

Original Research Article

Factors increasing the risk of flap complications following pectoralis major myocutaneous flap reconstruction for head and neck cancers

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ABSTRACT

Background: Oral cavity cancer is one of the most common cancers and a leading cause of cancer death in India. Pectoralis major myocutaneous flaps (PMMC) are still widely used for reconstruction of defects in the head and neck, though microvascular free flaps are the 'gold standard'. This study was aimed to identify the risk factors involved in increasing the post-operative PMMC flap complications.

Methods: Patients who underwent surgical resection of primary head and neck cancer with PMMC flap reconstruction were included and their demographic data, pre-operative laboratory values, surgery details and post-operative flap morbidity were collected retrospectively from the master case sheets from January 2013 to December 2019. Factors such as age, gender, stage of disease, pre-operative anemia, hypoproteinemia and radiation therapy, presence of diabetes and size of the flaps were analysed to find their relation in causing flap complications.

Results: Totally 285 patients were included for analysis and 9.82% (n=28) had major flap complications. On analysis we found that pre-operative hypoproteinemia (serum albumin <3.5) (p=0.001) and prior radiation therapy (p=0.02) significantly increased the risk of flap complications. Similarly, patients with larger bipaddled flaps had higher flap complication rates (p=0.0002) and previous radiation treatment further increased the major complication rates in bipaddle flaps.

Conclusions: PMMC flaps are still a viable option for head and neck reconstruction especially in patients with multiple comorbidities and where free microvascular flaps are not done routinely. Careful patient selection, pre-operative optimisation and good post-operative care will help to reduce flap complications.

Keywords: Pectoralis major myocutaneous flap, Complications, Pedicled flap, Risk factors

INTRODUCTION

Oral cavity cancer is the most common cancer among men in India constituting 10.4% of all cancers and the second leading cause of cancer deaths in whole population.¹ The primary risk factor is tobacco use, especially the habit of tobacco chewing is very common across all parts of the country.² Majority of the affected population belong to low socioeconomic group.³ More than two thirds of patients present with an advanced cancer.⁴ Hence, most of these patients require multi-

modality management of the disease and surgery is pivotal in the management of these cancers in addition to radiation and chemotherapy. Surgery has ever been a challenge, owing to the complicated anatomy of the head and neck region. Furthermore, there had been a dearth of reconstructive options for the head and neck, until the introduction of pectoralis major myocutaneous flap (PMMC) by Ariyan.⁵ The flap was widely popularised in the next two decades and became the 'work horse flap' of head and neck reconstruction. Later, microvascular free flaps became the gold standard of head and neck

reconstruction and many centres across the world started using free flaps.⁶ The PMMC flap was pushed to a second place from the workhorse flap to a 'salvage flap', as many at times it was used as a rescue flap following failure of free flaps.⁷

In developing countries like India, where microvascular free are not readily available in every centre, pedicled flaps are still the primary mode of reconstruction.⁸ The PMMC is a reliable flap with the advantages of simple technique, ability to cover large defects and has an edge over the free flaps in that the muscle over the pedicle can be used to cover the vessels in the neck.⁹ However, the flap has a number of drawbacks including, excessive bulk in some particularly female patients, donor site morbidity, flap necrosis and poor cosmetic and functional outcomes.

In our centre, we prefer PMMC flap reconstruction for most of the patients undergoing major resections of head and neck cancer, in both upfront and post-radiation settings. In this study we have analysed the various risk factors affecting the post-operative flap complications.

METHODS

This is a retrospective study of patients who underwent surgery for head and neck cancer in Government Royapettah Hospital from January 2013 to December 2019. We recorded the details of patients including demography, stage of the disease at presentation, pathology, pre-operative chemotherapy, pre-operative or radical radiotherapy, pre surgery nutritional status previous surgeries for the same disease, type of surgery and post-operative flap morbidity from the master case sheets and operative records.

Inclusion criteria

The patients who underwent primary or salvage reconstruction with pedicled PMMC flap for head and neck cancer during the study period.

Exclusion criteria

The patients who died in the immediate post-operative period (within 30 days of surgery) after a PMMC flap reconstruction.

Surgical procedure

The PMMC flap was harvested from the ipsilateral chest. All the flaps were myocutaneous flaps based on the pectoral branch of the thoracoacromian artery. The size and position of the flap was designed appropriately after measuring the defect size and the distance between the highest point of the defect to the pivotal point of arc of rotation of the flap in patients, who required only a single paddle, the flap was usually taken infero-medial to nipple areola complex, which has the most reliable vascularity.¹⁰

While raising the flap, the deltopectoral pedicles were carefully avoided as deltopectoral flaps were the important alternate for salvage of major PMMC flap losses. A lateral cut was given in the upper flap along the anterior axillary fold, without disturbing the future DP flap area, from the lateral edge of the planned flap for ease of rising upper skin flap, lateral division of the muscle and closure of donor site. Bipaddle flaps were de-epithelised, folded and sutured to both sides, giving an inner and outer lining to the defect. The flaps were sutured without tension avoiding excessive stretch on the pedicle, with absorbable polyglactin 3-0 sutures intra-orally and outer paddles were sutured with non-absorbable nylon sutures. All patients received an intravenous cephalosporin and metronidazole 30 minutes before surgery and for first three post-operative days, if uncomplicated.

All the flap related complications that occurred within 30 days of surgery were considered early post-operative morbidity and were analysed for risk factors causing those complications. The complications were grouped into major and minor for analysis. Minimal marginal necrosis of the flap and suture line dehiscence between the flap and recipient site and minor surgical site infections around the flap confirmed with microbial culture, not leading to flap necrosis and controlled with antibiotics were grouped under minor flap complications. Major flap loss of >20% of flap area either due to ischemia or major infections and necrosis, resulting in orocutaneous fistulas and needing secondary surgical procedures for debridement and alternate reconstruction were considered major morbidity. The mean age of 51.2 years was taken as cut-off to determine the effect of older age on major flap morbidity. Similarly, a pre-operative haemoglobin level <10 g, serum albumin <3.5 g, prior treatment with radiation therapy (RT) and presence of diabetes mellitus were considered as risk factors and analysed for their association in causing major flap morbidity. The difference in the rates of major flap complications between single paddle and bipaddle flaps were also checked.

Ethical approval for data retrieval and analysis was obtained from the Institution's ethical committee and we proceeded with the study.

Chi square contingency tables and independent samples T-test with IBM SPSS data editor software were used for data analysis.

RESULTS

A total of 285 patients who had PMMC flap reconstruction after resection of the primary head and neck cancer were included in this study. Of the 285 patients 202 were male and 83 were female. The mean age was 51.2 years (range 26 to 85). The most common primary was oral cavity squamous cell cancer and the commonest subsite being buccal mucosa (n=181)

followed by tongue (n=65), as the cause of majority of these cancers is attributed to the use of chewable tobacco. The less common subsites were retromolar area (n=19) and lip (n=4). PMMC was also used for covering the defect after extended radical parotidectomy (n=3), as salvage reconstruction for pharyngocutaneous fistula after total laryngectomy (n=2) and after extended radical neck dissection (n=2) for residual nodal disease after definitive radiation. Almost all patients had squamous cell cancer and other rare histologies were mucoepidermoid carcinoma of the minor salivary glands (n=3) and parotid (n=1) and adenoid cystic carcinoma of the parotid (n=2). The patients' demographic data is listed in Table 1.

Table 1: Patient characteristics.

Patient demographics	Number of patients
Gender	
Male	202
Female	83
Mean age in years (range)	51.2 (range 26-85)
T stage	
T2	3
T3	69
T4	195
Recurrence	18
Site	
Buccal mucosa	181
Tongue	65
Retromolar trigone	19
Floor of mouth	9
Lip	4
Parotid	3
Larynx	2
Neck nodal residue	2
Previous treatment	
Pre-operative RT	43
Radical RT	52
Induction chemo	21
Induction chemo + RT	5

Of the 285 patients 195 patients had locally advanced T4a disease and 69 with T3 and 3 had T2 tumours. 18 patients presented with recurrent malignancy after a prior multimodality management and a disease-free interval before the recurrence. Pre-operative RT was given to 43 patients with locally advanced disease to the primary and the draining nodal region, aimed to downstage and make the tumour operable with clear negative margins. 52 patients had received radical RT and presented with residual or recurrent disease. Both pre-operative RT and definitive RT were administered with sensitising dose of weekly cisplatin or three weekly cisplatin and 5-fluorouracil (5-FU). The median dose of pre-operative RT was 50 Gy and radical RT being 60 Gy. Induction chemotherapy was used to downsize the tumour in 26 patients with locally advanced disease. Out of the 26

patients, 21 patients were taken up for surgery after induction chemotherapy and remaining 5 patients were given radical RT after induction chemotherapy followed by salvage surgery for residual disease. Gender (p=0.21) and stage of disease (p=0.13) did not have a significant association with major complications.

Composite resection incorporating the primary tumour resection with hemimandibulectomy and a modified radical neck dissection type 1 with a single or bipaddled PMMC flap for reconstruction of the defect, was the most frequently performed surgery, in 92.3% of patients (n=263). 11 patients had undergone a similar surgery with a segmental mandibulectomy and reconstruction with plates and screws and a PMMC flap cover over the plates. PMMC flap was used in 3 patients after extended radical parotidectomy, in 2 patients with pharyngocutaneous fistula after total laryngectomy. PMMC flap was also used as salvage reconstruction following free flap necrosis in 2 patients. Hemi-mandibulectomy and PMMC flap reconstruction was done for osteoradionecrosis after definitive RT in 5 patients. In 88 patients larger PMMC flaps were harvested and de-epithelised in the central portion to have two paddles, one for the outer skin lining and the other for inner mucosal lining.

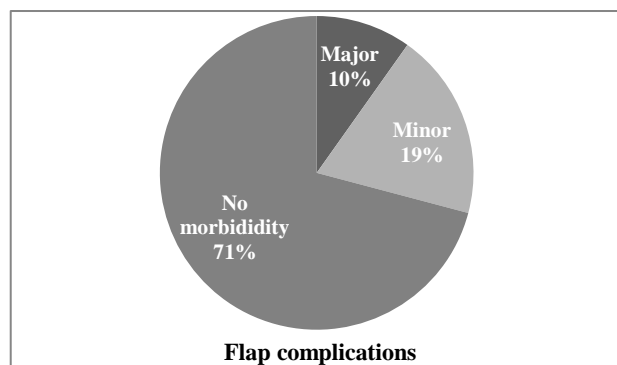


Figure 1: Proportion of major and minor complications among total number of patients.

Major flap morbidity was seen in 28 patients (9.82%), who had partial or complete flap loss due to ischemia or extensive infection causing necrosis of the flap and 55 patients (19.3%) experienced minor complications (Figure 1). The number of major and minor complications are listed in Table 2. Complete loss of flap occurred in 5 patients (1.75%). The devitalised flap was surgically debrided and allowed granulate. In 5 patients with loss of the outer paddle of the bipaddle flap, 1 patient had a split skin graft, forehead flap was used in 2 and deltopectoral flap was used in 2 patients to reconstruct the defect. Patients with partial loss of the inner lining of the bipaddle or the single paddle located intra-orally were allowed to granulate and heal by secondary intention. In 5 patients with complete loss of flap forehead flap reconstruction was performed in 2 and deltopectoral flap reconstruction in 1 patient and

latissimus dorsi myocutaneous flap was used in 2 patients. Flaps used for secondary reconstruction after PMMC flap failure are shown in Table 3. Orocutaneous fistula occurred in 46 patients with major or minor flap necrosis and 29 patients had minor fistula that healed with conservative management or limited suturing under local anaesthesia. 17 patients had major fistula that needed secondary flap reconstruction or flap revision and suturing under general anaesthesia.

Table 2: Number of major and minor complications.

Complications	Number
Minor (n=55)	
Infection only	14
Minimal suture line dehiscence	22
Minor orocutaneous fistula	29
Marginal flap necrosis	19
Major (n=28)	
Major orocutaneous fistula	17
Partial flap necrosis	23
Total flap loss	5

Table 3: Secondary reconstructions.

Secondary reconstruction for major flap necrosis	Number
Split skin graft	1
Deltpectoral flap	3
Forehead flap	4
Latissimus dorsi flap	2

Five patients aged 60 years and above had major flap morbidity. Older age (>51.2 years) was not found to be statistically significant cause of major morbidity ($p=0.8$). Among the patients with major complications 39.3% ($n=11$) had a serum albumin level <3.5 g, whereas, only 13.3% ($n=27$) of the 202 patients without any complication had albumin <3.5. Statistical analysis showed a significant association between pre-operative low serum albumin and major flap complications ($p=0.001$). Similarly, prior RT was found to be a significant cause of morbidity ($p=0.02$), as 53.6% (15/28) patients with major complications had RT before surgery (Figure 2). Pre-operative haemoglobin levels <10 g ($p=0.10$) and presence of diabetes mellitus ($p=0.11$) did not have a significant association with major flap morbidity. On comparing the size of the flaps, it was found that 18.2% ($n=16$) of bipaddle flaps and 6.1% ($n=12$) of the single paddle flaps had major flap necrosis. Larger the size of the flaps, higher was the risk of necrosis ($p=0.0002$). Among these 16 patients with bipaddle flap and major complications, 12 have received RT. Hence RT added to the risk of major complications in bipaddle flaps ($p=0.03$). The distribution of various risk factors and complications in the patients are listed in Table 4.

Table 4: Various risk factors and number of complications.

Risk factors	No compli-cations	Minor compli-cations	Major compli-cations
Gender			
Male	149	34	19
Female	53	21	9
Stage			
2	1	2	0
3	48	13	8
4	144	36	15
Recurrence	9	4	5
Age (years)			
<51.2	94	31	16
>51.2	108	24	12
Nutrition (serum albumin in g)			
<3.5	27	17	11
≥3.5	175	38	17
Haemoglobin (in g)			
<10	33	10	6
≥10	169	45	22
Radiation			
Prior RT	64	21	15
No RT	138	34	13
Size			
Single paddle	153	32	12
Bipaddle	49	23	16
Diabetes			
Non-diabetic	19	7	6
Diabetic	183	48	22

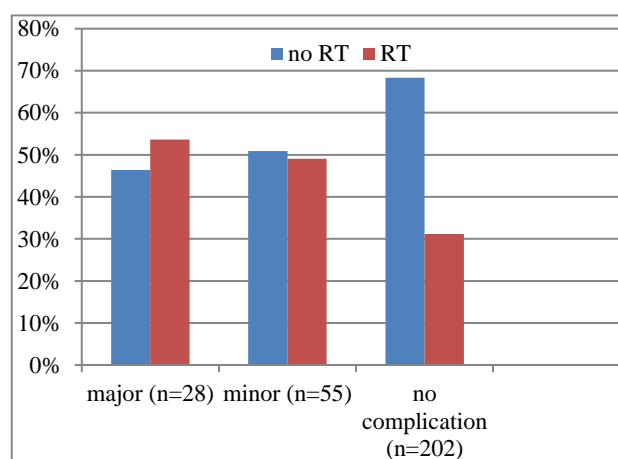


Figure 2: Major and minor complications in relation to RT.

DISCUSSION

The choice of treatment modality of a head and neck cancer is greatly influenced by the reconstructive options available. The structures in the oral cavity are involved in complex physiological activities including speech, taste,

mastication, swallowing and respiration. Hence an ideal flap should be able to match all these functions at least to a minimum of the natural quality. Though microvascular free flaps are proven to be superior to pedicled flaps in all aspects, the PMMC flap cannot be relegated from the list of flaps for head and neck reconstruction.¹¹ It is still the reconstruction of choice in many situations like failure of free flap or when the patient has multiple comorbidities and free flap failure is highly expected.¹² Studying the cohort of 285 patients with PMMC flap reconstruction we have found that patients with prior radiation therapy, low serum albumin pre-operatively and larger flaps are prone to major flap complications in early post-operative period.

In Muyuan et al, retrospective study of 783 patients 118 has PMMC flap reconstruction and 73.8% (87 out of 118) had PMMC as the primary flap and in the remaining 31 it was done as a salvage or emergency reconstructive surgery.¹³ The indications for using PMMC as the primary reconstructive option were poor vascular status due to previous radiation >60 Gy to neck, poorly controlled diabetes, systemic vascular sclerosis and compromised general condition indicated by ASA grade 3-4, age >75 years. Primary PMMC reconstruction was also done for patients who needed major vessel protection of the neck. Avery et al, in his retrospective study of 100 consecutive PMMC flap reconstruction, 80.4% (n=82) had primary PMMC flap reconstruction and other 19.6% were used for free flap failure.¹⁴ The indications for selecting PMMC primarily were similar to Muyuan et al, including medical comorbid conditions, high volume neck disease, vessel coverage, parotid or cheek defect and to close fistula.¹³ In our centre PMMC flap is the first choice for head and neck reconstruction and in 98.6% of our patients PMMC flap was the primary mode of reconstruction. PMMC was used secondarily in 2 patients after free flap failure and in 2 patients for treating post-laryngectomy orocutaneous fistula. Sumarroca et al reported the outcomes of 50 PMMC flap reconstructions for post-laryngectomy pharyngocutaneous fistula. 94% of the patients has resumed oral intake of food, nevertheless, 44% (n=22) patients had recurrent fistula, of them, 19 patients were treated conservatively and the fistula resolved, 2 were salvaged with contra-lateral PMMC flap and 1 patient died during follow-up before resolution of the fistula.¹⁵ Emergency surgery was shown to be the only risk factor associated with formation of recurrent fistula.

In our study, 9.82% (n=28) had major flap complications including total loss of flap in 5 patients and partial loss in 23 patients. Milenović et al in his series of 500 cases reported a major flap loss of 2% (n=10), partial flap necrosis in 10.4% (n=52) and orocutaneous fistula in 5.6% (n=28).¹⁶ IJsselstein et al studied 224 PMMC flap reconstructions and found partial flap necrosis in 29 patients (13%) and no total flap necrosis, orocutaneous fistula in 48 (22%) patients. There were no significant

relations of flap complications with gender, alcohol or tobacco use, previous radiotherapy, tumour stage and location of tumour.¹⁷ Bipaddled PMMC flaps used for larger reconstructions had more complication rates in our study (p=0.0002). This may be attributed to more area of these flaps being randomly based, falling outside the boundaries of the pectoralis major muscle. Further pre-operative RT added the risk of increasing the complications in larger flaps (p=0.03). These complications can potentially be reduced by carefully designing the skin portion of the flap lie within the muscle boundaries.

Among the 100 patients who had received RT in our series, 15 had major flap complications and prior radiation therapy was found to have a significant association with flap complication. The healing of the flap and recipient skin interface probably was affected by prior RT to the primary tumour, which made the recipient skin thick, edematous and less vascular, prone to wound dehiscence and infection. Liu et al reported a total complication rate of 35% (85/244 patients) including major and minor complications and found that the higher complications were associated with salvage procedures, number of pack years of cigarettes smoked and number of comorbidities.¹⁸ In another study by Fang et al, 251 patients who have pedicled flap reconstructions for head and neck cancers were analysed and showed that older age, cardiac morbidity, hypertension, diabetes, hypoproteinemia and drug induced liver injury were the risk factors significantly associated with major flap complications.¹⁹ On analysing the different variables in our patients, we did not find a significant association of either older age or pre-operative diabetes with major flap complications. However, hypoproteinemia (serum albumin <3.5 g) was found to be significantly associated with major complications. This signifies the importance of maintaining adequate pre-operative and post-operative nutritional status of the patient to minimize the morbidity. Since, majority of the patients presented with an advanced stage of disease and associated trismus due to disease itself, pain and submucous fibrosis, many of them were nutritionally depleted due to poor oral intake as a result of above-mentioned factors. We had encouraged oral high protein diet, and in patients who had severe trismus nasogastric feeding was started before commencing any treatment. In patients with complete dysphagia as in advanced hypopharyngeal cancers, a feeding jejunostomy was done to improve the patients' nutrition. The complication rates after PMMC flap reconstruction recorded in some major studies are listed in Table 5. Anaemia before surgery did not have any impact on complication. PMMC flap was used in the salvage setting in 9 patients (5 osteoradionecrosis, 2 free flap failures, 2 post-laryngectomy pharyngocutaneous fistulas). In two different studies by Aničin et al and Wei et al, showed higher complication rates of PMMC flap reconstruction used secondarily for salvage.^{20,21}

Table 5: Complication rates in various studies.

Study	No of patients	Total flap necrosis (%)	Partial flap necrosis (%)	Minor complications (%)
Avery et al ¹⁴	71	2.8	-	-
Pinto et al ⁸	58	0	12	25.8
Milenovic et al ¹⁶	500	2	10.2	21.2
Liu et al ¹⁸	244	1.2	4.5	29.3
Ijalsstein et al ¹⁷	224	0	13	44
Shah et al ²⁵	211	1.4	13.7	40.8

Donor site morbidity especially shoulder dysfunction has been largely propagated as one of the major drawbacks of PMMC flap, other than excessive bulk of the flap, poor cosmetic and functional results. Apart from this, neck dissection and radiation therapy also contribute to shoulder morbidity following multi-modality treatment of head and neck cancer. Sun et al compared the differences in shoulder dysfunction between patients who underwent PMMC flap reconstruction with those who had any other flap reconstruction.²² Shoulder dysfunction was significantly higher in PMMC flaps and the larger flaps were found to be significantly associated with post-operative shoulder morbidity. Refos et al, similarly compared the shoulder morbidity between patients with PMMC flap reconstruction versus those who had only neck dissection without flap reconstruction. He concluded that the shoulder morbidity was more frequent with PMMC flap reconstruction.²³ The patient education and counselling regarding the post-operative morbidity and good physiotherapy rehabilitation programmes will help to reduce the severity of shoulder dysfunction. Studies have shown that post-operative quality of life was similar for various domains including global quality of life, chewing, taste, swallowing, salivation and pain. There were significant differences in appearance and shoulder morbidity.²⁴

The main limitation of our study is that, it is a retrospective study which made the grading of complications difficult and post-operative quality of life could not be assessed. A prospectively collected data will be more accurate in determining the risk factors and guide to make necessary modifications in flap harvesting techniques to minimise complications.

CONCLUSION

In the era of microvascular free flaps, PMMC still holds a vital position in head and neck reconstructions, with the advantages of reliable vascularity, proximity to the head and neck region, ease of harvesting and adequate bulk to cover large defects. Even though various drawbacks have been levied on, it is still the choice of reconstruction for patients with multiple comorbidities and salvage after free flap failures. In our study we found a significant relation of major complications of PMMC flap with pre-operative hypoproteinemia, radiation therapy and larger bipaddled flaps. There has to be a careful selection of the type of reconstruction for each patient considering the

comorbidities, prior radiation, nutritional status, size and region of the defect. The patients with increased risk for flap complications should be identified pre-operatively and optimisation of nutritional status pre-operatively, sound surgical technique and maintaining good oral hygiene post-operatively will help to reduce the complications.

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