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ORIGINAL ARTICLE

Maintaining endotracheal tube cuff pressure at 20 mmHg during anterior cervical spine surgery to prevent dysphagia: a double-blind randomized controlled trial

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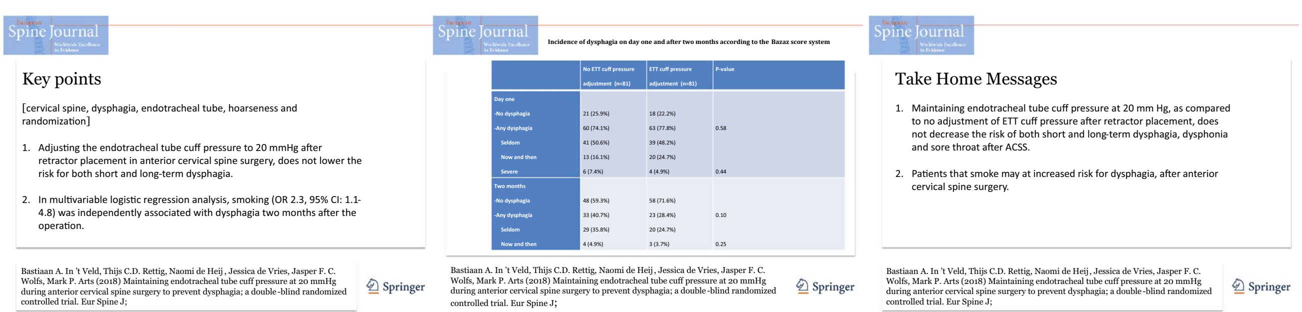
Abstract

Purpose Anterior cervical spine surgery is associated with postoperative dysphagia, sore throat and dysphonia. It is unclear, whether this is caused by increased endotracheal tube (ETT) cuff pressure after retractor placement. This study aims to assess the effect of ETT cuff pressure adjustment on postoperative dysphagia, sore throat and dysphonia.
Methods In this, single-centre, observer and patient-blinded randomized controlled trial patients treated with anterior cervical spine surgery were randomized to adjustment of the ETT cuff pressure to 20 mmHg after placement of the retractor versus no adjustment. Primary outcome was the incidence and severity of postoperative dysphagia. Secondary outcomes were sore throat and dysphonia. Outcomes were evaluated on day one and 2 months after the operation.
Results Of 177 enrolled patients, 162 patients (92.5%) could be evaluated. The incidence of dysphagia was 75.9% on day one and 34.6% 2 months after surgery. Dysphagia in the intervention and control group was present in 77.8% versus 74.1% of patients on day one (odds ratio (OR) 1.2, 95% confidence interval (CI) (0.6–2.5)) and 28.4% versus 40.7% of patients after 2 months (OR 0.6, 95% CI 0.3–1.1), respectively. Severity of dysphagia, sore throat and dysphonia was similar in both groups.
Conclusions Anterior cervical spine surgery is accompanied by a high incidence of postoperative dysphagia, lasting until at least 2 months after surgery in over a third of our patients. Adjusting ETT cuff pressure to 20 mmHg after retractor placement, as compared to controls, did not lower the risk for both short- and long-term dysphagia.
Netherlands National Trial Registry Number: NTR 3542.

Graphical abstract These slides can be retrieved under electronic supplementary material.



Keywords Cervical spine · Dysphagia · Endotracheal tube · Hoarseness and randomization

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Extended author information available on the last page of the article

Introduction

Approximately two-thirds of patients undergoing anterior cervical spine surgery (ACSS) suffer from postoperative dysphagia, dysphonia or a sore throat [1–4]. This may be the result of neuropraxia of the recurrent laryngeal nerve, postoperative haematoma or oedema. Another possible cause is an increased endotracheal tube (ETT) cuff pressure. In order to expose the anterior cervical spine in patients undergoing ACSS, a retractor is used. This retractor is placed between the carotid sheath laterally, and the trachea and the oesophagus medially. The ETT cuff pressure commonly exceeds 60 mmHg after positioning and opening of the retractor [5]. Structures trapped between the retractor and the ETT, like the recurrent laryngeal nerve, may then be compromised.

Targeting an ETT cuff pressure below 25 mmHg after intubation is recommended in patients undergoing general surgery to reduce endotracheal intubation-related complications [6, 7]. Reducing the ETT cuff pressure after placement of the retractor in patients undergoing ACSS may therefore decrease the occurrence of postoperative dysphagia, sore throat and dysphonia. However, in a recent systematic review Liu et al. [8] showed that there is no high-quality evidence for recommending standard adjustment of ETT cuff pressure in patients undergoing ACCS.

The aim of this study was to investigate the effect of ETT cuff pressure adjustment after retractor placement in patients undergoing ACSS on the incidence and severity of postoperative dysphagia, sore throat and dysphonia.

Methods

Study design

The study protocol was approved by the medical ethics committee Zuid-West Holland, the Netherlands (trial number NL35829.098.11), and published previously [9]. Written informed consent was obtained in each patient. We designed a single-centre, observer and patient-blinded randomized controlled trial comparing adjustment of ETT cuff pressure after retractor placement with no adjustment in patients undergoing ACSS. The null hypothesis of this study was that there was no difference in incidence of dysphagia in patients in which we adjusted ETT cuff pressure after retractor placement as compared with no adjustment in patients undergoing ACSS.

Patients were recruited between January 2012 and January 2015. The follow-up period was 2 months. The study was performed in accordance with the guidelines for good clinical practice and followed the Declaration of Helsinki.

Participants

All patients between 18 and 90 years of age requiring primary ACSS were eligible for inclusion. Patients were excluded, a priori, in the presence of preoperative dysphagia, dysphonia or a sore throat; preoperative recurrent laryngeal nerve palsy; earlier ACSS; insufficient proficiency of the Dutch language; a planned fiberoptic or rapid sequence intubation; and in case the patient was mentally disabled or planned peroperative use of N_2O. During the patient's visit to the preoperative outpatient clinic, the anaesthesiologist decided whether the patient was eligible for this trial. The study was explained, and in case of a positive reaction, patients received written information. A research nurse contacted the patient a few days after the visit to the outpatient clinic to ask whether the patient was willing to participate.

Intervention and randomization

The randomization was performed using an online randomization program (www.randomization.com) using the method of randomly permuted blocks. After induction of general anaesthesia, the attending anaesthesiologist opened an envelope and the allocated treatment was performed. Patients were randomized to either adjustment of the ETT cuff pressure after retractor placement (intervention group) or no adjustment of the ETT cuff pressure (control group). After intubation, the ETT cuff pressure was manually inflated to 20 mmHg in all study patients. In the intervention group, the ETT cuff pressure was maintained at 20 mmHg after placement and after removal of the retractor. Air was withdrawn when the ETT cuff pressure exceeded 20 mmHg. In the control group, the ETT cuff pressure was not adjusted after placement of the retractor. In the absence of a device to measure the ETT cuff pressure continuously electronically, the cuff pressure was measured after placement and before removal of the retractor.

The attending anaesthesiologist determined the anaesthetic management during surgery, which typically consisted of propofol, fentanyl and rocuronium for induction with subsequently sevoflurane and fentanyl and a reversal agent if necessary. A skilled laryngoscopist (> 1 year experience) performed the intubation. A GlideScope was used to increase the first pass success rate and to standardize airway management. The use of the GlideScope is associated with a high overall success rate and a low complication rate [10, 11]. Endotracheal tube size was 7.0 mm for women and 8.0 mm for men. All patients received dexamethasone after induction of anaesthesia. After the operation, patients were treated with oral acetaminophen, oral celecoxib and piritramide subcutaneously. Patients, surgeons and research nurses were unaware of the allocated treatment during the follow-up of 2 months.

Next to standard patient data, we recorded the time of retraction, duration of surgery, level of operation, number of levels operated on, the use of a cage or other implant [12], the attending neurosurgeon and the dose of neuromuscular blocking agent. Post hoc, we examined our anaesthesia records and recorded in which patient the intubation caused problems.

Surgical procedure

All patients were positioned supine with their neck in neutral position or slightly extended. The affected cervical disc level was verified with fluoroscopy. A small transverse incision was made on the right side in all patients. The prevertebral space was approached between the carotid sheath laterally, and the trachea and oesophagus medially. The retractor systems used were Caspar Cervical Retractor System (CCR) (Braun Aesculap) or the Trimline retractor (Medtronic). Depending on the pathology of the patients, the following surgical procedures were performed: one level anterior cervical discectomy with interbody fusion (ACDF) or disc prosthesis, two-level ACDF, or corpectomy with the placement of an expandable cage.

Outcome measures

The primary outcome was the incidence and severity of postoperative dysphagia. This was evaluated on day one and 2 months after the operation using the Bazaz dysphagia score. This is a validated questionnaire for the assessment of dysphagia and defines dysphagia into four grades: none (no episode of swallowing difficulty), seldom (experienced only rare episodes of dysphagia and not considered a significant problem), now and then (occasional swallowing difficulty with specific foods, e.g. bread, steak) and severe (frequently difficulty swallowing, e.g. with the majority of foods) [13]. In addition, we scored dysphagia as a cluster score (none/present). Secondary outcome measures were dysphonia and sore throat. For the auditory-perceptual evaluation of dysphonia, we used the GRBAS scale [14, 15]. This scale grades five aspects of voice (G = grade of dysphonia, R = roughness, B = breathiness, A = asthenicity and S = strain) on a four-point scale ranging from 0 to 3 (0 = none, 1 = slight, 2 = moderate, 3 = severe), while patients read out a Dutch standardized text of the International Phonetic Alphabet [16]. We analysed the grade (severity) component of the GRBAS scale. Voice recordings were taken preoperatively on day one and 2 months after the operation (Philips, Voice tracer®) and were subsequently assessed by three independent speech therapists. Sore throat was assessed using a numeric rating scale (NRS) [17]. A trained blinded research nurse assisted the patients for the completion of the forms and the voice recordings. In addition to the assessment of the main outcomes, we examined whether there was evidence for other factors being predictive for long-term dysphagia. Age, female gender, smoking, level of surgery, number of levels operated upon and duration of endotracheal intubation have earlier been associated with an increased risk of dysphagia [18–20].

Statistical analysis

Continuous data are described as mean and standard deviation, categorical data by numbers and percentages. To compare continuous variables between the intervention and the control group, the ANOVA was used. To compare categorical variables between the groups, the χ^2 test or Fisher's exact test was used.

For the analyses of the GRBAS score, we used the rounded mean of three individual assessments. Any within-group differences in GRBAS score were compared using the Wilcoxon signed-ranks test.

In addition to the assessment of the effect of the intervention on primary outcome we assessed whether, given randomization, baseline characteristics or intraoperative variables were individually associated with dysphagia. For this purpose, we used logistic regression analyses. Variables associated with dysphagia in univariate analysis were entered in the model ($p \leq 0.1$).

Our sample size calculation was based on the hypothesis that the incidence of dysphagia in the intervention group would be 20%, being 50% less than in the control group (40%). Assuming a power of 80%, $\alpha = 0.05$ and an expected loss to follow-up of 8% and necessitating a final 81 patients in each arm, we should therefore include 177 patients [9]. SPSS version 22.0 was used for statistical analysis. A p value < 0.05 was considered significant in all analyses.

Results

Patient characteristics

During the study period, 208 patients undergoing ACSS were screened and 177 patients were included. Eight patients were excluded for various reasons: incorrectly executed study procedure ($n = 3$), unrecognized exclusion criteria ($n = 2$), transfer to an operation theatre without the possibility to perform the study procedure ($n = 2$) and insufficient motivation to proceed in the study procedure ($n = 1$). In addition, 7 patients were lost to follow-up. The remaining 162 patients were included in the analysis: 81

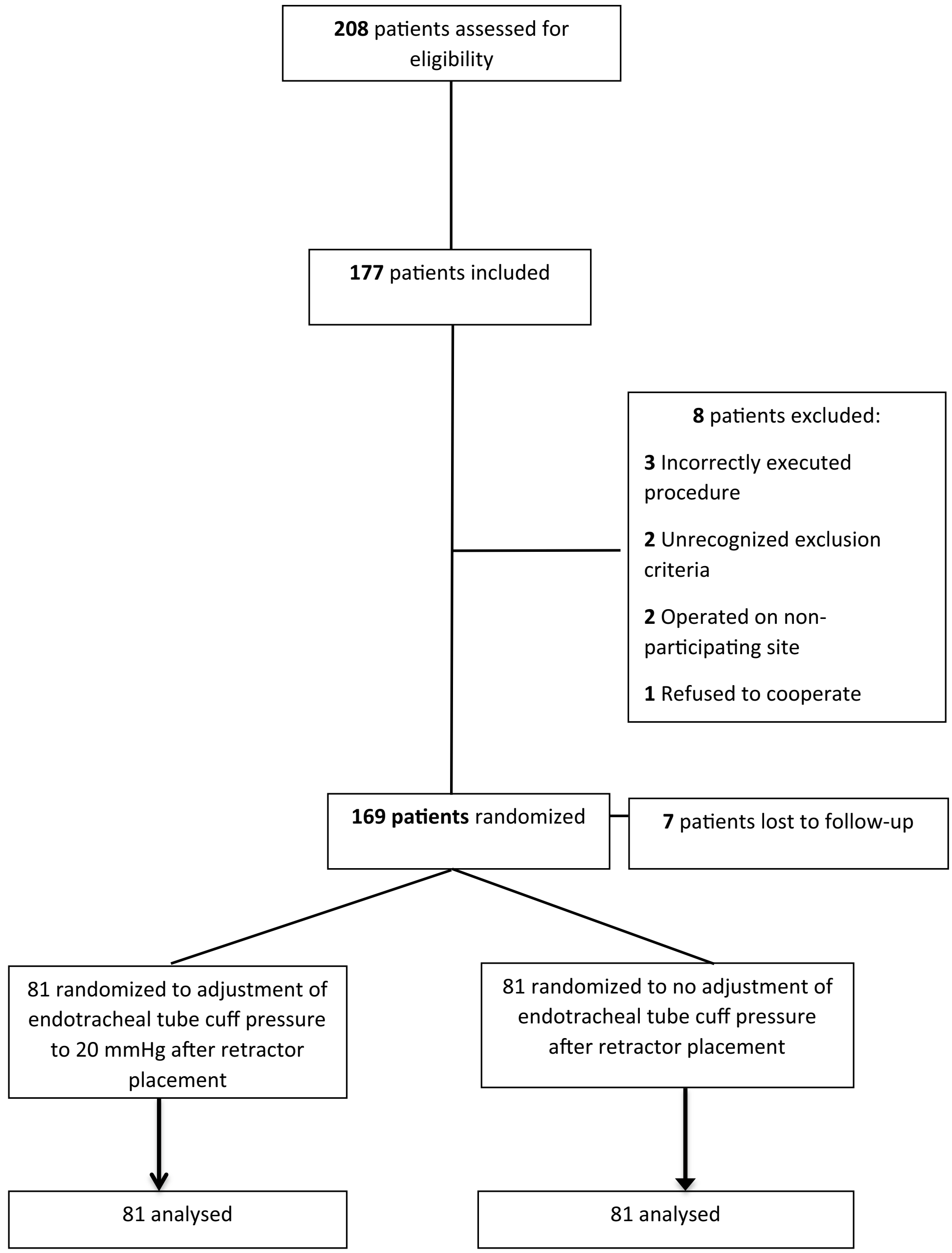

Fig. 1 Patient selection

patients in the intervention group and 81 patients in the control group (Fig. 1).

The mean age was 51 years and 44% of patients were male (Table 1). Variables previously associated with dysphagia, such as retraction time and duration of surgery, were similar in the intervention and control group (Table 2). ETT cuff pressure was 20 mmHg (SD $\pm$ 4.0) in the intervention group vs. 33 mmHg (SD $\pm$ 13.2) in the control group ($p < 0.001$).

Main outcomes

In general, the incidence of dysphagia was 76% on day one, which decreased to 35% after 2 months ($p < 0.01$). None of the patients experienced severe dysphagia after 2 months (Table 3). Dysphagia in the intervention and control group was present in 77.8% versus 74.1% of patients on day one (OR 1.2, 95% CI 0.6–2.5) and 28.4% versus 40.7% of patients after 2 months (OR 0.6, 95% CI 0.3–1.1),

Table 1 General preoperative characteristics

	No ETT cuff pressure adjustment ($n=81$)	ETT cuff pressure adjustment ($n=81$)	p value
Male gender [n (%)]	38 (46.9%)	34 (42.0%)	0.53
Age (years)	50.4 ± 1.01	50.5 ± 1.15	0.94
ASA classification [n (%)]			
1	31 (38.3%)	29 (35.8%)	
2	46 (56.8%)	49 (60.5%)	
3	4 (4.9%)	3 (3.7%)	0.86
BMI (kg/m^2)	27.4 ± 4.7	26.7 ± 3.8	0.37
Preoperative haemoglobin (mmol/l)	9.2 ± 0.44	9.2 ± 0.44	0.79
Preoperative systolic blood pressure (mmHg)	137.1 ± 16.1	139.7 ± 16.9	0.30
Preoperative diastolic blood pressure (mmHg)	86.4 ± 10.2	84.6 ± 11.6	0.30
Smoking [n (%)]	30 (37%)	33 (40.3%)	0.63
Alcohol use [n (%)]	48 (59.3%)	50 (61.7%)	0.75

Chi-square statistic, Fisher's exact test and ANOVA were used when appropriate

ETT, endotracheal tube; *ASA,* American Society of Anaesthesiology; *BMI,* body mass index

Table 2 Perioperative characteristics

	No ETT cuff pressure adjustment ($n=81$)	ETT cuff pressure adjustment ($n=81$)	p value
First pass intubation [n (%)]	78 (96.3%)	77 (95.1%)	$p=0.53$
Level of surgery (n)			
C3–4	11 (13.6%)	10 (12.3%)	0.82
C4–5	10 (12.3%)	13 (16.0%)	0.49
C5–6	53 (65.4%)	42 (51.9%)	0.08
C6–7	27 (33.3%)	35 (43.2%)	0.20
C7–Th1	1 (1.2%)	2 (2.5%)	0.56
Levels			
1	58 (71.6%)	61 (75.3%)	
2	23 (28.4%)	18 (22.2%)	
3	0	2 (2.5%)	0.26
Retraction time (min)	39.2 ± 19.0	37.6 ± 18.1	0.60
Surgery time (min)	59.7 ± 19.7	54.0 ± 18.6	0.14
ETT cuff pressure at time of spreader removal (mmHg)	32.9 ± 13.2	20.0 ± 4.0	< 0.01
Cage implant (n)	77 (95.1%)	78 (96.3%)	0.70

Percentage or standard deviation between brackets. Chi-square statistic or ANOVA where used when appropriate

ETT, endotracheal tube

respectively. The severity of dysphagia did not differ between the groups.

A sore throat (NRS ≥ 4) on day one was present in 20% of patients in the control group versus 19% in the intervention group ($p=0.85$). After 2 months, the incidence decreased to 1% in both groups ($p=1.00$).

Although preoperative dysphonia was one of the exclusion criteria, the preoperative voice recordings revealed no abnormalities in only 7% of all patients (Table 4). According to the grade parameter, 2 months after surgery 16% of patients improved and 14% deteriorated as compared to the preoperative situation. However, the severity of dysphonia was similar in the intervention group and the control group, both on day one and after 2 months. In addition, none of the other variables of the GRBAS score yielded any significant difference between intervention and control group (not shown).

Other potential causes of dysphagia

In subsequent ad hoc analyses, we examined which of the baseline variables was univariately associated with

Table 3 Incidence of dysphagia on day one and after 2 months according to the Bazaz score system

	No ETT cuff pressure adjustment ($n=81$)	ETT cuff pressure adjustment ($n=81$)	p value
Day one			
No dysphagia	21 (25.9%)	18 (22.2%)	
Any dysphagia	60 (74.1%)	63 (77.8%)	0.58
Seldom	41 (50.6%)	39 (48.2%)	
Now and then	13 (16.1%)	20 (24.7%)	
Severe	6 (7.4%)	4 (4.9%)	0.44
2 months			
No dysphagia	48 (59.3%)	58 (71.6%)	
Any dysphagia	33 (40.7%)	23 (28.4%)	0.10
Seldom	29 (35.8%)	20 (24.7%)	
Now and then	4 (4.9%)	3 (3.7%)	0.25

Chi-square statistic was used to test differences between the groups

Table 4 Dysphonia according to GRBAS scale (grade component)

	Control ($n=81$)	Intervention ($n=81$)	p value
Preoperative grade			
0	4 (4.9%)	7 (8.6%)	
1	49 (60.5%)	51 (63.0%)	
2	26 (32.1%)	23 (28.4%)	
3	2 (2.5%)	–	0.39
Day one grade*			
0	3 (3.8%)	1 (1.2%)	
1	37 (46.3%)	35 (43.2%)	
2	34 (42.5%)	40 (49.4%)	
3	6 (7.5%)	5 (6.2%)	0.65
2 months* grade			
0	8 (10.0%)	6 (7.4%)	
1	39 (48.8%)	48 (59.3%)	
2	31 (38.8%)	26 (32.1%)	
3	2 (2.5%)	1 (1.2%)	0.58

Chi-square statistic was used to test differences between the groups

*Incomplete follow-up in one control patient

long-term dysphagia (Table 5). In this analysis, we also added cuff pressure before spreader removal, initially left out (because of being an intermediate of the randomization). In a multivariable logistic regression analysis, including all variables with a $p \leq 0.1$, smoking (OR 2.3, 95% CI 1.1–4.8) was the only variable that remained significantly associated with long-term dysphagia. Female gender, cuff pressure and duration of surgery were no longer significantly associated.

Documented complications were infection ($n=2$), reoperation because of a malpositioned cage or infection ($n=4$), voice cord paralysis ($n=2$), speech therapist consultation ($n=3$) and severe myalgia in the upper body ($n=2$). The incidence of complications did not differ between intervention and control group.

Discussion

In this double-blind randomized controlled trial, postoperative dysphagia occurred in 75% of patients undergoing ACSS and lasted until at least 2 months in one-third of patients. Adjustment of the ETT cuff pressure to 20 mmHg after placement of the retractor, as compared to no adjustment of the ETT cuff pressure, did not lead to a decreased risk of both short- and long-term dysphagia. In addition, adjustment of the ETT cuff pressure to 20 mmHg after retractor placement did not decrease the risk of dysphonia or a sore throat.

Until now, it was unclear whether routine ETT cuff pressure adjustment after retractor placement in patients undergoing ACSS should be recommended to decrease postoperative dysphagia. [21] Although adjusting the ETT cuff pressure after retractor placement seems a natural way to reduce the stress on structures between the retractor and the ETT cuff and complications such as dysphagia after ACSS, only two randomized controlled trials are conducted on this topic. Ratnaraj et al. [3] randomized 51 patients undergoing ACSS to adjustment of ETT cuff pressure (< 20 mmHg) after retractor placement versus no adjustment. Dysphagia, sore throat and hoarseness were assessed 1 h, 24 h and 1 week after surgery. Except for less sore throat 24 h after surgery (74% in the control group vs. 51% in the intervention group, $p < 0.05$), adjustment of the ETT cuff pressure after retractor placement did not result in a decreased incidence of dysphagia (57% in the control group vs. 48% in the intervention group after 24 h, $p > 0.05$) or hoarseness (52% in the control group vs. 37% in the intervention group, $p > 0.05$) on any of the time intervals. Kowalczyk et al. studied whether adjustment of the ETT cuff pressure to 15 mmHg decreased dysphagia after ACSS in 50 patients [22]. The results showed that maintaining the ETT cuff pressure did not decreased the risk of dysphagia.

This study in patients undergoing ACSS is the largest of its kind. Other strengths are the double-blind randomized design of the study, the use of validated questionnaires, standardized ETT intubation and the use of speech therapists to analyse the voice recordings.

The incidence of dysphagia in our study is in accordance with the reported dysphagia rates after ACSS for radiculopathy [21, 22]. However, the reported rates vary widely between the studies. This wide variance can be attributed to different surgical techniques, the extent and duration of surgery, type of implants used, as well as variations in definitions and measurements of dysphagia, time intervals of postoperative evaluations and small sample sizes [22].

Table 5 General characteristics preoperative and perioperative in patients with or without dysphagia 2 months after surgery

Characteristics	No dysphagia after 2 months ($n=106$)	Dysphagia after 2 months ($n=56$)	p value
Randomized to intervention [n (%)]	58 (54.7%)	23 (41.1%)	0.10
Female gender [n (%)]	53 (50.0%)	37 (66.1%)	0.05
Age (years)	50.5 ± 10.5	50.4 ± 8.3	0.95
BMI (kg/m^2)	27.0 ± 4.4	27.2 ± 4.0	0.77
ASA classification [n (%)]			
1	43 (40.6%)	17 (30.4%)	
2	59 (55.7%)	36 (64.3%)	
3	4 (3.8%)	3 (5.4%)	0.77
Preoperative haemoglobin (mmol/l)	9.2 ± 0.7	9.3 ± 0.8	0.40
Preoperative systolic blood pressure (mmHg)	138.2 ± 15.6	138.8 ± 18.2	0.81
Preoperative diastolic blood pressure (mmHg)	86.2 ± 11.3	84.3 ± 10.2	0.31
Smoking [n (%)]	34 (32.1%)	29 (51.8%)	0.01
Level of surgery [n (%)]			
C3–C4	15 (14.2%)	6 (10.7%)	0.54
C4–C5	15 (14.2%)	8 (14.3%)	0.28
C5–C6	63 (59.4%)	32 (57.1%)	0.86
C6–C7	36 (34.0%)	26 (46.4%)	0.13
C7–Th1	1 (0.9%)	2 (3.6%)	0.37
Levels			
1	84 (79.2%)	35 (62,5%)	
2	21 (19.8%)	20 (35.7%)	
3	1 (0.9%)	1 (1.8%)	0.07
Retraction time (min)	36.8 ± 17.3	42.0 ± 20.5	0.13
Surgery time (min)	53.6 ± 20.8	63.3 ± 30.4	0.02
First-pass intubation success [n (%)]	101 (95.3%)	54 (96.4%)	0.76
ETT cuff pressure at time of spreader removal (mmHg)	33.4 ± 13.6	40.8 ± 18.5	0.01
Surgery with cage implant [n (%)]	103 (97.2%)	52 (92.9%)	0.24

Percentage between brackets or ± standard deviation. Chi-square statistic, Fisher's exact test and ANOVA were used when appropriate

ETT, endotracheal tube; *ASA,* American Society of Anaesthesiology; *BMI,* body mass index

Although there was a significant difference in ETT cuff pressure between the intervention and control group, we found no difference in the incidence of dysphagia after ACSS. What are possible explanations for a lack of a protective effect of decreasing ETT cuff pressure in our study? It is possible that the ETT cuff pressure in the control group was not sufficiently high to cause injury. Although the ETT cuff pressure was significantly different between the groups, this does not necessarily lead to a clinically relevant contrast between the intervention and the control group. In addition, in the causal chain both pressure and time of exposure may be relevant. One might suggest that only if the sum of these variables exceeds a certain threshold, dysphagia may occur. An alternative explanation for the lack of effect of adjustment of ETT cuff pressure may be insufficient statistical power. In our sample size calculation, we assumed a long-term dysphagia rate of 40% in the control group and 20% in the intervention group, while the incidence turned out to be 28% in the intervention group. This could mean that our sample size was too small to show a significant risk reduction. However, if adjustment of the ETT cuff pressure would lead to less dysphagia, a difference between the groups would already be expected 1 day after ACSS. Another plausible explanation for our findings is that surgical exploration of the anterior cervical spine itself is responsible for dysphagia. If so, ETT cuff pressure is merely an intermediate in the chain of events instead of an independent cause.

In addition to a possible lack of statistical power, our study has several other limitations. First, pre-existing dysphonia was present in a substantial amount of patients. This was not recognized during the inclusion procedure and discovered after surgery by the speech therapist while scoring the voice recordings. In our sample, using GRBAS, only a minority of patients were recognized as having no preoperative dysphonia at all. Since this was an exclusion criterion, using the group with no dysphonia at all, would leave us few patients for analysis. However, there is no evidence that the presence of dysphonia confounds the relation between cuff pressure and dysphagia.

Second, use of steroids was not noted in all patients. Steroids may mitigate the severity of dysphagia, thereby potentially obscuring differences between intervention and the control group. However, in a recent study steroids did not decrease the severity of dysphagia [23].

In conclusion, maintaining an ETT cuff pressure at 20 mm Hg, as compared to no adjustment of ETT cuff pressure after retractor placement, did not decrease the risk of both short- and long-term dysphagias, dysphonia and sore throat after ACSS. In addition, we found evidence that smokers are at increased risk of dysphagia after ACSS. This is in line with a large long-term multicenter retrospective study [24]. Based on our results, we do not recommend routine ETT cuff pressure adjustment after retractor placement in patients undergoing ACSS.

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Compliance with ethical standards

Conflict of interest The authors declared that they have no conflict of interest.

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