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Use of a non-ICU specialty ward for immediate post-operative management of head and neck free flaps; a randomized controlled trial

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ABSTRACT

Objectives: Compare length of stay, flap failure rate, medical and surgical complications and cost when patients undergoing head and neck free flap reconstruction are monitored in an intensive care unit (ICU) versus a specialty ward unit postoperatively.

Materials and methods: A prospective, non-inferiority, randomized controlled trial was conducted from 7/22/2016 to 9/12/2018 at a single institution. Patients were randomized to the ICU or specialty ward unit. Flap check protocols were identical between the groups. Perioperative and postoperative outcome variables were assessed and compared.

Results: 131 patients were enrolled in the study and 118 ultimately underwent head and neck free flap reconstruction. 57 were randomized to the ICU and 61 to the specialty ward unit. There were no significant differences between the ICU and specialty ward unit groups with regard to demographic variables including age, gender, co-morbidities, tobacco or alcohol use, prior chemotherapy or radiation therapy treatment. There were no significant differences in perioperative variables including need for transfusion, tracheostomy, ischemia time, blood loss, fluid administration or post-operative antibiotic use. There was no significant difference in the primary outcome variable, length of stay. There were no significant differences in the number of the medical or surgical complications, flap failure rate, or hospital costs.

Conclusion: In this prospective, randomized controlled trial, head and neck free-flap patients cared for on a specialty ward in the immediate post-operative period had equivalent outcomes to those cared for in the ICU.

Introduction

Free flaps have now become the standard of care for most large head and neck surgical defects. These procedures have a very high overall success rate, quoted as upwards of 95% [1]. Vascular compromise resulting in free flap failure occurs mostly within the first 48 to 72 h with 5–10% of patients suffering some flap ischemia [2]. Close monitoring in the immediate post-operative period is therefore of paramount importance for successful salvage of ischemic flaps. However, the ideal monitoring protocol remains controversial and practices are quite variable between, and even within institutions.

Over the last decade there has been a trend toward de-escalation of care in the post-operative period. Some historical post-operative management protocols dictated that patients be paralyzed during the immediate post-operative period in an effort to protect the vascular pedicle [3]. This has evolved to the most common accepted standard where patients are spontaneously breathing at the conclusion of surgery, however admitted to an ICU for close monitoring. Spiegel et al. surveyed free flap surgeons in 2007 and found that 88.9% of free flap surgeons send patients to the ICU for a mean of 2.4 days following reconstructive surgery [4]. However, admission to the ICU is not without its drawbacks. ICU stay has been associated with increased use of sedation, prolonged mechanical ventilation, late ambulation, increased delirium and increased cost [3,5,6]. Two recent retrospective series directly assessed free flap and patient outcomes with management in an ICU versus a step down or ward level of care and found that there were no significant differences in morbidity, mortality or flap failure between the groups. Both studies observed an increased length of stay (LOS) for

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patients who had been admitted to the ICU [5,6].

There is no prospective data supporting post-operative free flap management in an ICU versus a ward unit. We designed a double armed, non-inferiority randomized controlled trial in free flap patients to assess if any significant difference exists in LOS, flap failure rate, medical and surgical complication rate, or cost when patients are monitored in a head and neck specialty ward unit versus ICU in the immediate post-operative period.

Materials and methods

Study patients

Patients undergoing free flap reconstruction following ablative head and neck cancer surgery, traumatic injury or osteoradionecrosis at the University of California Davis Medical Center were eligible for the study. Exclusion criteria included an anticipated need for post-operative ICU care, patients under the age of 18, and vulnerable populations unable to consent.

Trial design

A double arm, randomized, non-inferiority trial with 1:1 randomization to the specialty ward versus the ICU was designed. Because of the higher incidence of wound infections in mucosal reconstructions, two separate arms, mucosal and cutaneous reconstruction, were created. Redcap ™ was used for randomization and deidentified patient information was maintained in a protected Microsoft Excel™ database. IRB and University of California Davis Cancer Center approvals were obtained. Interim assessment evaluated by the IRB was without termination or modification of trial protocol.

Post-operative monitoring protocols

The University of California Davis head and neck specialty care unit typically receives post-operative free flap surgical patients from the Medical Surgical Intensive Care Unit. For this study, medical center nursing administration approved the specialty care unit to accept these patients immediately following surgery. Rooms were equipped with additional suction regulators and centrally monitored pulse oximetry was utilized. The majority of nurses on the unit had a background in head and neck surgical postoperative management and in addition attended a formal educational course on free flap evaluation created for this study. Nursing ratios during the study were between 1:3 and 1:4 depending on patient acuity. The ICU maintained either a 1:1 or 1:2 nursing ratio throughout the study protocol. The nursing and resident flap checks were identical between the groups; doppler flow checks were performed every hour by the nursing staff for the first 24 h, and the resident assessed the flaps every 3 h overnight, then every 6 h until post-operative day 3. Resident flap checks consisted of pin prick assessment of blood flow as well as doppler assessment. Patients in the ICU arm were typically maintained in the ICU for 12–24 h prior to transfer to the specialty ward. The specialty ward subgroup was maintained in the same unit throughout the hospitalization unless there was a post-operative medical need for ICU care.

Follow up

Following discharge, patients returned for outpatient visits approximately 2 weeks and 1 month post-operatively. If the second visit was not performed, a 30-day phone call assessed for post-operative medical or surgical complications following discharge. This concluded the patient's enrollment in the study.

Study outcomes

The primary outcome was LOS and secondary outcomes were flap failure rate, surgical and medical complications, and total cost of hospitalization between the subgroups. Relative costs were approximated from hospital charge values submitted with insurance claims. Though these values do not to reflect the true costs of care or final hospital reimbursement, they were interpreted as proportional to the true cost and an accurate method of comparing our groups.

Statistical analysis

A difference in LOS between postoperative free flap patients sent to the ICU versus a step-down unit (SDU) or specialty ward has been reported in retrospective studies [5,6]. We therefore chose LOS as our primary outcomes variable in designing our study. Based on historically observed differences in LOS, a power calculation with a standard deviation of 6 [5,6], non-inferiority margin of 1 and error rate of 5% determined that we would need at least 112 patients to detect a difference in LOS of one day. An intention to treat analysis was used when comparing our outcomes data. Patients who were deemed to require ICU admission post-operatively, but who had been assigned to the specialty ward were included in the statistical analysis as belonging to ward group rather than being withdrawn from the study. This eliminated the potential bias of withdrawing a higher proportion of patients from the ward assigned group. The significance of observed differences in categorical variables was assessed with a chi squared analysis. Continuous variables were compared by an independent *T*-test. In our cost analysis, we compared charge data for the entire hospitalization, non-operative hospital charges and room specific charges. A multinomial logistic regression was used to assess the associations of patient factors with post-operative wound infections. All statistical analyses were performed using SPSS™ for Windows version 25.

Results

Over the 31-month enrollment period (7/2016–2/2019), 131 patients were enrolled in the study. Of this group, 13 did not undergo a free flap reconstruction and were therefore withdrawn from the study (Fig. 1). Of 118 patients, 57 were randomized to the ICU and 61 to the specialty ward. Seven patients randomized to the specialty ward were sent to the ICU immediately post-operatively due to medical necessity (6 patients) or need for intensive flap monitoring due to concern for impending flap failure (1 patient). Four additional patients in the specialty ward group were transferred to the ICU in a delayed fashion during their admission due to medical disease (2 patients: sepsis, delirium) or following a second surgery (2 patients: re-resection of a positive surgical margin, flap salvage).

There were no significant differences in the percentage of assigned mucosal or cutaneous defects, medical comorbidities, smoking and alcohol use, prior radiation or chemotherapy treatment, or other perioperative treatment variable such as ischemia time, blood loss, transfusions or post-operative antibiotics given between the two groups (Tables 1 and 2).

The primary outcome variable was LOS. The mean overall LOS was 8.93 (4–30) days with a mean LOS of 8.89 (4–30) in the ICU group and 8.97 (4–21) in the specialty ward group. There was no significant difference between the two groups ($p = 0.93$). Rates of flap ischemia, defined as observable changes secondary to decreased blood flow, were similar between the two groups: 7% in the ICU group and 4.9% in the specialty ward group ($p = 0.63$). There was only one flap failure in a patient who was randomized to the specialty ward (Table 3). We looked at surgical complications including hematoma, wound infection, need for reoperation, and did not find a significant difference between the groups in any of these variables (Table 3). We assessed medical complications such as pneumonia, thromboembolic events, sepsis,

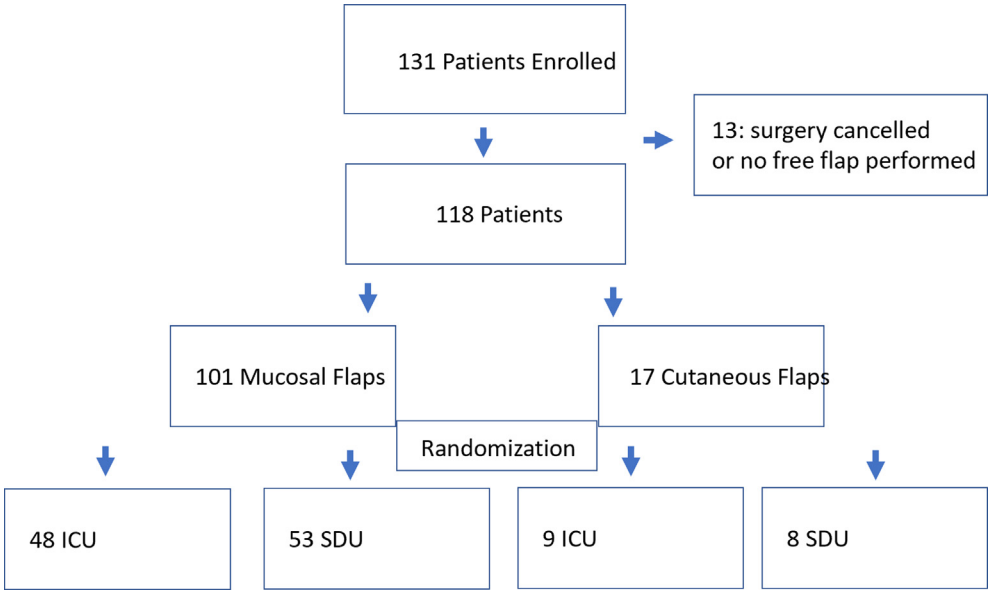

Fig. 1. Flowchart demonstrating the randomization assignment of patients enrolled in the study.

Table 1
Demographic data and preoperative risk factors.

	Overall n = 118	ICU n = 57	Specialty Ward n = 61	P
Age > 65	50 (42.4%)	23 (40.4%)	27 (44.3%)	p > 0.05
Male	89 (75.4%)	45 (78.9%)	44 (72.1%)	p > 0.05
Female	29 (24.6%)	12 (21.1%)	17 (27.9%)	p > 0.05
Diabetes	20 (16.9%)	12 (21.1%)	8 (13.1%)	p > 0.05
COPD	16 (13.6%)	7 (12.3%)	9 (14.8%)	p > 0.05
CAD	11 (9.3%)	3 (5.3%)	8 (13.1%)	p > 0.05
CHF	3 (2.5%)	1 (1.8%)	2 (3.3%)	p > 0.05
PAD	11 (9.3%)	4 (7.0%)	7 (11.5%)	p > 0.05
Renal insufficiency	10 (8.5%)	4 (7.0%)	6 (9.8%)	p > 0.05
Depression	8 (6.8%)	3 (5.3%)	5 (8.2%)	p > 0.05
Prior VTE	5 (4.2%)	1 (1.8%)	4 (6.6%)	p > 0.05
BMI	25.6 (12.7–14.1)	26.0 (12.7–43.1)	25.1 (14.1–36.7)	p > 0.05
Active tobacco use	22 (18.6%)	11 (19.3%)	11 (18.0%)	p > 0.05
Active ETOH use	52 (44.1%)	30 (52.6%)	22 (36.1%)	p > 0.05
Prior chemotherapy	21 (17.8%)	9 (15.8%)	12 (19.7%)	p > 0.05
Prior Radiation	37 (31.4%)	17 (29.3%)	20 (32.8%)	p > 0.05
Tracheostomy	59 (50.0%)	33 (55.9%)	26 (44.1%)	p > 0.05

ventilatory requirement, delirium, cardiovascular complication, and need for secondary ICU admission and found no significant differences (Table 3). Readmission rates were not significantly different between the ICU and specialty ward subgroups. The mean hospital charge was $466,199 in the ICU group and $486,150 in the specialty ward group

Table 3
Post-operative surgical and medical complications (intention to treat).

	Overall n = 118	ICU n = 57	Specialty Ward n = 61	P
Total post op surgical complications/patient	0.37 (0–3)	0.44 (0–3)	0.31 (0–3)	p = 0.34
Flap ischemia	7 (5.9%)	4 (7.0%)	3 (4.9%)	p = 0.63
Hematoma	8 (6.8%)	2 (3.5%)	6 (9.8%)	p = 0.17
Wound Infection/ breakdown	16 (13.6%)	11 (19.3%)	5 (8.2%)	p = 0.078
Reoperation	18 (15.3%)	9 (15.8%)	9 (14.8%)	p = 0.88
Flap loss	1 (0.8%)	0	1 (1.6%)	p = 0.33
Total medical complications/patient	0.20 (0–3)	0.30 (0–3)	0.11 (0–1)	p = 0.10
Pneumonia	4 (3.4%)	2 (3.5%)	2 (3.3%)	p = 0.95
Thromboembolic event	3 (2.5%)	2 (3.5%)	1 (1.6%)	p = 0.52
Sepsis	3 (2.5%)	3 (5.3%)	0	p = 0.07
Ventilatory requirement	4 (3.4%)	2 (3.5%)	2 (3.3%)	p = 0.95
Delirium	5 (4.2%)	4 (7.0%)	1 (1.6%)	p = 0.147
Cardiovascular complication	1 (0.8%)	0	1 (1.6%)	p = 0.33
Post op transfusion	4 (3.4%)	1 (1.8%)	3 (4.9%)	p = 0.34
ICU admission	4 (3.4%)	2 (3.5%)	2 (3.3%)	p = 0.95
Mortality	0	0	0	–
LOS	8.93 (4–30)	8.89 (4–30)	8.97 (4–21)	p = 0.93
Readmission	18 (15.4%)	9 (16.1%)	9 (14.8%)	p = 0.84

Table 2
Defect type and perioperative data.

	Overall n = 118	ICU n = 57	Specialty Ward n = 61	P
Mucosal defects	101 (85.6%)	48 (84.2%)	53 (86.9%)	p > 0.05
Skin defects	17 (14.4%)	9 (15.8%)	8 (13.1%)	p > 0.05
Operative time	593 (360–1140)	570 (370–960)	615 (360–1140)	p > 0.05
Intraoperative transfusion	21 (17.8%)	11 (19.3%)	10 (16.4%)	p > 0.05
Ischemia time	145 (60–246)	141 (60–240)	149 (60–246)	p > 0.05
EBL	291 (20–1700)	285 (20–1700)	298 (50–850)	p > 0.05
Intraoperative colloid	642 (0–1500)	663 (0–1500)	624 (0–1400)	p > 0.05
Intraoperative crystalloid	3275 (900–7550)	3290 (900–7000)	3327 (1300–7750)	p > 0.05
Post operative days of antibiotics	2.01 (0–10)	1.77 (0–7)	2.25 (1–10)	p > 0.05

Table 4
Hospital charges data.

	ICU n = 57	Specialty Ward n = 61	P
Total hospital charges (mean)	$466,199	$486,150	p = 0.52
Non-surgical hospital charges (mean)	$158,841	$155,115	p = 0.87
Total hospital room charges (mean)	$79,729	$66,298	p = 0.22

Table 5
Multinomial regression analysis for the impact of pre-operative and peri-operative variables on wound infections.

	OR	P
Age > 65	0.92	1.0
Active ETOH use	1.02	0.98
Prior radiotherapy	1.24	0.78
Prior chemotherapy	0.083	0.69
Prior surgery	2.45	0.14
Current tobacco use	3.67	0.056

and the difference between these values was not significant (p = 0.52) (Table 4). We then looked specifically at non-surgical hospital charges by subtracting the operating room and anesthesia charges from the total hospital charge and found that the mean charge in the ICU group was marginally higher at $158, 841 versus $155,115 in the ward group (p = 0.87) The mean total room charge was also higher in the ICU group ($79,729) than in the ward group ($66,298). This difference was also not statistically significant (p = 0.22) (Table 4).

On multinomial regression we looked at the association of age, active alcohol use, active tobacco use, prior radiotherapy, prior chemotherapy and prior surgery with wound infection and found no significant associations. Current tobacco users were more likely to suffer a wound infection (OR 3.67), an association that neared significance (p = 0.056) (Table 5).

Discussion

The majority of head and neck reconstructive surgeons send their free flap patients to the ICU in the immediate post-operative period [7,8]. While these patients do not typically meet cardiopulmonary indications for ICU care, this practice is supported by the high nurse:-patient ratios that allow for hourly nursing flap checks [7]. However, ICU admission is not without its own risks, including a higher incidence of pneumonia, less ambulation, increased narcotic use and of particular interest in the era of value medicine, increased cost [3,5,6].

Creation of a ward-level unit with specialty nursing to provide heightened monitoring and wound care comparable to the ICU setting has been described [5,6,9]. In this model, patients that do not meet the cardiopulmonary indications for ICU care are sent to a specialized unit capable of performing frequent flap assessments and have staff trained in free flap management. These types of units have been compared to ICU care in retrospective studies which suggest equivalent medical and surgical outcomes with increased measures of utilization [5,6]. In order to better compare these post-operative settings, we designed a double armed, randomized controlled trial looking at LOS, flap failure, medical and surgical complications and cost in patients managed in a specialty ward unit versus an ICU.

The primary outcome we examined was LOS. Recent retrospective studies by Panwar et al. and Arshad et al observed an increase in LOS for patients sent to an ICU following free flap surgery (Panwar: 9 days ICU vs 7 days SDU ; p = 0.0017, Arshad: 9 days ICU vs 8 days SDU; p = 0.008). In contrast, our study did not detect a significant difference in LOS between our groups (8.89 for ICU and 8.97 for specialty ward unit, p = 0.93). One possible explanation for the discrepancy is the Arshad et al. and Panwar et al. studies are comparing two groups that are temporally separated. It is therefore difficult to discern if the peri-operative and post-operative management was improving with time, or if the finding was related to the post-operative destination itself.

Similar to the results described by Panwar et al. and Arshad et al., we found no statistical increase in flap failure or surgical complications [5,6]. This was true of ischemic episodes, hematoma, wound infection and flap failure. There was only one instance of flap failure in our study, which occurred in a patient randomized to the specialty ward who suffered multiple episodes of flap compromise intraoperatively and required a second free-flap the following day. We also assessed medical complications including venous thrombosis, sepsis, pneumonia, delirium, cardiovascular compromise, need for further ICU management, need for ventilatory support and mortality and found no significant differences between the groups. This also mirrors what has been shown in the previously mentioned retrospective series [5,6].

It has been reported that an ICU admission results in a higher overall cost of care than SDU or ward level of care [5,6]. In our study, we used hospital charge data as a surrogate for cost given the difficulty in obtaining true cost data. While we did find that the total hospital room charge and the non-surgical hospitalization charges were marginally higher in the ICU group, these differences were not statistically significant. The observed equivalence of costs may be related to the short time many patients spent in the ICU. We found that 74% of patients spent 24 h or less in the ICU prior to transfer to the ward. In contrast, Arshad et al describes a mean ICU length of stay of 3.5 days [5]. As we introduced our new ward care pathway, our threshold for sending ward designated patients to the ICU was low, and 11 of the 61 patients assigned to ward care ultimately required ICU level care at some point during their hospitalization. This likely further minimized any difference in costs between our groups.

The overall rate of wound infections in our study was 13.6%. The rate was higher in the ICU group (19.3%) than in the specialty ward group (8.2%), however this difference was not significant (p = 0.078). Given that our study was not powered to detect a difference in wound infections, it is possible there is a significant association with the intensive care unit. Similarly, both total number of medical complications and sepsis were seen more frequently in the ICU group but without a significant difference. A larger study cohort may reveal these to be true significant differences between the groups. To evaluate pre-operative variables associated with wound infections, we performed a multinomial regression analysis assessing the relationship of age, active alcohol use, active tobacco use, prior surgery, prior radiation and prior chemotherapy. Active tobacco use was the strongest predictor of wound infection (OR 3.67 p = 0.056) though this association was not significant.

Our study demonstrates the feasibility of creating a free-flap capable specialty ward that yields equivalent outcomes to an ICU for head and neck free-flap patients. Prior to initiation of the study, rooms were updated with additional suction regulators and centrally monitored pulse oximetry was utilized. While nurses had experience taking care of head and neck free flaps patients, they were required to attend a 1-hour course on flap monitoring prior to study initiation. Nurses were able to comply with hourly flap checks within the 1:3 or 1:4 staffing ratio. In a recent review looking at a SDU or specialty ward care for free flap patients, Varadarajan et al. describes the ideal free flap patients for ward level care and the typical characteristics of the unit itself [9]. While we agree with their recommendation for telemetry, pulse oximetry and access to consultants and ancillary services (respiratory, speech and physical therapy), our study demonstrates that these patients do not require a nursing ratio of 1:2 patients. Panwar et al. and Arshad et al. also describe decreasing nursing rations below 1:2 on the ward while preserving the same frequency of flap checks [5,6]. Mandating 1:2 nursing ratios requires a significant increase in unit staffing and may not be achievable at some centers.

A number of our patients randomized to the ward ultimately required an ICU level of care with seven sent to the ICU immediately after

surgery and four sent in a delayed fashion. Most of these instances occurred early in the study when there was still some apprehension on the part of the nurses and physicians with regard to ward care and the threshold for ICU transfer was consequently low. While our initial intent was to withdraw these patient from the study it quickly became apparent that due to the unblinded nature of this study, it would be difficult to withdraw patients in a comparable way from the ICU group. An intent-to-treatment analysis was therefore adopted to account for this bias.

Another limitation of our study was that it was powered to discern a difference in LOS, not flap survival rates. Because of the very high flap success rate, the number of patients needed to see a significant difference in flap failure rates would not be feasible in a prospective trial. While we were able to establish a protocol to perform hourly flaps checks on a specialty ward without changing our unit nursing to patient ratios, this may not be possible at some institutions. Consequently, these results may not be applicable to every institution.

Conclusion

In a prospective randomized controlled clinical trial, we demonstrated that head and neck free flap patients recovering on a specialty ward had similar peri-operative complication rates, LOS and cost of hospital care, compared to those who were initially sent to the ICU.

Declaration of Competing Interest

The authors declared that there is no conflict of interest.

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