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Safety of Reconstructive Microsurgery in the Elderly Population: a Multicentric Prospective Study☆

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Summary *Background:* Safety of reconstructive microsurgery in elderly patients is still a topic of debate, because no conclusive evidence exists that provides indications and risk evaluation in elderly patients.
The purpose of this study, which the Italian Society for Plastic, Reconstructive, and Aesthetic Surgery (SICPRE) has promoted, is to evaluate the safety and the complication risk of elective reconstructive microsurgery in elderly patients as well as to identify patient- or procedure-related risk factors. The secondary aim is to evaluate the predictive role for complications of the Geriatric 8 score (G8).
Methods: A total of 194 consecutive patients from 18 centers, aged 65 or older, who received an elective microsurgical flap between April 2018 and April 2019 were prospectively evaluated. Patient-related, treatment-related, and outcomes data were recorded and statistically analyzed through multiple-adjusted logistic regression models.
Results: Our study showed an increased risk of complications and a longer hospitalization in patients aged $\geq$75 years with the American Society of Anesthesiologists (ASA) score $\geq$3 (or G8 score $\leq$11) as compared to patients $>$65 years of age and $<$75 years of age who undergo reconstruction with a microsurgical flap. Instead, flap survival did not significantly vary with age, but was associated only with ASA score $\geq$3 (or G8 score $\leq$11) and surgeries that last longer than 480 min; however, flap survival (92.3%) was slightly lower than that commonly reported for in the general population.
Conclusions: Reconstructive microsurgery in the elderly is generally safe. The ASA score is easier and quicker than the G8 score and equally useful for risk stratification.

Introduction

The rise in life expectancy and the spread of microsurgical practices have led to an increase in the number of elderly patients who undergo reconstructive microsurgery.

Whether microsurgical procedures are safe in elderly patients is still debatable, and there is no agreement on how to define when a person can be temporally defined as elderly. The literature suggests that the chronological age itself is not statistically related to postsurgical complications. A higher rate of systemic complications but a similar rate of surgical complications and flap survival are generally reported, but no conclusive evidence exists to provide indications and risk evaluation in elderly patients.[1-5]

No standard or specific tools to evaluate the risk of complications of microsurgical procedures in the elderly patients exist. Categorization of these patients in accordance with risk could be useful to refine surgical indications, improve perioperative care, and provide more detailed information in the informed consent. Among the many different scores described in the literature for patient and risk evaluation, we chose to focus on the American Society of Anesthesiologists (ASA) score and the Geriatric G8 score. The ASA score is easy and quick, it is routinely used for preoperative patient assessment and thus it is already available for all patient candidates for surgery; also, it has been identified as one of the main predictors of postoperative complications in elderly patients.[6] The Geriatric 8 (G8) score, although longer and not routinely used for presurgery evaluation, is specifically designed for elderly patients; it has already been used for the evaluation of preoperative frailty in elderly patients and was found to correlate with postoperative outcomes and quality of life.[7,8]

In this paper, we present a multicentric prospective study of elderly patients undergoing a reconstructive procedure with a free flap. The Italian Society for Plastic, Reconstructive, and Aesthetic Surgery (SICPRE) among the

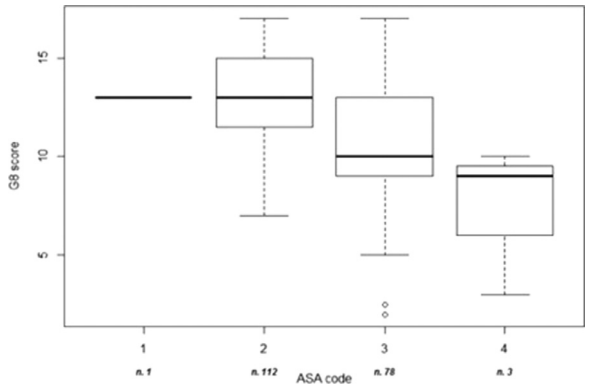

Figure 1 Distribution of the G8 scores by ASA code.

main 18 Italian centers for reconstructive microsurgery promoted the study.

The primary aims were to evaluate the safety of surgery with respect to both systemic and flap-related complications and to identify patient- or procedure-related risk factors. The complication risk related to age subgroups among elderly patients was specifically evaluated. The secondary aim was to evaluate the predictive role for complications of the G8 score, which is specifically designed for elderly people.

Materials and methods

We present a prospective cohort study performed according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. The study was performed in accordance with the Declaration of Helsinki; a written informed consent from each patient was obtained. Inclusion criteria included patients aged 65 years or older who underwent elective reconstructive surgery with free flaps. No patient was excluded based on comorbidities or type of elective procedure. A total of 194 consecutive patients from 18 centers were recruited between April 2018 and April 2019. The minimum follow-up was 3 months, and the following data were recorded for each patient:

- patient-related data: age, gender, smoking habit, ASA code, G8 score, diagnosis, and defect site;
- treatment-related data: primary/secondary/tertiary reconstruction, election/emergency procedure, type, and length of the procedure; and
- outcomes data: duration of hospitalization, flap survival, complications (evaluated through the Clavien-Dindo classification)[9] (Table 1) one month after surgery, and flap survival.

Statistical analysis

Three different logistic models were explored by using the following dependent variables: Clavien-Dindo grade greater than I; hospitalization over 14 days; and flap survival. The proposed logistic regression models included all the possible combinations up to a four order term for interactions among the following independent variables: diagnosis, site of the defect, type of procedure; sex, age, and smoking habits were treated as potential confounders. ASA and G8 were alternatively considered in the multiple logistic models, with a stepwise selection of variables with a p-value $<$ 0.10. P-value was set at $p<0.05$.

Results

Flap survival in the whole study group was 92.3%. Clavien-Dindo grade (Table 1) was I or II for most patients (137; 70.6%). Detailed data on the characteristics of the study population and association with the Clavien-Dindo grade are reported in Table 2.

The results of the multiple logistic regression models are presented in Table 3. Clavien-Dindo grade $\geq$ II associated with age $\geq$75 years, documenting a +22% excess of risk as compared to a younger age, both when considering the ASA ($\geq$ 3) or the G8 score ($\leq$11), alternatively. Clavien-Dindo grade alone, irrespective of age, was not associated with a higher ASA score or with a lower G8 score, although this latter combination approached statistical significance for a slight increase in risk.

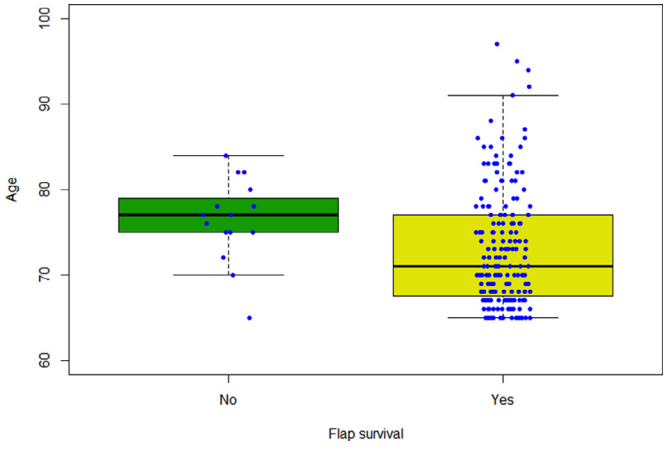

Figure 2 Distribution of age by flap survival.

Table 1 Clavien-Dindo Classification of Surgical Complications

Grade	Definition
Grade I	Any deviation from the normal course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions@@@Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications@@@Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic, or radiological intervention
III a	Intervention not under general anesthesia
III b	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
IV a	Single organ dysfunction (including dialysis)
IV b	Multiorgan dysfunction
Grade V	Death of a patient

* Brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; and ICU, intensive care unit.

Increased length of hospitalization (greater than 14 days) was also associated with patients aged 75 years or older, both when considering the ASA or the G8 score, with an increased risk of longer hospitalization of 15%; secondary/tertiary reconstruction of the upper limb increased this risk by 62% irrespective of age, both when considering the ASA or the G8 score. Length of hospitalization alone was not associated with a higher ASA or with a lower G8 score.

Flap loss was associated with the length of surgery (risk + 45% if surgery was longer than 8 h), both when including ASA score or G8 score.

The G8 score inversely decreased through the ASA score, with a significant association between G8 score $\leq$11 or $>$11 and ASA "1-2" or "3-4" (Fig. 1).

Discussion

Our study revealed an increased risk for complications and longer hospitalizations for patients aged $\geq$75 years, with ASA 3 or more (or with G8 score $\leq$11) as compared to patients $>$65 and $<$75 years old undergoing reconstruction with a free flap. Instead, flap survival did not significantly vary with age (Fig. 2), but was only associated with ASA 3 or more (or G8 score $\leq$11) and length of surgery (over 8 h). However, flap survival was slightly lower than that commonly reported for the general population (92.3%), and was usually reported in the range (94-99.2%).[10] Also, the study exposed that ASA is an easy and effective tool for risk evaluation, while the G8 score showed no superior predictive role.

In our series, the severity of complications evaluated by the Clavien-Dindo grade was associated with ASA 3 or more (or with G8 score $\leq$11) in patients $\geq$75 years; these data indicate a subgroup of patients at risk for more severe complications, which could be used to refine preoperative risk evaluation and treatment plan. In patients $<$75 years, ASA or G8 scores were not associated with a statistical increased risk for complications, but only with borderline p-values, which however, could prove to be different in a larger sample of patients.

We compared the predictive role for complications of the G8 and the ASA scores. The predictive power of the G8 score was comparable to the ASA score, which is faster to calculate and already available for patients who undergo surgery under general anesthesia. Thus, we do not recommend the routine use of the G8 score as it does not add useful data for the graduation of the complication risk.

The cut-off for defining a patient as elderly varies significantly among studies, ranging from 60 to 70 years old.[2,3,10,11] Defining a cut-off is challenging because general conditions and comorbidities may vary significantly among patients of the same chronological age.

In general, increased age has been perceived as a relative contraindication to microvascular free flap surgery.[12] Several authors[13-17] advocate a similar rate of overall complications; some authors have shown that age is an independent factor related to medical or surgical complications, prolonged hospital stay, and mortality.[13,18,19] In contrast, others reported no significant difference in postoperative complications in patients aged $>$70 years and in patients aged 70-79 years as compared to those aged 80 years or older.[11,20]

In our study, we set the cut-off age at 65 years, which corresponds to the retirement age in Italy. The U.S. National Institute of Aging and National Institute of Health further distinguishes 3 different subgroups: (1) the "young old," between 65 and 74 years; (2) the "older old," between 75 and 85 years; and (3) the "oldest old," over 85 years.[21] Our data support a predictive role of complications for this subgroup classification and indicates that patients in the "young old" group are at a lower risk for complications, and that risk evaluation can be refined by the evaluation of general health through the ASA or the G8 score.

The ASA score is the most commonly used evaluation despite its interobserver variability. Elderly patients tend to have more comorbidities and higher ASA scores,[1,3,13,15,22] which have been associated with an overall increase of complication rates.[13,14,17,22-26] With regard to the type of

Table 2 Characteristics of the 194 patients recruited in the study, by Clavien-Dindo grade (0-I, II-III, and IV-V)

	0-I (n = 84)	II-III (n = 95)	IV-V (n = 15)	Total (n = 194)
Gender				
M	48 (57.1%)	51 (53.7%)	9 (60.0%)	108 (55.7%)
F	36 (42.9%)	44 (46.3%)	6 (40.0%)	86 (44.3%)
Age (years)				
Mean (SD)	71.6 (6.62)	74.5 (6.60)	76.3 (7.60)	73.4 (6.84)
Median [Min, Max]	70.0 [65.0, 95.0]	74.0 [65.0, 94.0]	75.0 [67.0, 97.0]	72.0 [65.0, 97.0]
Smoking habit				
Yes	15 (17.9%)	18 (18.9%)	2 (13.3%)	35 (18.0%)
No	44 (52.4%)	57 (60.0%)	6 (40.0%)	107 (55.2%)
Former	25 (29.8%)	20 (21.1%)	7 (46.7%)	52 (26.8%)
ASA code				
1	1 (1.2%)	0 (0%)	0 (0%)	1 (0.5%)
2	55 (65.5%)	56 (58.9%)	1 (6.7%)	112 (57.7%)
3	27 (32.1%)	39 (41.1%)	12 (80.0%)	78 (40.2%)
4	1 (1.2%)	0 (0%)	2 (13.3%)	3 (1.5%)
G8 score				
Mean (SD)	12.4 (2.68)	11.6 (2.85)	9.83 (4.02)	11.8 (2.95)
Diagnosis				
Trauma	3 (3.6%)	5 (5.3%)	0 (0%)	8 (4.1%)
Oncological	74 (88.1%)	84 (88.4%)	14 (93.3%)	172 (88.7%)
Other	6 (7.1%)	6 (6.3%)	1 (6.7%)	13 (6.7%)
Missing	1 (1.2%)	0 (0%)	0 (0%)	1 (0.5%)
Site of the defect				
Head & neck (except oral cavity)	19 (22.6%)	16 (16.8%)	4 (26.7%)	39 (20.1%)
Oral cavity	49 (58.3%)	60 (63.2%)	8 (53.3%)	117 (60.3%)
Upper limb	2 (2.4%)	3 (3.2%)	0 (0%)	5 (2.6%)
Breast	9 (10.7%)	7 (7.4%)	1 (6.7%)	17 (8.8%)
Abdomen	0 (0%)	0 (0%)	1 (6.7%)	1 (0.5%)
Lower limb	5 (6.0%)	9 (9.5%)	1 (6.7%)	15 (7.7%)
Type of flap				
ALT	48 (57.1%)	43 (45.3%)	7 (46.7%)	98 (50.5%)
Radial forearm	8 (9.5%)	18 (18.9%)	1 (6.7%)	27 (13.9%)
DIEP	9 (10.7%)	7 (7.4%)	1 (6.7%)	17 (8.8%)
Gracilis	1 (1.2%)	0 (0%)	0 (0%)	1 (0.5%)
LD	2 (2.4%)	5 (5.3%)	3 (20.0%)	10 (5.2%)
Fibula	13 (15.5%)	18 (18.9%)	3 (20.0%)	34 (17.5%)
SCIP	1 (1.2%)	0 (0%)	0 (0%)	1 (0.5%)
Other	2 (2.4%)	4 (4.2%)	0 (0%)	6 (3.1%)
Associated oncological resection				
No	54 (64.3%)	69 (72.6%)	15 (100.0%)	138 (71.1%)
Yes	30 (35.7%)	26 (27.4%)	0 (0%)	56 (28.9%)
Reconstruction				
Primary	75 (89.3%)	84 (88.4%)	13 (86.7%)	172 (88.7%)
Secondary or tertiary	9 (10.7%)	11 (11.6%)	2 (13.3%)	22 (11.3%)
Length of surgery (min)				
Mean (SD)	481 (154)	514 (149)	519 (186)	500 (154)
Length of hospitalization (days)				
Mean (SD)	14.9 (7.27)	26.3 (18.5)	37.7 (22.5)	22.3 (16.7)
Flap survival				
No	1 (1.2%)	11 (11.6%)	3 (20.0%)	15 (7.7%)
Yes	83 (98.8%)	84 (88.4%)	12 (80.0%)	179 (92.3%)

Table 3 Multiple logistic regression models on factors associated ($p < 0.05$) with complications (Clavien-Dindo > I), prolonged hospitalization or flap loss, including ASA code or G8 score, alternatively. Only significant variables are reported. Age, secondary/tertiary reconstruction and length of surgery were significant risk factors only in patients with ASA ≥ 3 or G8 ≤11.

Evaluation scores	Risk factors	Clavien-Dindo>I		Length of hospitalization >14 days		Flap loss	
		OR [95% CI]	p-value	OR [95% CI]	p-value	OR [95% CI]	p-value
ASA code	ASA ≥ 3	-	-	-	-	1.21 [1.06-1.37]	0.005*
	Age ≥ 75	1.22 [1.07 - 1.41]	0.007*	1.15 [1.07-1.24]	<0.001*	-	-
	Upper limb & Secondary/Tertiary reconstruction	-	-	1.62 [1.13-2.32]	0.010*	-	-
	Length of surgery ≥ 480 min	-	-	-	-	1.45 [1.28-1.65]	<0.001*
G8 score	G8 ≤11	-	-	-	-	1.20 [1.05-1.37]	0.007*
	Age ≥ 75	1.22 [1.06 -1.40]	0.007*	1.15 [1.07-1.25]	<0.001*	-	-
	Upper limb and Secondary/Tertiary Reconstruction	-	-	1.63 [1.13-2.34]	0.009*	-	-
	Length of surgery ≥ 480 min	-	-	-	-	1.45[1.27-1.66]	<0.001*

surgery, in our series, we observed that elderly patients were more likely to undergo a microsurgical flap transfer for postoncological reconstruction of the head and neck area, an observation Hwang et. al. and Sierakowski et al. also made.[3,20] Moreover, these patients are more likely to have a positive history of smoking habits and multiple comorbidities, which could also justify the lower flap survival (92.3% in our study), as has been pointed out in previous studies.[2,11,13] Of note, our study indicates that tumor removal at the time of reconstruction was not associated with an increased risk for complications.

Length of surgery also contributes to an increase in the risk of complications. In our study, surgery longer than 8 h significantly increased (by 45%) the risk of flap loss if ASA ≤3 or G8 ≤11. Its predictive role is still debated in medical literature: while some authors report no association between increased surgical operation time and either postoperative surgical procedures[13,27] or medical complications.[16,28] Benjamin et. al. identified it as the only independent risk factor for developing postoperative hematoma requiring surgical revision.[24]

Other risk factors, such as diagnosis (oncologic/posttraumatic), concomitant oncological resection, and type of flap, were not associated with increased complications in logistic regression analysis.

The data also provide a general description of reconstructive microsurgery in the elderly in Italy, which is mainly performed for oncological reasons (88.7%) and mostly in the oral cavity and head and neck district (80.4%). The ALT was by far the most used flap (50.5%), while the radial forearm accounted only for 13.9% of cases.

Increased length of hospitalization was associated with patients ≥75 years, both when the ASA or the G8 score with an increased risk of longer hospitalization of 15% was considered. The literature is controversial with respect to the length of hospitalization: some authors report an association between increasing age [10,12,13,19,29-31] and increased average hospital length of stay[12,13,19,31] while others report no significant variation with increasing age.[10,29,30]

Data on the effect of age on mortality risk are also controversial. Several authors reported no significant correlation between increasing age and mortality,[4,5,8,32] while others claim a statistically significant association of age with an increased perioperative mortality rate.[1,3,11,13] In our series, the overall mortality rate was 2% (4/194 patients). We did not perform a statistical analysis of the mortality risk due to the extremely small number of deaths. However, the mortality rate was higher in patients aged ≥75 years than that of patients <75 years of age in our series (3.0% vs 1.5%). Mortality was also higher in ASA 3-4 patient subgroups (3.8% and 33.3%, respectively, vs 0% in ASA 1 and 2 subgroups) and in patients with G8 score ≤11 (7.8% vs 0% if G8 score >11). Also, all deaths occurred after head and neck (including oral cavity) surgery (2.56%).

A limitation of this study is the lack of a control group with younger patients. Also, only elective cases were included in the series. Nevertheless, the study showed that microsurgery on the elderly is generally safe, and the study identified risk factors for complications, prolonged hospitalization, and flap loss.

Conclusions

Reconstructive microsurgery in the elderly is generally safe. Patients aged ≥75 years with an ASA score of 3 or more (or with a G8 score ≤11) are at increased risk for complications

evaluated through the Clavien-Dindo Grade and for longer periods of hospitalization.

Flap survival does not significantly vary with age, but is associated with ASA 3 or more (or G8 score ≤11) and prolonged length of surgery.

The ASA score is easier and quicker to determine than the G8 score and equally useful for risk stratification.

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Conflicts of interest

None declared.

Ethical approval

Not required.

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