ORIGINAL ARTICLE

Reconstructive

Reconstruction with Free Flaps of Head and Neck Cancer Defects: A National Cohort Study

Giancarlo Buitrago, MD, PhD*†
Felipe Caballero, MD†‡
Giovanni E. Montealegre, MD‡§

Background: The purpose of this study was to determine the perioperative mortality rate, reintervention rate, and total healthcare costs for head and neck cancer patients who underwent free tissue transfer (FTT) in Colombia. The prognostic factors associated with those results were estimated.
Methods: A retrospective cohort study was performed using administrative data from patients of all ages diagnosed with head and neck cancer who underwent FTT between 2013 and 2016 in Colombia's contributory health system. Postoperative mortality rates were estimated at 30, 90, and 180 days, as well as reintervention rates at 30 and 90 days. Total healthcare costs were calculated. Generalized linear models were generated to determine prognostic factors associated with outcomes.
Results: A total of 485 patients were included, 215 (44.33%) of which were women. Mean age was 61.4 years. Mortality rate was 3.09 at 30 days, 9.28 at 90 days, and 15.26 at 180 days, per 100 surgeries. Reintervention rate was 5.77 at 30 days and 8.25 at 90 days, per 100 surgeries. The 30-day reintervention rate was lower for 40- to 59-year-old group and for a Charlson Index ≤ 3. The median total healthcare cost of an episode was USD 12,403.68 (interquartile range, 5754–16,736). The bivariate and multivariate models determined that age, the Charlson Index, and geographic region were associated with outcomes.
Conclusion: For patients undergoing FTT in Colombia, differences in reintervention and total costs incurred by the national health system exist, and these differences are associated with age, the Charlson Index, and the geographic region. (*Plast Reconstr Surg Glob Open 2020;8:e3018; doi: 10.1097/GOX.0000000000003018; Published online 19 August 2020.*)

INTRODUCTION

Free tissue transfer (FTT) is currently the treatment for reconstructing complex and large defects of the head and neck.[1,2] This type of transfer has become popular because of its versatility, variety of donor sites, and adequate functional results. Head and neck reconstruction follows the reconstructive ladder for wound closure in reconstructive plastic surgery. Free flap transfer is at the top of the ladder and is usually reserved for complex defects.[3] Head and neck cancer is the sixth most common cause of cancer,

with an estimated global incidence of 600,000 new cases annually, and microvascular surgery is currently essential in the clinical management of head and neck defects.[4]

Given the increasing cost of health services incurred by the health system, it is important to establish well-founded indications for complex surgeries, such as free flap transfer.[2,5] Thus, interest has grown in quantifying the measurements of quality, for example, by measuring the complication rates of medical procedures. Complications are related with increased mortality, hospitalization time, and reintervention rates.[5]

The Lancet Commission recommends using perioperative mortality estimates as a core indicator for monitoring surgery-related outcomes worldwide.[6] In the field of head and neck reconstruction, it has been considered that the procedure affects the operative mortality indirectly, usually considering the long operative duration of the free flaps. Retrospective studies with large patient cohorts have estimated 30-day postoperative mortality rates between 0.88% and 1.0% for FTT head and neck reconstruction, in relationship with age and comorbidities. Nevertheless, none of those studies have been performed in developing countries.[7–9]

Colombia is a middle-income country with universal health coverage (97% of the total population of 47,661,787 residents in the year 2014).[10] Its health system is based on mandatory insurance, and its benefit plan covers free flap reconstruction. Colombia has 2 insurance systems: contributory and subsidized. The contributory system (48%) includes citizens whose minimum income exceeds the legal minimum wage, and the subsidized health system (51%) is composed of citizens whose income is less than the legal minimum wage.[11,12] Several population studies have described the clinical outcomes and costs associated with surgical procedures in the country[12–14]; nevertheless, these are not related with FTT. The present study was aimed at determining the clinical and economical outcomes of FTT for patients in Colombia's contributory system who were previously diagnosed with head and neck cancer.

METHODS

Type of Study and Population
This was a retrospective cohort study based on administrative claims data that contained all patients who belonged to Colombia's contributory health system and who underwent FTT between January 1, 2013, and November 30, 2016. Only patients with a previous diagnosis of head and neck cancer who underwent FTT were included. The Integrated Social Protection Information System (SISPRO in Spanish) was used. This system contains information from all healthcare providers for all individuals registered in the system through the Unit Per Capitation (UPC) sufficiency database (The UPC database corresponds to the information sent by the insurers of the Colombian Health System to the Ministry of Health for the estimation of the premium that the system recognizes for each affiliate. This database is highly standardized and has a very low rate under registration for health services provided to the affiliated population. The UPC sufficiency database contains detailed information about all of the health services used by individuals affiliated with the contributory regime, including the type of services provided, the cost paid to the provider, the date, the municipality, and the provider. The information used was anonymous. See https://www.minsalud.gov.co/salud/POS/Paginas/unidad-de-pago-por-capitacion-). This study obtained information about all healthcare services consumed by individuals who were enrolled in the contributory system and reported by the insurers for the years 2013, 2014, 2015, and 2016.[13,14] The cohort was assembled using the FTT codes of SISPRO and the *International Classification of Diseases-10* codes related with head and neck cancer.

Clinical Outcomes
The main clinical outcome was 30-day postoperative mortality, which was obtained from vital statistics records. Other clinical outcomes included 90-day mortality, 180-day mortality, and reintervention at 30 and 90 days. The total healthcare cost associated with hospitalization for FTT was obtained and estimated from the perspective of the third-party payer. That is, it corresponds to the costs of the invoices paid by the insurers and issued by each of the corresponding providers in the care episode of FTT. The costs were adjusted to 2016 US dollar values (USD) and calculated according to the 2016 exchange rate. The variables that were evaluated as possible prognostic factors were age, sex, geographic region, insurer, and comorbidities of the patient at the time of surgery. The Charlson Comorbidity Index (CCI) was calculated based on the information that the health services supplied up to 1 year before each patient's surgery.[15–17]

Analysis
Clinical and sociodemographic variables were described for each cohort. The 30-day, 90-day, and 180-day mortality rates and 30-day and 90-day reintervention rates per 100 surgeries were calculated. Median and interquartile range (IQR) of total cost of the medical episode associated with FTT were also estimated. These outcome variables were presented by geographic region, age, and CCI.

Generalized linear models were generated to determine the prognostic factors associated with the outcomes evaluated. The mortality outcome was not modeled because the number of events was low. Multivariate logistic regression models were generated for the 30-day reintervention outcome. Unadjusted results and those obtained from bivariate and multivariate models are presented with odds ratios (OR) and 95% confidence intervals (CIs). Finally, linear models were generated to identify the prognostic factors associated with total healthcare costs. All the analyses were performed with Stata 15 software (StataCorp, College Station, Tex.). This study was approved by the ethics committee of the National University of Colombia's School of Medicine.

RESULTS

Descriptive
We identified a total of 485 patients with a diagnosis of head and neck cancer who underwent FTT in Colombia's contributory health system between the years 2013 and 2016. Table 1 presents other sociodemographic and clinical characteristics of these patients. The majority were over 40 years old (87%), 44% were women, and 43.4% had at least one comorbidity (CCI = 2). The majority (63%) of FTT cases occurred in Bogota and in the central regions of the country. One single insurer covered the costs of 47% of the patients. Table 2 presents baseline comorbidities of the entire population.

For all the individuals in the cohort, the 30-day mortality rate per 100 surgeries was 3.09, the 90-day rate was 9.28, and the 180-day rate was 15.26 (Table 3). As patients' age increased, mortality rates also increased. Rates were 0 for patients younger than 20 years, and for the group of patients of 80 years old or over, the mortality rates were 5.8, 21.7, and 30.49 for 30-day, 90-day, and 180-day mortality, respectively. Individuals with fewer comorbidities (CCI ≤ 4) presented lower mortality rates. Finally, mortality rates were higher in the Pacific region than in the other regions.

Table 1. Demographic and Clinic Characteristics of Patients (N = 485)

Characteristics	N (%)
Age	
Median (IQR), y	61.49 (6.16; 97.33)
Groups, No. (%)	
≤20	11 (2.27)
20–39	52 (10.72)
40–59	126 (25.98)
60–79	227 (46.80)
≥80	69 (14.23)
Sex, No. (%)	
Male	270 (55.67)
Female	215 (44.33)
Comorbidity Charlson Index, No. (%)	
2	210 (43.30)
3	124 (25.57)
≥4	151 (31.13)
Geographic region, No. (%)	
Atlantic	32 (6.60)
Bogota	159 (32.78)
Central	145 (29.90)
Eastern	78 (16.08)
Pacific	70 (14.43)
Other departments	1 (0.21)
Insurer, No. (%)	
A	232 (47.84)
B	20 (4.12)
C	31 (6.39)
D	24 (4.95)
E	39 (8.04)
F	139 (28.75)

Table 2. Prevalence of Comorbidities in a Sample of Patients

Condition	Proportion, %	95% CI
Acute myocardial infarction	2.47	1.40–4.31
Congestive heart failure	3.71	2.34–5.81
Peripheral vascular disease	0.82	0.30–2.18
Cerebral vascular accident	0.82	4.01–8.24
Dementia	0.82	0.30–2.18
Pulmonary disease	15.67	12.69–19.19
Connective tissue disorder	3.29	2.02–5.32
Peptic ulcer	1.03	0.42–2.45
Liver disease	0.41	0.10–1.63
Diabetes	20.41	17.05–24.24
Diabetes complications	3.29	2.02–5.32
Paraplegia	0.41	0.10–1.63
Renal disease	13.60	10.82–16.96
Cancer	1	NA
Metastatic cancer	22.06	18.58–25.98
Severe liver disease	0	NA
HIV	0.82	0.30–21.81

The 30-day and 90-day reintervention rates increased with increasing age and comorbidities and were higher for patients who were 80 years old or older and for those with a high CCI. The reintervention rates were highest in the Pacific region (Table 4).

Clinical Outcomes and Prognostic Factors

Table 5 presents unadjusted and adjusted ORs for the associations between 30-day reintervention and the clinical and sociodemographic characteristics of the patients. In the bivariate analysis, being in the 40- to 59-year-old group and having a CCI ≤ 3 were statistically significant protective factors for reintervention. Belonging to the Pacific region was a statistically significant risk factor for reintervention when the relation between these 2

variables was direct. These factors were included in our multivariate analysis, which showed that being between 40 and 59 years old (OR, 0.21; 95% CI, 0.05–0.77; $P = 0.01$) and having fewer morbidities [CCI = 2 (OR, 0.33; 95% CI, 0.13–0.82; $P = 0.01$) and CCI = 3 (OR, 0.05; 95% CI, 0.00–0.42; $P = 0.00$)] were statistically significant protective factors for reintervention. Risk factors associated with reintervention included procedures performed in the Atlantic region (OR, 1.14; 95% CI, 0.20–6.37; $P = 0.87$) and in the Pacific region (OR, 2.77; 95% CI, 0.96–8.03; $P = 0.05$), though not statistically significant.

Healthcare Costs

The median total cost was USD 12,403.68 (IQR, 5754.92–16,736.88). A difference in cost between the highest and lowest age categories was observed, with USD 10,963.74 (IQR, 5618.06–14,592.8) for patients under 20 years old and USD 13,657.65 (IQR, 4970.72–20,285.67) for patients 80 years or over. Regarding geographic region, the lowest median cost was in the Atlantic (USD 8012.49; IQR, 1149.66–13,449.06), followed by the eastern region (USD 10,730.88; IQR, 4557.96–13,662.61), Bogota (USD 11,557.06; IQR, 6414.05–14,569.97), the central region (USD 11,660.26; IQR, 4280.75–17,152.75), and the Pacific region (USD 19,847.78; IQR, 15,033.56–24,574.63). A median of USD 4724.52 (IQR, 4724.52–4724.52) was found in other regions, although only 1 procedure was presented during the study period.

The total cost was USD 6015,787 for all the healthcare services associated with hospitalization for FTT during the study period. The multivariate linear regression model found statistical differences between the categories ≥80 years old and the other age groups (Table 6). Being less than 80 years old reduced the costs, which were much lower for the 40- to 59-year-old group (USD 1727.26 less per episode). Additionally, the total cost was less for patients with a CCI of 2 or 3 than the cost for those with CCI ≥ 4 (USD –3767.92 and USD –3140.82, respectively). The multivariate linear regression model confirmed that costs in the Pacific region were USD 7627.73 (95% CI, 4913.1–10,342.36; $P = 0.00$), higher than those in Bogota, and this was statistically significant.

DISCUSSION

The use of FTT has become one of the principal procedures for head and neck reconstruction.[18] It is one of the plastic surgeon's most important tools, as it provides excellent aesthetic and functional results for patients who require complete reconstruction of ablative defects. This is the first study in a low- to middle-income country that compares clinical and economic results from FTT using nationally representative data. This study was performed in Colombia, a middle-income country with mandatory universal health coverage, using a sample that was representative of the population belonging to the formal workforce (approximately 50%). Unfortunately, we do not have information on individuals from the subsidized regime. The administrative claims data of the country that come from the contributory regime are of better quality; for this

Table 3. Rate of 30-day, 90-day, and 180-day Postoperative Mortality by Age, Region, and Comorbidities

Characteristic	Deaths/Total		
	30-day Rate per 100 Surgeries	90-day Rate per 100 Surgeries	180-day Rate per 100 Surgeries
Age groups			
≤20	0/11 (0.0)	0/11 (0.0)	0/11 (0.0)
20–39	0/52 (0.0)	1/52 (1.92)	2/52 (3.85)
40–59	1/126 (0.79)	6/126 (4.76)	16/126 (12.70)
60–79	10/227 (4.41)	23/227 (10.13)	35/227 (15.42)
≥80	4/69 (5.80)	15/69 (21.74)	21/69 (30.49)
Charlson Comorbidity Index			
2	4/210 (1.90)	14/210 (6.67)	27/210 (12.86)
3	3/124 (2.42)	11/124 (8.87)	16/124 (12.90)
≥4	8/151 (5.30)	20/151 (13.25)	31/151 (20.53)
Geographic region			
Atlantic	0/32 (0.0)	0/32 (0.0)	1/32 (3.13)
Bogota	5/159 (3.14)	15/159 (9.43)	22/159 (13.84)
Central	4/145 (2.76)	14/145 (9.66)	23/145 (15.86)
Eastern	3/78 (3.85)	8/78 (10.26)	14/78 (17.95)
Pacific	3/70 (4.29)	8/70 (11.43)	14/70 (20.00)
Other departments	0/1 (0.0)	0/1 (0.0)	0/1 (0.0)
Total Colombia	15/485 (3.09)	45/485 (9.28)	74/485 (15.26)

Table 4. Rate of 30-day and 90-day Reintervention by Age, Region, and Comorbidities

Characteristic	Reintervention/Total	
	30-day Rate per 100 Surgeries	90-day Rate per 100 Surgeries
Age groups		
≤20	0/11 (0.0)	0/11 (0.0)
20–39	2/52 (3.85)	2/52 (3.85)
40–59	4/126 (3.17)	10/126 (7.94)
60–79	14/227 (6.17)	19/227 (8.37)
≥80	8/69 (11.59)	9/69 (13.04)
Charlson Comorbidity Index		
2	8/210 (3.81)	12/210 (5.71)
3	1/124 (0.81)	4/124 (3.23)
≥4	19/151 (12.58)	24/151 (15.89)
Geographic region		
Atlantic	2/32 (6.25)	2/32 (6.25)
Bogota	7/159 (4.40)	9/159 (5.66)
Central	6/145 (4.14)	10/145 (6.90)
Eastern	3/78 (3.85)	7/78 (8.97)
Pacific	10/70 (14.29)	12/70 (17.14)
Other departments	0/1 (0.0)	0/1 (0.0)
Total Colombia	28/485 (5.77)	40/485 (8.25)

Table 5. Prognosis Factors for 30-day Reintervention: Bivariate and Multivariate Analysis

Prognosis Factors	Bivariate Analysis		Multivariate Analysis*	
	OR (95% CI)	P	OR (95% CI)	P
Age groups				
≤20	1.00		1.00	
20–39	0.30 (0.06–1.50)	0.14	0.25 (0.04–1.37)	0.11
40–59	0.25 (0.07–0.86)	0.02	0.21 (0.05–0.77)	0.01
60–79	0.50 (0.20–1.25)	0.13	0.39 (0.14–1.05)	0.06
≥80	Reference		Reference	
Female	0.57 (0.25–1.30)	0.18	0.57 (0.24–1.36)	0.21
Charlson Comorbidity Index				
2	0.27 (0.11–0.64)	0.00	0.33 (0.13–0.82)	0.01
3	0.05 (0.00–0.42)	0.00	0.05 (0.00–0.42)	0.00
≥4	Reference		Reference	
Geographic region				
Atlantic	1.44 (0.28–7.31)	0.65	1.14 (0.20–6.37)	0.87
Bogota	Reference		Reference	
Central	0.93 (0.30–2.85)	0.90	0.90 (0.28–2.85)	0.86
Eastern	0.86 (0.21–3.45)	0.84	0.74 (0.18–3.08)	0.68
Pacific	3.61 (1.31–9.94)	0.01	2.77 (0.96–8.03)	0.05
Other departments	1.00		1.00	

*Multivariate logistic regression analysis.

Table 6. Prognosis Factors for Healthcare Costs: Bivariate and Multivariate Analysis

Prognosis Factors	Bivariate Analysis			Multivariate Analysis*		
	Coefficient†	95% CI	P	Coefficient†	95% CI	P
Age groups						
≤20	−2693.90	−9145.02 to 3757.21	0.41	−1332.48	−7487.63 to 4822.67	0.67
20–39	−1055.55	−4.704.58 to 2593.47	0.57	−351.99	−3879.52 to 3175.54	0.84
40–59	−1951.50	−4927.40 to 1024.4	0.19	−1727.56	−4584.41 to 1129.28	0.23
60–79	−1223.62	−3955.24 to 1507.98	0.37	−1554.51	−4134.97 to 1025.87	0.23
≥80	Reference			Reference		
Female	−181.59	−1995.71 to 1632.51	0.84	−563.41	−2303.16 to 1176.32	0.52
Charlson Comorbidity Index						
2	−4011.69	−6095.63 to −1927.75	0.00	−3767.92	−5845.88 to −1689.97	0.00
3	−3962.97	−6329.96 to −1595.98	0.00	−3140.82	−5452.75 to −828.89	0.00
≥4	Reference			Reference		
Geographic region						
Atlantic	Reference			Reference		
Bogota	−3544.56	−7206.40 to 117.27	0.05	−4209.54	−7896.27 to −522.82	0.02
Central	103.19	−2067.05 to 2,273.45	0.92	−108.24	−2274.52 to 2058.04	0.92
Eastern	−826.18	−3438.85 to 1786.48	0.53	−1284.14	−3887.03 to 1318.73	0.33
Pacific	8290.72	5579.74 to 11,001.7	0.00	7627.73	4913.1 to 10,342.36	0.00
Other departments	−6832.53	−25,791.62 to 12,126.56	0.47	−8750.55	−27,662.78 to 10,161.68	0.36

*Multivariate lineal regression analysis.
†US Dollar 2016.

reason, the Ministry of Health provides only information on the contributory regime. However, this information represents 48% of the Colombians. This study found that the results varied widely among regions, patient comorbidities, and patient ages.

The 30-day mortality rates in our study were higher than those reported in the developed countries. Tanaka et al[8] reported mortality rates of 0.88 per 100 surgeries in Japan, and Pohlenz et al[9] reported intrahospital mortality of 1.0 per 100 surgeries in Germany. Our study found the 30-day mortality rate to range from 3.14 in Bogota to 4.29 in the Pacific region, per 100 surgeries. These results indicate large geographic differences, which may be related with the characteristics of the regions themselves, such as the health services offered, socioeconomic conditions of the population, or other factors as low urbanization in some regions, high levels of poverty, providers' networks structural and organizational limitations, armed conflict, and cultural differences.[19–21] Even though geographic and economic differences in access to healthcare in Colombian health system have been reported by some studies, future investigations are needed. This is the first report on mortality rates associated with FTT in Colombia, which follows Lancet Commission guidelines for monitoring and reporting surgical indicators in all countries worldwide.[6]

Unplanned reinterventions are useful indicators of surgical quality. Previous studies have reported 30-day reintervention rates of 8%–16% for FTT. In studies performed in the United States, Kwok and Agarwal[22] reported 30-day reintervention rates of 12.92%, and of these, 18.04% involved head and neck reconstruction. Zhao et al[23] reported 30-day reintervention rates of 20% for head and neck FTT. In our study, the overall 30- and 90-day reintervention rates were significantly lower: 5.77% and 8.25%, respectively. Nevertheless, for patients over 80 years old and for those with a CCI ≥ 4, reintervention rates were similar to those found by Zhao et al and Kwok and Agarwal. Prospective studies need to be conducted with sufficient follow-up and with clinical information specific

to patients in Colombia to obtain estimates that are comparable with those studies.

The costs that were analyzed by this study represent net expenses paid by the insurers for healthcare related to hospital services, which included the surgical procedure and the services provided until the time of discharge. Gao et al[24] estimated approximate costs in the United States for FTT of USD 85,761 with flap loss, USD 67,115 with complications, and USD 36,024 without complications. In our study, the median cost of an episode was lower (USD 12,403.68).[25] This difference could be explained by lower healthcare cost and smaller economic system (cost of living). Unfortunately, we do not have studies on the impact of high-cost surgeries on the total costs of the health system. This is one of the first studies to report on national cost information. However, we know that the total cost of the contributory regime for 2014 was USD 7,325,535,490; on the other hand, according to our estimates, the total cost of all FTTs for 2014 was USD 1,451,710, which means that the total cost of all FTTs in the contributory regime is approximately 0.0198% of the total cost of the contributory scheme.

The regional analysis found large differences in mortality, reintervention rates, and costs, even though the health system has universal coverage and its benefit plan provides the same coverage to all members. The latter suggests that equal coverage does not necessarily translate into equality of clinical outcomes.[10] As we mentioned before, these differences could be explained by sociodemographic and clinical baseline differences, differences in quality of healthcare, differences in technology, etc.

As in other similar studies, we found that age and comorbidities are risk factors. Many cases occur after 60 years old, with approximately 60% of all tumors presenting in patients over 65 years old. In our study population, 61.03% of the patients were over 60 years old. A high CCI is a predictor of complications and perioperative mortality,[26] and in our study population, patients over 60 years old and with a CCI ≥ 4 presented higher mortality and

reintervention rates. Nevertheless, studies have documented that although systemic complications are more likely in older age groups, they are more closely related with the presence of concomitant comorbidities and a diminished functional status than with age per se.[27]

By using retrospective, observational administrative data, this study presents some weaknesses, and therefore, the results should be carefully interpreted. First, information bias is likely due to the retrospective nature of the information. Second, it does not provide detailed clinical information for making recommendations about the effectiveness of the intervention in terms of quality of life, functionality, pain management, flap survival, or other clinical risk factors as location of tumor or cancer stage. The literature has reported that these variables affect mortality and other clinical outcomes.[28–31] Nevertheless, it is important to mention that the primary source of the information is a highly standardized database that contained all the health services consumed by the country and paid for by the health system. On the other hand, given that the 30-day mortality indicator was constructed based on national death certificates, all patients who underwent FTT and who died within 30 days of the procedure were identified, regardless of whether or not death occurred in the hospital where the surgery was performed.

Finally, our current health system was born after a Constitutional reform in 1991. Contributory and subsidized regimes were created with this reform; however, some special regimes continued within the health system. These still survive and correspond to approximately 1% of the system.

CONCLUSIONS

In conclusion, this is the first study in a developing country that reports national information on mortality and costs associated with FTT. It found that the mortality rates in Colombia's contributory health system are higher than those reported in developed countries, while reintervention rates and costs are lower. Nevertheless, it does not include clinical data for characterizing these findings. In Colombia, underreporting of the use of FTT for treating head and neck cancer defects is very likely, particularly about the *International Classification of Diseases-10* codes that are recorded for these cases, which may not be updated during the hospital stay.

Giancarlo Buitrago, MD, PhD
Clinical Research Institute
School of Medicine
Universidad Nacional de Colombia
Unidad Camilo Torres
Bloque C4
Bogotá, Colombia
E-mail: gbuitragog@unal.edu.co

ACKNOWLEDGMENT

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