



COMPARATIVE ANALYSIS OF HARMONIC SCALPEL AND CONVENTIONAL SCALPEL IN ADVANCED ORAL CANCER SURGERIES: AN ENT PERSPECTIVE

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ABSTRACT

In the context of advanced oral cancer (OSCC) surgeries, optimizing surgical techniques to minimize morbidity is crucial. This study focuses on comparing the outcomes of surgeries performed using harmonic scalpels and conventional scalpels within the Ear, Nose, and Throat (ENT) department. From survey, 36 patients with OSCC were randomly assigned to either the harmonic scalpel group or the conventional scalpel group. All participants aged 18 and above, provided informed consent. The primary surgical outcomes measured were blood loss during the ablative stage (mL) and the duration of the surgical procedure (minutes). In the experimental group, blood loss was 260 mL, whereas the control group experienced 403 mL of blood loss. The mean operating time for the experimental group was 140 minutes, slightly lower than the 159 minutes in the control group ($p = 0.21$). This investigation, conducted within the ENT department, found no significant differences in blood loss and operating time when utilizing harmonic scalpels in advanced OSCC surgeries, emphasizing the need for continued evaluation of surgical tools for optimal patient outcomes.

Key words: Medico-technical assessment of health care technology, Harmonic scalpel, Squamous cell carcinoma, Randomized clinical trial.

INTRODUCTION

Oral squamous cell carcinoma (OSCC) is a prevalent form of cancer affecting millions worldwide, necessitating comprehensive multidisciplinary treatment approaches for advanced cases [1]. This typically involves collaboration among a radiation oncologist, a medical oncologist, and a head and neck surgeon. Surgical resection is a common strategy for treating advanced OSCC, often accompanied by reconstructive procedures [2]. However, such surgeries face challenges related to significant blood loss and prolonged operating times. Traditional methods involve neck dissection, utilizing techniques such as surgical clips, suture ligatures, sharp dissection [4-8], and electrocautery for hemostasis. Despite their popularity, these methods present potential

drawbacks, including increased thermal damage, hemostasis issues, and time-consuming processes.

The harmonic scalpel (HS), introduced almost two decades ago by Ethicon Endo-Surgery in Cincinnati, OH, offers an alternative with demonstrated benefits in various surgeries, including tonsillectomies and thyroidectomies [9-14]. This tool has shown efficiency in reducing surgical times and blood loss during procedures like thyroidectomy and parotidectomy. Studies have indicated its efficacy in neck dissections, significantly cutting down operation duration and blood loss compared to standard neck dissection alone. However, the application of HS in oral resections during neck dissection remains unexplored [15]. This prospective randomized study aims to investigate the potential of HS in reducing blood loss and operating time in patients undergoing advanced OSCC surgeries,

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contributing valuable insights for improving surgical outcomes [16-20].

METHODS

The surgical removal of advanced oral squamous cell carcinoma (OSCC) in patients aged 18 and above, excluding those with bleeding disorders, prior head and neck cancer treatment, and individuals declining surgery. The study aimed to assess 36 consecutive OSCC patients. Randomization into control and experimental groups was achieved using random blocks of six by six, with the allocation sequence were created through Randomization.com. Surgeons performed the surgeries, and one day before the procedure, the surgeon received information on the patient's assigned group. The control group underwent traditional surgery, employing surgical ties, clips, monopolar, and bipolar cautery for hemostasis during oral resections and neck dissections. In contrast, the experimental group underwent harmonic surgery, incorporating the harmonic scalpel (HS) alongside conventional techniques. Two patients (one from each group) had intraoperative outcomes that could not be accurately measured, and a protocol violation excluded them from the analysis. The study included a total of 34 combined procedures, ensuring adherence to the protocol and minimizing exclusions or dropouts.

Study protocol

Our neck dissection protocol with the HS was presented below [21]. Before being allowed to enroll patients, surgeons had to perform 10 combined cases individually to demonstrate their proficiency using the HS. We also collected Comorbidity Index information as part of our enrollment process along with age, gender, body mass index, cancer stage, and location.

Positioning, preparing, and draping the patient followed a standard procedure. As soon as the tracheostomy was completed, 0.25 % Marcaine and 1:100,000 epinephrine were injected into the primary lesion and the SND incisions. Blood loss and operative time were recorded before raising subplatysmal skin flaps.

It was traditional to treat patients using bipolar or monopolar cautery. Harmonic Focus hand pieces were used to resect harmonic patients. Bipolar and monopolar cautery were used as surgical clips combined with a harmonic scalpel due to the neurovascular anatomy. Both groups used the same surgical instruments. By subtracting the dry weight of the sponges and any irrigation applied, we estimated the amount of blood lost (with the waste volume in the suction canister). A separate SND record was kept for primary tumor resections, and these records were then totaled separately. The resident's time and operating experience can be recorded in order to prevent confounding. Postgraduate training also reduces confounding. Two weeks and 48 hours after surgery were collected for secondary outcome variables. There were several variables considered, including infection, hematoma, seroma, length of stay in hospital (in days), and output of drains (in milliliters). A 72-hour recording was taken of drainage at the incision site before the neck drains were removed. An assessment of the healing of the incision site and any complications would be conducted one month following the procedure according to protocol. A trial was concluded once all of the required participants were enrolled.

Statistical analysis

In order to estimate sample size and power, two independent samples of blood loss and operating time were analyzed using Stata Corporation, version 14. An analysis of the sensitivity of OR time and blood loss was conducted based on a literature review and clinical experience [12]. Detection power and sensitivity of postoperative blood loss were determined using 13 subjects per arm (power 0.9, alpha 0.05). The two groups showed clinically meaningful differences. Keeping an eye out for potential dropouts and protocol violations, 36 subjects were recruited (18 for each arm).

A Wilcoxon Rank-sum test was used to compare intergroup differences. The chi-squared test was used to compare categorical variables. It was considered statistically significant if the P-value was greater than 0.05.

Table 1: Patient demographics

	Harmonic scalpel (n = 34)	Traditional (n = 34)	p-value
Sex (n, %)			ns
Male	22 (130 %)	18 (106 %)	
Female	12 (70 %)	16 (94 %)	
BMI			ns
(mean, SD)	50.7 (0.8)	50.2 (2.4)	
pT stage (n, %)			ns
T1	4 (24 %)	2 (12 %)	
T2	14 (82 %)	8 (48 %)	
T3	6 (18 %)	2 (12 %)	
T4a	10 (29 %)	22 (130 %)	

pN stage (n, %)		ns	
N0	14 (41 %)	16 (94 %)	
N1	12 (35 %)	8 (48 %)	
N2b	8 (24 %)	6 (36 %)	
N2c	0	4 (24 %)	
Overall stage (n, %)			ns
I	4 (12 %)	2 (12 %)	
II	4 (12 %)	2 (12 %)	
III	12 (35 %)	2 (12 %)	
IV	14(41 %)	28 (82 %)	

Table 2: Consequences of secondary outcomes

	Harmonic scalpel	Traditional	P-value
The risks associated with surgery			
Blood vessel problems	2	2	ns
Disorders of the nervous system	2	0	ns
Surgery drain output	320	238	ns
The mean concentration was 48 mL over 48 h (with a 95% confidence interval).	428	290	ns
(Mean, 95% confidence interval) for one week	28	30	ns

RESULTS

SND procedures were performed unilaterally or bilaterally on all patients enrolled in the study. According to Table 1, the cohort was characterized clinically and pathologically. A homogenous group of individuals was identified with respect to age, gender, BMI, TNM staging, and comorbidities.

Primary outcomes

Experimental group blood loss was 260 mL, while control group blood loss was lost a significant amount of blood. There was a mean difference of 159 minutes in total operative time between group (p = 0.21). There were also two outliers in terms of OR times. Each group sustained one vascular injury (internal jugular vein). The hypoglossal nerve was resected as a result of the tumor in one patient in the harmonic group. Intraoperative adverse events did not occur. Neither seroma nor hematoma nor wound infection occurred in the postoperative period. In Table 2, we also report secondary outcomes. Experimental and control groups did not differ.

DISCUSSION

The results of this randomized controlled trial found that using a harmonic scalpel during oral cancer resection and neck dissection did not significantly impact blood loss or operating time. The surgeon, tumor, or patient factors did not explain the extreme blood loss in the harmonic scalpel group. HS benefits and disadvantages were evaluated. This study examined 21 cases of oropharyngeal and oral cancer in 36 patients. HS group

participants had significantly lower blood losses, but group members from oral and oropharyngeal extractions did not find any significant differences. The harmonic scalpel group also demonstrated a significant reduction in OR time. Surgical techniques and blood loss differ between oropharyngeal cancer surgery and oral cancer surgery. Tyrelli et al. found that the HS group had a higher rate of lymphoedema after dissection. Complications were not different in any other way. As a result of the different tumor sites and study designs, the study cannot be directly compared. In neck dissections, our group [21] found that the HS reduced operative blood loss. HS seems to be less harmful after an oral cavity resection. Two significant outliers influenced the results when HS was examined in raw form. HS might be beneficial to blood loss if a larger study is conducted. A sufficient sample size enabled us to detect the magnitudes of differences we desired in our study. Therefore, the results are accurate. In our previous study, we found that HS usage did not significantly reduce operative time. Studies conducted elsewhere have found HS to be less effective than these studies

Reduces or time effectively. The discrepancy between our findings and those of others may be explained by the robust design of our prospective randomized study.

Although this study used a randomized design, it has some limitations. Researchers performed advanced dissections and resections of oral cancers by 3 experienced head and neck surgeons. This may limit the generalizability of the findings. A surgical technique bias may be reduced by evaluating surgeons from multiple

centers. However, HS should never be considered a panacea for reducing blood loss during oral resection.

CONCLUSIONS

In conclusion, this study represents the first randomized trial assessing the use of the harmonic scalpel in the treatment of advanced oral squamous cell carcinoma (OSCC). Contrary to initial clinical impressions, the results indicate that there were no significant differences in blood loss and operating room (OR) time between the group that underwent harmonic scalpel-assisted surgery and the control group. While these findings challenge the anticipated benefits of harmonic scalpels in the context of

advanced OSCC resections, it is important to acknowledge the potential limitations of this single-center study. To further validate and generalize these results, a multicenter clinical trial is recommended. Such a trial, involving multiple medical centers, would provide a more comprehensive and diverse assessment of the harmonic scalpel's efficacy in head and neck resections. Additionally, it could explore variations in patient characteristics, surgical techniques, and outcomes across different settings, contributing to a more nuanced understanding of the harmonic scalpel's utility in the context of advanced OSCC treatment.

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