Original article

Effectiveness of sternocleidomastoid muscle flap in preventing pharyngocutaneous fistula after total laryngectomy: an open-label clinical trial

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Abstract:

Background: *Total laryngectomy (TLG) is a complex surgical procedure used to remove the larynx, often for the treatment of laryngeal cancer. One potential complication following this surgery is the development of pharyngocutaneous fistula (PCF), an abnormal connection between the pharynx and the skin of the neck. This complication significantly affects patient's health, prolongs hospital stays, and increases healthcare costs. The sternocleidomastoid muscle (SCM) flap has emerged as an effective technique to prevent PCF by providing well-vascularized tissue for wound healing and minimizing complications.* ***Objectives:*** *This study aimed to compare the effectiveness of the SCM flap in preventing PCF after TLG.* ***Methods:*** *An open-label clinical trial was conducted, involving 16 patients who underwent TLG. The patients were divided into two groups: the control group, which underwent standard primary pharyngeal closure, and the study group, which received SCM flap augmentation. Various patient characteristics and outcomes were compared between the two groups.* ***Results:*** *None of the patients in the control group developed PCF, while two patients in the SCM flap group did. However, the difference between the groups was not statistically significant (p = 0.466). The length of hospital stay was similar between the groups. Although our study did not find a significant difference in fistula occurrence, the SCM flap still offers advantages in healing and reduces complications at the donor site. Further research with more participants is needed to evaluate the effectiveness of the SCM flap and to explore other preventive measures for PCF.* ***Conclusions:*** *PCF is a challenging complication after TLG. Our study, without pre-operative radiotherapy, found no significant difference in fistula occurrence between the SCM flap group and the control group.*

Keywords: ● *Total laryngectomy* ● *Pharyngocutaneous fistula* ● *Sternocleidomastoid muscle flap*

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นิพนธ์ต้นฉบับ

ประสิทธิผลของการใช้ sternocleidomastoid muscle flap ต่อการป้องกันภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด: การทดลองทางคลินิกแบบ Open-Label

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บทคัดย่อ

บทนำ *Total laryngectomy เป็นการผ่าตัดที่ซับซ้อนและมีความยากในการเอากล่องเสียงออกทั้งหมด ซึ่งมักทำเพื่อรักษามะเร็งกล่องเสียง หนึ่งในปัญหาที่อาจเกิดขึ้นหลังการผ่าตัดคือ ภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด ซึ่งเป็นการเชื่อมต่อที่ผิดปกติระหว่างแผลเย็บที่คอหอยกับผิวหนังบริเวณคอ ภาวะรูรั่วนี้มีผลกระทบอย่างมากต่อสุขภาพของผู้ป่วย ระยะเวลานอนโรงพยาบาล และค่าใช้จ่ายในการดูแลสุขภาพ การใช้ SCM flap เป็นเทคนิคที่มีประสิทธิภาพในการป้องกันภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด โดยช่วยส่งเสริมการฟื้นตัวและลดภาวะแทรกซ้อน* ***วัตถุประสงค์*** *การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบประสิทธิผลการใช้ SCM flap ในการป้องกันภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด ในผู้ป่วยที่ยังไม่ได้ฉายรังสี* ***วิธีการศึกษา*** *การทดลองคลินิกแบบ Open-Label โดยมีผู้ป่วยที่ทำการผ่าตัดกล่องเสียงออกทั้งหมดจำนวน 16 ราย และแบ่งเป็น 2 กลุ่ม กลุ่มควบคุมซึ่งทำการผ่าตัดปิดช่องคอโดยวิธีมาตรฐาน และกลุ่มศึกษาซึ่งทำการเสริมกล้ามเนื้อสเตอร์โนไคโดมาสตอยด์บริเวณแผลเย็บ จากนั้นเปรียบเทียบผลลัพธ์ระหว่างกลุ่มทั้งสอง* ***ผลการศึกษา*** *ไม่มีผู้ป่วยในกลุ่มควบคุมที่พบภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด ขณะที่ผู้ป่วย 2 รายในกลุ่มที่ใช้ SCM flap พบภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด อย่างไรก็ตามทั้งสองกลุ่มไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.466$) เช่นเดียวกับระยะเวลานอนโรงพยาบาล แม้ว่าการศึกษาของเราจะไม่พบความแตกต่างที่สำคัญในการเกิดภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด การใช้ SCM flap ยังมีประโยชน์ในการฟื้นตัวและลดภาวะแทรกซ้อนของ donor site ควรมีการศึกษาเพิ่มเติมที่ใช้ขนาดตัวอย่างมากขึ้นและวิธีการเชิงลึกเพื่อประเมินประสิทธิผลของการใช้ SCM flap ในการป้องกันภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด* ***สรุป*** *ภาวะรูรั่วที่คอหอยเป็นภาวะแทรกซ้อนที่ท้าทายหลังผ่าตัดกล่องเสียงออกทั้งหมด การศึกษาของเราพบว่าไม่มีความแตกต่างที่สำคัญในการเกิดภาวะรูรั่วที่คอหอยก่อนได้รับการฉายรังสี ระหว่างกลุ่ม SCM flap และกลุ่มควบคุม*

คำสำคัญ: ● *การผ่าตัดกล่องเสียงออกทั้งหมด* ● *ภาวะรูรั่วที่คอหอยหลังผ่าตัดกล่องเสียงออกทั้งหมด*
● *การผ่าตัดย้ายเนื้อเยื่อกล้ามเนื้อสเตอร์โนไคโดมาสตอยด์*

เวชสารแพทย์ทหารบก 2566;76(3):101-8.

ได้รับต้นฉบับ 14 มิถุนายน 2566 แก้ไขบทความ 16 กันยายน 2566 รับลงตีพิมพ์ 30 กันยายน 2566
ต้องการสำเนาต้นฉบับติดต่อ นายแพทย์นรุตม์ วงศ์สาคร กลุ่มงานโสต ศอ นาสิก โรงพยาบาลสวรรค์ประชารักษ์ อำเภอเมืองนครสวรรค์ จังหวัดนครสวรรค์ 60000

Introduction

TLG is a complex surgical procedure used in the treatment of laryngeal cancer. While it can be a life-saving intervention, the intricacy of the procedure requires skilled surgeons and specialized techniques, making it a less commonly performed surgery.

A potential complication following TLG is the development of PCF, an abnormal connection between the pharynx and the skin of the neck. The incidence of PCF after TLG varies between 3% to 65%, usually occurring between the 7th and 11th day after surgery.[1] This complication significantly increases patient's morbidity, hospitalization duration, and even the risk of mortality.[2,3]

Diagnosis of PCF involves clinical examination and barium swallowing tests, with the latter having a sensitivity of 55% and specificity of 97% in patients without preoperative radiotherapy.[4] The barium swallowing test should be conducted at least two weeks after surgery.[4,5]

One technique that has emerged as a potential solution is the use of the SCM flap, which provides well-vascularized tissue for wound healing and minimizes complications. However, despite its potential benefits, there is a lack of sufficient research in this area, which hinders its widespread adoption and optimal patient outcomes.

The SCM muscle flap offers several advantages in this context. Firstly, it provides a reliable source of well-vascularized tissue, promoting healing and reducing the risk of infection and fistula formation. The abundant blood supply to the flap ensures adequate oxygenation and nutrient delivery, facilitating tissue regeneration and minimizing complications. Secondly, the SCM muscle flap is easily accessible in the neck region, allowing convenient reconstruction of the pharyngeal defect without the need for extensive dissection or microsurgical techniques. This local tissue transfer eliminates the necessity for distant donor sites, thereby reducing donor site morbidity.[6-8]

Previous reviews have demonstrated statistically significant results in using the SCM flap to prevent PCF.[9,10] However, other studies have reported inconclusive results.[11]

The limited research and absence of evidence-based guidelines on using the SCM flap in TLG create challenges for surgeons. Our study aims to overcome these obstacles by comparing the effectiveness of the SCM flap in preventing PCF after TLG. Through this research, we strive to improve patient outcomes and provide valuable insights for surgeons.

Materials and Methods

An open-label clinical trial was conducted, involving 16 patients who underwent TLG at Sawanpracharak Hospital from June 2021 to May 2023. This trial was registered with the identifier TCTR20230916001. Ethical approval was obtained from the relevant committee to ensure adherence to ethical guidelines and participant well-being. All participants provided informed consent before being included in the study. The study included patients with advanced laryngeal cancer, aged up to 60 years, who had not received pre-operative radiotherapy. Patients were required to have a pre-operative hemoglobin level of 12.5 gm/dL or higher, and those with early-stage laryngeal cancer were excluded from the study.

To prevent selection bias, participants were randomized into their respective groups using a computer-generated random number sequence. The 16 patients were equally divided into two groups: Group A (control group) and Group B (study group). In Group A, patients underwent standard primary closure of the pharynx without any flap augmentation. In Group B, patients underwent standard primary closure of the pharyngeal defects along with the creation of the SCM flap for augmentation.

Various aspects were considered during the study,

including age, sex, underlying disease, previous tracheostomy, preoperative hemoglobin levels, primary site of the tumor, tumor staging according to TNM classification, and length of hospital stay.

The surgical technique involved the following steps:

1. The distal attachment of the sternal head was cut in full thickness.
2. The flap was dissected superiorly until the middle of the muscle, approximately 1 cm distal to the entry point of the spinal accessory nerve into the muscle (Figure 1).
3. After neck dissection, TLG was performed (Figure 2)
4. The pharynx mucosa was closed using the Connell suture technique in a T-shaped suture line, utilizing size 3-0 vicryl.
5. The overlying fascia and the remaining inferior constrictor muscle were closed using simple interrupted sutures.
6. The released part of the muscle was reflected to the contralateral side to fully cover the suture line of the neopharynx (Figure 3).
7. The lateral edge of the cut muscle was sutured to the contralateral SCM muscle.
8. The upper surface of the flap was sutured to the tongue base.
9. In both groups, two Redivac drains were placed at the site of the neck dissection.
10. The wound was closed in the subcutaneous tissue and skin.
11. Prophylactic antibiotics (clindamycin) were administered, and daily wound dressing was performed. Nasogastric tube feeding was initiated and continued for 10 days.
12. On the 7th day postoperatively, a fistula test was conducted by asking the patient to swallow water and observing any fluid leakage through the wound edges. If the test was negative, the nasogastric tube was removed, and the diet was gradually advanced to a liquid and soft diet in the following days.
13. Both groups were followed up for 2 weeks post-operatively to monitor the development of PCF using barium swallowing (Figure 4).

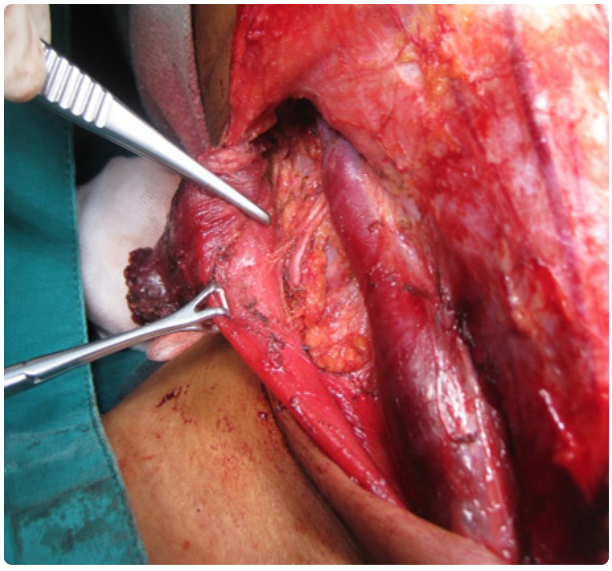


Figure 1 The SCM flap was dissected until approximately 1 cm distal to the point of entry of the spinal accessory nerve into the muscle.

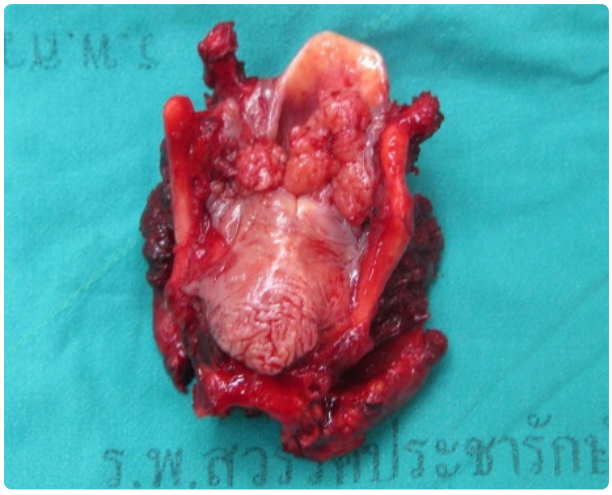


Figure 2 TLG was performed to remove the laryngeal tumor.

Statistical analysis was conducted using SPSS software, version 20.0. The data were presented as range and mean for quantitative variables. Comparison of the

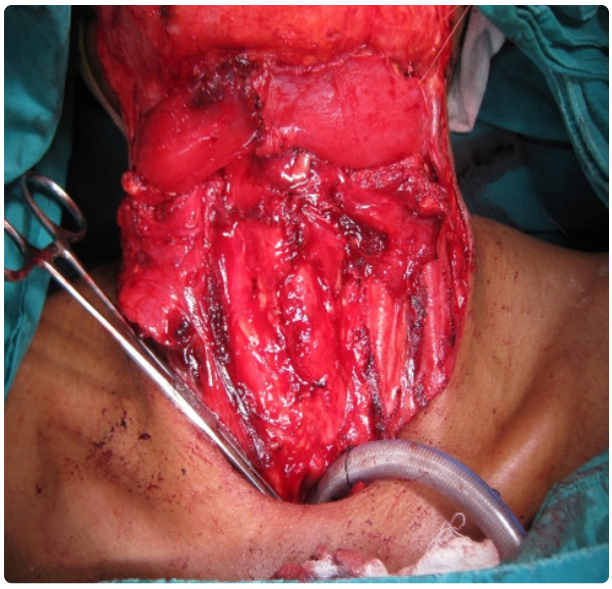


Figure 3 The SCM flap was reflected to cover the suture line of the neopharynx.

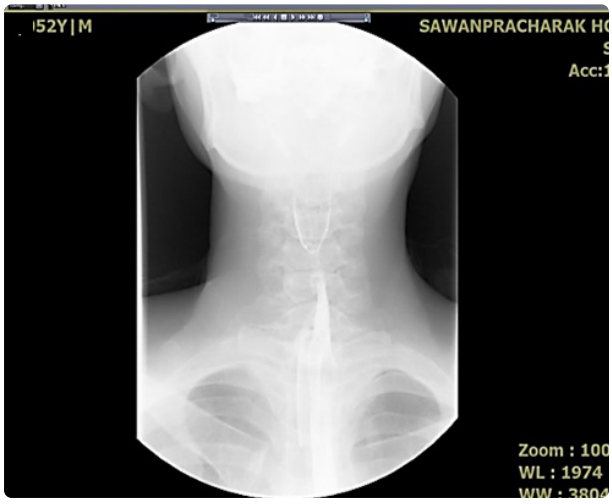


Figure 4: Barium swallowing was conducted 2 weeks post-operatively, and no PCF was detected.

means of two independent groups was conducted by Independent t-test. Fisher's exact test and Chi-square test were used to analyze categorical variables. A p-value of less than 0.05 was considered statistically significant.

Results

Sixteen patients were equally divided into two groups: Group A, consisting of 8 patients who received standard primary pharyngeal closure (control group), and Group B, consisting of 8 patients who underwent standard primary closure of pharyngeal defects along with SCM flap creation (study group).

All patients in the study were male. The mean age in Group A was 53.5, while in Group B it was 57.0, with no statistically significant difference between the two groups (p = 0.395). The parameters of underlying disease, previous tracheostomy, preoperative hemoglobin levels, primary site, and tumor stage were similar in both groups (Table 1).

In a comparison between the control group and the SCM flap group, both consisting of 8 patients each, various outcomes were assessed. The incidence of pharyngocutaneous fistula was found to be different between the two groups. Specifically, none of the patients in the control group experienced this complication, whereas 2 patients (25%) in the SCM flap group did. Despite this, the difference was not statistically significant with a p-value of 0.466.

The average hospital stay was slightly longer in the SCM flap group (15.33 days) compared to the control group (11.17 days). However, this difference was also not statistically significant (p = 0.204). The duration of wound healing was identical for both groups, with patients taking an average of 7 days to heal.

When examining pain scores, the SCM flap group had a slightly higher mean score (2.75) than the control group (3.12). The p-value for this difference was 0.285.

In terms of blood loss, the SCM flap group had a mean blood loss of 263.12 mL while the control group had a mean blood loss of 235.62 mL. The difference in blood loss between the two groups was not statistically significant (p = 0.106).

Lastly, the average cost for procedures was higher in the SCM flap group (90,150 baht) compared to the control group (80,963 baht), but this difference was also not statistically significant with a p-value of 0.168. (Table 2).

Table 1 Comparison between both groups regarding age, sex, underlying disease, previous tracheostomy, preoperative hemoglobin, primary site, and tumor stage

	Control Group (n = 8)	SCM flap group (n = 8)	*p*-value
Age (mean)	53.5	57.0	0.395
Sex			-*
- Male	8	8	
Underlying disease			-*
- HT	2	2	
- COPD	1	1	
Previous tracheostomy			-*
- Yes	7	7	
- No	1	1	
Preop Hb			-*
- ≥ 12.5 g/dL	8	8	
Primary site			-*
- Supraglottis	8	8	
Tumor staging			-*
- T3	1	1	
- T4	7	7	

* no difference between the two groups

Table 2 The results

	Control Group (n = 8)	SCM flap group (n = 8)	*p*-value
Pharyngocutaneous fistula			0.466
- Yes	0 (0%)	2 (25%)	
- No	8 (100%)	6 (75%)	
Hospital stay (mean; days)	11.17	15.33	0.204
Duration of wound healing (days)	7	7	-
Pain score (mean)			
Blood loss (mean; mL)	2.75	3.12	0.285
Cost (mean; baht)	235.62	263.12	0.106
	80,963	90,150	0.168

Discussion

PCF is a common complication after TLG that can significantly affect patient outcomes and increase healthcare costs. In this study, we investigated the effectiveness of using the SCM flap to prevent PCF after TLG. Our goal was to improve the quality of laryngeal cancer treatment by targeting at 6% occurrence rate of PCF based on previous research.[12]

Previous meta-analyses have identified several statistically significant risk factors associated with PCF, including age, smoking, coronary atherosclerotic heart disease, T-stage, previous radiotherapy, preoperative albumin, and preoperative hemoglobin. Common causes of PCF include infection, suture dehiscence, devascularized or irradiated tissues, closure under tension, and lack of wound support.[13]

Patients with supraglottic laryngeal cancer seem to have a higher risk of PCF development compared to other laryngeal subsites. A possible reason might be the extensive resection often required for these tumors,

which could interfere with the blood supply and tissue viability necessary for pharyngeal closure healing.[14]

Neck dissection has been suggested to influence the incidence of PCF after TLG. When a neck dissection is performed concurrently with laryngectomy, it can potentially disrupt the blood supply to the neck flaps used for closure, leading to decreased flap viability and increased risk of fistula formation.[15]

The standard treatment for PCF is the pectoralis major myocutaneous flap.[16-19] However, in this study, we focused on the effectiveness of the SCM muscle flap. Two patients in the SCM flap group developed PCF and received treatment with the pectoralis major myocutaneous flap, allowing them to consume soft diet before discharge.

Our results did not show a statistically significant difference in the occurrence of PCF between the SCM flap group and the control group. Although two patients in the SCM flap group developed fistula, none were observed in the control group. However, the p-value of 0.466 suggests that this difference is not statistically significant. These findings align with previous studies that have reported mixed results regarding the effectiveness of the SCM flap in preventing PCF.[9-11]

It is important to note that the SCM flap offers advantages such as providing well-vascularized tissue for wound coverage, promoting healing, and reducing risk of infection. Additionally, using local tissue transfer eliminates the need for distant donor sites, minimizing donor site complications. These benefits make the SCM flap a viable option for reconstruction in TLG patients, even though it may not significantly impact the occurrence of PCF.

In patients who have not undergone irradiation, using the SCM flap has several benefits. Their tissues usually show better vascularity and less fibrosis, resulting in more successful flap procedures. These non-irradiated tissues also heal better, allowing quicker and efficient wound recovery. Additionally, there is a potentially lower risk of complications like wound breakdown, infection, or flap necrosis.

However, there are also downsides to using the SCM flap in such patients. If they receive radiation after the flap procedure, the flap might develop fibrosis, shrink, or even necrosis. If post-radiation complications or tumor recurrence occurs, further surgeries can become complex due to the effects of radiation on the flap.

For patients who have already been irradiated, the challenges are different. Their irradiated tissues may not heal as effectively, making SCM flap procedures riskier. Moreover, there is a higher chance of complications such as flap failure, infections, and fistulas in these previously irradiated areas.[20]

Although our study did not find a statistically significant difference, it had limitations. The small sample size and open-label clinical trial limit the generalizability of our findings. Additionally, we only focused on the SCM flap and did not explore other preventive measures or advanced wound closure techniques. Future research with larger sample sizes and a comprehensive approach is needed to further evaluate the efficacy of the SCM flap and explore alternative preventive measures for PCF.

Conclusion

PCF is a challenging complication after TLG. Our study found no significant difference in fistula occurrence between the SCM flap group and the control group. However, the SCM flap showed promises in promoting wound healing and reducing donor site complications. Further research is needed to enhance our understanding and management of PCF in TLG patients. Our findings contribute to the existing knowledge and emphasize the importance of continued research in this area. We hope our study will inspire further advancements for improved patient outcomes.

Conflict of interest

The authors declare that they have no conflict of interest.

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