for normality of continuous variables and these data are expressed as mean ± standard deviation or median (range). χ² test was used to compare compliance to local guidelines in each of the three categories (low, partial and high) before and after the intervention. P-values ≤0.05 were considered significant. Inter-rater agreement between the subjects and the independent assessor was assessed using Cohen’s kappa. Kappa values <0.2 indicate poor, 0.21-0.4 fair, 0.41-0.6 moderate, 0.61-0.8 good and ≥0.8 excellent agreement.²¹

3 | RESULTS

3.1 | Baseline characteristics

During the study period, we recorded 849 RSI procedures conducted by anaesthetists and nurse-anaesthetists, of which 38 were excluded due to age <18. A flow chart of the inclusion procedure is presented in Figure 1. There were no differences in baseline characteristics between the pre- and post-intervention cohorts (Table 1). During the pre-interventional observation, an average of 25 observations were collected per month, this increased to 51 observations per month during the post-intervention period.

The inter-rater agreement between the assessments reported by anaesthetists/nurse anaesthetists and the independent observer was excellent, with a kappa value of 0.83.

3.2 | Compliance to guidelines

The median (range) pre-interventional and post-interventional compliance scores were 5 (0-7) and 6 (1-7) respectively (P < .001). Low and partial compliance scores accounted for about 50% of pre-intervention observations. Compared to pre-intervention, there was a decrease in the proportions of the low and partial compliance groups post-intervention, by 10% (P < .001) and 11% (P < .001) respectively. A 21% increase (P < .001) in the proportion of high compliance RSIs was observed after the intervention (Figure 2).

3.3 | Complications

The complication rate was 16% pre- and 17% post-intervention (P = .57). The most common complication observed was hypotension following induction of anaesthesia. There were no significant differences in incidence of individual or total complications pre- and post-intervention (Table 2).

A post-hoc analysis was performed to investigate the change in each of the seven parameters examined. All patients observed in the study received pre-oxygenation; however, pre-oxygenation according to guidelines (100% FiO₂ with FGF ≥ 10 L/min for ≥3 minutes) showed the greatest increase in compliance after intervention (P < .001). (Table 3).

4 | DISCUSSION

4.1 | Principal findings

The main finding of this study is that improved compliance to local RSI guidelines can be achieved by a structured intervention.
The most common complication observed was hypotension, which accompanied by a significant difference in complication rates in this study. To our knowledge, this is the first study investigating and comparing compliance towards better compliance to evidence-based guidelines.

The improved compliance to local RSI guidelines was not accompanied by a significant difference in complication rates in this study. The most common complication observed was hypotension, which has also been reported in previous studies. One case of regurgitation, one of the more serious complications of RSI, was recorded before intervention. Since the number of complications was low, there is a significant risk of incurring a Type II error for this analysis. Notably, the present study was designed and powered to detect relevant differences in compliance rates rather than complication frequencies. Previous studies using the WHO SSC show that the adherence to checklists reduced frequencies of complications in perioperative settings. It is, therefore, reasonable to suspect that the present RSI checklist may be a useful tool not only to reduce variation in anaesthetic practice but also to reduce the frequency of complications. Future investigations with adequate sample sizes are required to obtain sufficient power to detect differences in complication rates.

This study was designed to analyse if a structured intervention could increase the compliance to existing clinical guidelines. The RSI procedure was chosen because it is a well-established procedure in clinical work. Although evidence-based support for RSI is weak, there are studies that show advantages with the technique such as higher first success intubation rate with no increase in complications compared to non-RSI induction. Furthermore, RSI is a step-by-step procedure that is readily adapted to the checklist principle.

The educational part of the intervention served a dual purpose. Firstly, it is paramount to understand how to use the checklist and, second, it increases the general knowledge about the RSI procedure itself. Studies have shown that advanced technical skills are perishable and require training/use in regular intervals. As not all staff practice RSI on a daily basis, maintenance training could be implemented on a regular, yearly basis to prevent skill decay.

Whether the use of checklists compensates for skill decay or not, needs further investigation.

As shown in the secondary analysis, improvement in compliance to the pre-oxygenation guideline was the main reason for the increase in compliance scores. This may have been the result of the intervention lecture, or more likely, the incentive to pre-oxygenate the patient while going through the steps of the checklist. Pre-oxygenation and subsequent apnoea without desaturation is one of the parts of the RSI procedure with highest grade of evidence (Grade A) and also one of the major causes of morbidity and mortality due to anaesthesia. The post-interventional compliance to the pre-oxygenation variable was 40% (n = 158). The low compliance to this guideline could indicate an underestimation of its importance.

The current practice of RSI is highly variable depending on local guidelines, location and situation. In the light of these results, a pre-RSI checklist could be a useful tool to improve compliance to strive towards better compliance to evidence-based guidelines.

### 4.2 Strengths

Compared to self-reported clinician surveys, this study provides a less subjective view of the clinical environment. To our knowledge, we provide the first structured report on compliance to RSI guidelines and propose an intervention that may improve the standard of care. We suggest that the results of this study may be used as a basis for a sample size calculation for future interventional studies on RSI.

### 4.3 Limitations

As an observational study, we cannot exclude the possibility of bias, in particular, selection and reporting bias. For example, senior anaesthetists (>10 years experience) represented 40% of this sample. However, this is in line with the current distribution of anaesthesiologists at both hospitals. Reporting bias is a risk with self-reported data. However, we took steps to mitigate this by designing a study with a completely anonymized questionnaire, as well as an independent observer reporting findings in a subset of observations. We did not record times and dates in each questionnaire, however, we acknowledge that this information may have been useful for evaluating the possibility of a Hawthorne effect and short-term skill decay.
There are other limitations—we did not evaluate the effect of separate parts of the intervention. We arbitrarily categorized compliance into three groups that we believe would be clinically relevant, but this remains an arbitrary classification.

The study was conducted in Sweden; the hospitals differed in size with different surgery profiles. Not all types of surgery are included (e.g., ambulatory surgery, thoracic surgery, vascular surgery). This may affect the generalizability of the study, although a wide variety of surgical procedures were included.

### 4.4 Conclusion

A targeted intervention consisting of a structured introduction of an RSI checklist increases the compliance to local guidelines. This may be a useful method of reducing practice variation during this high-risk procedure. A reduction in RSI-related complications could not be demonstrated and remains to be evaluated in larger studies.

### ACKNOWLEDGEMENTS

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### CONFLICT OF INTEREST

None.

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### REFERENCES


SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section.