

Short-term Effect of Chewing Gum in Patients with Mild-moderate Dysphagia After Anterior Cervical Fusion

Study Protocol & Statistical Analysis Plan

(version 20180427)

1. Trial design: A randomized, two arms, parallel-controlled, superiority trial.
Allocation ratio = 1:1

2. Participants:
 - 2.1 Eligibility criteria for participants
 - (1) Inclusion criteria:
 - age from 18 years to 80 years.
 - underwent anterior cervical fusion surgery for degenerative cervical disease.
 - diagnosed with mild or moderate postoperative dysphagia 1 day after surgery using Bazaz scale.
 - (2) Exclusion criteria:
 - Patients underwent revision procedures or procedures treating conditions other than degenerative cervical disease.
 - Patients with preoperative dysphagia.
 - Patients unable to chew, or unable to follow the directions for chewing gum.
 - Patients unable to attend follow-up visits or finish the dysphagia questionnaires.
 - 2.2 Settings and locations of data collection

The data is obtained face to face at the time of hospitalization, and via telephone after discharge.

3. Interventions
 - 3.1 Arms:
 - 1) Chewing Gum Group - standard cares + chewing gum
 - 2) Control Group - standard cares only
 - 3.2 Chewing Gum Group

Subjects assigned to the Chewing Gum Group are asked to chew gum four times a day for 5 days (15 minutes each time) after surgery in addition to standard cares. Standard cares include cleaning the wound every 2 days, wearing a collar, pain management, and education.
 - 3.3 Control Group

Subjects assigned to the Control Group receive standard cares and are asked not to chew gum within 5 days after surgery. Standard cares include cleaning the wound every 2 days, wearing a collar, pain management, and education.

4. Outcomes
 - 4.1 Primary outcome measurement

Name: Dysphagia Short Questionnaire score (DSQ)

Construct: DSQ is designed for the evaluation of swallowing difficulty after anterior cervical spine surgery. It is calculated by summing up the points given for each item, from 0 point to a maximum of 18 points, where lower scores represent milder symptoms and vice versa. (see Appendix I, quoted from *Skeppholm M, et al. Spine, 2012, 37(11):996*)

Time Frame: change from the 1st day after surgery to the 7th day after surgery.

4.2 Secondary outcome measurement

1) Name: Bazaz grading system

Construct: Bazaz grading system is designed for the evaluation of swallowing difficulty after anterior cervical spine surgery. The patients are graded as having none, mild, moderate, or severe dysphagia based on their symptoms. A none or mild dysphagia is considered to be a better outcome. (see Appendix II, quoted from *Bazaz R, et al. Spine, 2002, 27(22):2453-2458.*)

Time Frame: change from the 1st day after surgery to the 7th day after surgery.

2) Name: Prevertebral soft tissue swelling

Construct: The measurement of the soft tissue space is made on the line parallel to the upper end plate from the midpoint of the anterior surface of each vertebral body to the border of the airway shadow. This scale ranges from 0 to approximately 30 mm for each vertebra, where a lower value represents a milder soft tissue swelling. (see Appendix III, quoted from *Suk K, et al. International Orthopaedics, 2006, 30(4):290-4.*)

Time Frame: the 3rd days after surgery.

5. Sample size

It is estimated that 90 participants (45 per group, allowing for 15% attrition) would be required to detect a 1 score difference of DSQ between the groups with 80% power and alpha of 0.05, based on our preliminary results.

6. Randomisation

At the first study visit after surgery, patients are invited to participate by providing written informed consent. Participants are randomly allocated according to a randomization schedule, which is generated by a designated person in our statistics department, who is not involved in the rest of the study.

7. Blinding

The outcomes assessors are masked to patient allocation, but patients and treatment providers are open-labelled.

8. Statistical analysis plan

The differences of change value of DSQ and postoperative Prevertebral Soft-tissue Swelling between two group are compared using *student t-test*. The differences of change grading of Bazaz scale between two groups are compared using *Wilcoxon rank sum test*. $P < 0.05$ is considered statistically significant.

9. Appendix

Appendix I: Dysphagia Short Questionnaire

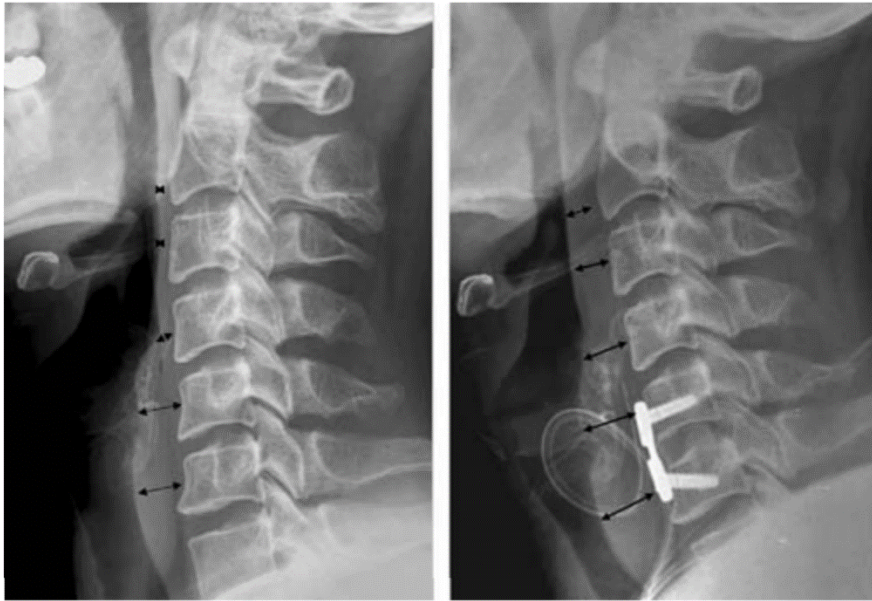
Please tick one box only, under each heading.

Ability to swallow	Points
I have no difficulty in swallowing	0
Food occasionally gets stuck in my throat if I have not chewed it thoroughly enough	1
I find it hard to swallow solid food	2
I find it hard to swallow liquid food	3
I find it hard to swallow saliva	4
Incorrect swallowing	
I do not feel that I swallow incorrectly	0
I sometimes feel I'm swallowing incorrectly, though it does not cause me to cough	1
I sometimes cough in connection with swallowing	2
I frequently cough in connection with swallowing	3
I always get a fit of coughing when I swallow	4
Lump feeling	
I do not have the feeling there is a lump in my throat	0
I sometimes have the feeling there is a lump in my throat	1
I always have the feeling there is a lump in my throat	2
Involuntary loss of weight	
I have not lost weight recently	0
I have lost three or four pounds recently	2
I have lost more than five pounds recently	4
Pneumonia	
I have not had pneumonia	0
I have had the occasional bout of pneumonia	2
I have had repeated bouts of pneumonia	4

Appendix II: Bazaz grading system

Severity of dysphagia	Symptoms	
	Liquid	Solid
None	None	None
Mild	None	Rare
Moderate	None or rare	Occasionally (only with specific food)
Severe	None or rare	Frequently (majority of solids)

Appendix III: Prevertebral soft tissue swelling



*The prevertebral soft tissue swelling is measured as the distance between the anterior surface of each vertebral body and the air shadow of the airway.