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DOES ANTIBIOTIC IMPREGNATED GEL FOAM DECREASE WOUND MORBIDITY IN BIPADDLED PMMC FLAP IN HEAD & NECK CARCINOMA?- A PROSPECTIVE STUDY."

Oncology

Subbiah Shanmugam HOD Deptt of Surgical Oncology, Govt Royapettah Hospital, Chennai

Syed Afroze Hussain* Asst Proff ,Govt royapettah Hospital,Chennai *Corresponding Author

Prem Kishore Mch surgical oncology, Govt royapettah Hospital,Chennai

ABSTRACT

In India head and neck cancer patients usually present in the advanced stage. We have attempted to reduce the local morbidity and wound infection by placing broad spectrum antibiotic-impregnated gel foam in between the two paddles and discuss the results of our prospective study. In group A consisting of 6 patients local ceftriaxone impregnated gel foam pad was placed between the two paddles of the PMMC flap and in group B consisting of 10 patients no local prophylaxis was given. Systemic IV antibiotics were given for both groups of patient. Within the limitation of small sample size, review of results of our pilot study point towards increased wound-related morbidity and secondary hemorrhage in patients with placement of local antibiotic in between the two paddles of PMMC flap likely due to potential infection and foreign body reaction.

KEYWORDS

PMMC=pectoralis major myocutaneousflap, CRT=chemoradiotherapy,HNSCC = head and neck squamous cell cancer

INTRODUCTION

Surgical resection play a definitive role in the multimodality management of locally advanced HNSCC, reconstruction remain the major concern in these patient. PMMC flap reconstruction remains workhorse in the majority of cancer institutes in India.

As the oral cavity has diverse indigenous microbial flora and the presence of cancers in it significantly alter the microbial flora to such extent that it may lead to increase infection of the flap. These microorganisms migrate before complete epithelialization of paddles of this flap. Further seroma formation may lead to the creation of potential nidus of infection between the paddles.Wound infection results in failure of wound healing with subsequent increased treatment costs, a greater likelihood of admission to the intensive care unit, prolonged hospital stay, and higher postoperative mortality[1-4]. Therefore, there is interest in wound infection and its prevention amongst surgeons and amongst many other healthcare professionals, because of the increased patient morbidity and the associated financial burden[5,6]. Amongst the many interventions advocated to prevent wound infection, the effectiveness of pre-operative intravenous antibiotic prophylaxis has been extensively studied and has been shown to be effective. Earlier studies examining the efficacy of the local application of antibiotics as prophylaxis in other surgery failed to demonstrate a clinical benefit[7].

MATERIALS AND METHODS

Institutional Ethics Committee approval was taken (Protocol ID NO.131/2018, APPROVED). All patients with locally advanced SCC undergoing composite resection with bipaddled PMMC either upfront or post neoadjuvant therapy for oral cavity cancers between August 2018 to March 2019 (until the study was stopped) were included. Group A patients(6 patients) were selected randomly for antibiotic-impregnated gel foam drug delivery system at the time of surgery and surgery in Group B(10 patients) was done without a local drug delivery system. Both the groups received the same preoperative, intraoperative, parenteral antibiotic. Post operatively both groups received parenteral antibiotic until tracheostomy was reversed. All surgeries were done by experienced oncosurgeons with standardized parameters. Both groups with the PMMC flap were assessed for wound infection like seroma, erythema, pus discharge, and margin discoloration, and if there were any ,they were recorded in five-point scale. similarly the flap dehiscence either inner or outer paddle was recorded. Univariate analysis done for both groups for the presence of wound morbidity and if significant then multivariate analysis, FisherT-test for comparison were used. Patients age b/w 25-75years,upfront/ post NACT with locally advanced oral cavity squamous cell carcinoma primary or recurrent with extensive skin involvement who need composite resection and bipaddle PMMC.

RESULTS

A total 16 patients were assigned from August 2018 to March 2019 until the study was stopped. By randomization, group A included 6 patients and Group B included 10 patients.In group A two patients had upfront surgery without any neoadjuvant therapy(Table 1). In group B a total of 6 patients underwent surgery after neoadjuvant therapy. Average duration of surgery was (3 hrs 50 minutes, range: 3 hrs 15 min to 4 hrs 30 min) in both groups, the average blood loss in both the groups was 450ml (range: 350 to 550 ml), in both groups, the tracheostomy reversal was done from post op day 5th to day 7th. In group A patient with post neoadjuvant therapy, one patient had major complication- secondary hemorrhage that was managed surgically(Table 2). The minor complications in group A were seen in all patient undergoing upfront surgery and in three fourth patient with neoadjuvant therapy. In group B no major complication occurred. Only minor complication to the extent of 50 % of the upfront and post neoadjuvant therapy equally. No statistically significant difference is noted in the incidence of complications such as seroma formation, erythema, pus discharge, and flap margin necrosis, wound dehiscence between group A and B. In view of the absence of significant benefit and a slight increase of wound morbidity in Local antibiotic group A, the study was stopped(Table 3).

Table 1 Patient particulars of both the groups

Group A						
S.No	**Age/sex**	**Nutritional status**	**Comorbidities**	**Site of tumor**	**Preoperative treatment**	**Type of lesion**
1	34/M	Avg	Nil	Rt BM	66Gy RT + weekly cisplatin	Residual
2	65/M	Poor	DM	Lt L Alv	Nil	Primary
3	26/M	Avg	Nil	Rt BM	Nil	Primary
4	42/M	Avg	Nil	Lt BM	67Gy RT + weekly cisplatin	Residual
5	56/F	Poor	Nil	Rt BM	50Gy RT + weekly cisplatin	Residual
6	67/M	Avg	DM	Rt BM	3 cycles carbodoce	Complete Response
Group B						
1	50/F	Avg	Nil	Lt BM	Nil	Primary

2	68/M	Avg	DM	Rt BM	Nil	Primary
3	45/F	Avg	Nil	Rt BM	Nil	Primary
4	48/M	Avg	DM	Lt BM	50Gy RT	Residual
5	65/M	Poor	Nil	Rt BM	2 cycle induction	Complete response
6	40/F	Poor	Nil	Lt BM	2 cycle induction	Complete response
7	43/M	Poor	Nil	Lt BM	2 cycle induction	Complete response
8	39/M	Avg	Nil	Lt BM	2 cycle induction	Complete response
9	52/M	Avg	Nil	Rt BM	2 cycle induction	Complete response
10	46/F	Poor	Nil	Lt BM	Nil	Primary

Table 2 Postoperative outcomes in each group

Group A								
S.no	**Wound Infection**				**Wound Dehiscence**	**Day of DT Removal**	**Lab Test**	
	Seroma	**Erythema**	**Pus discharge**	**Flap margin discoloration**			**Avg Hb**	**Avg Alb**
1	+	+	+	+	+	12	15	3.6
2	-	+	-	+	-	10	12.4	3.9
3	+	+	+	+	+	11	12.4	3.8
4	+	+	+	+	+	12	13.9	3.4
5	+	+	+	+	+	16	10.2	3.6
6	+	+	+	+	+	15	12.1	3.8
Group B								
1	+	+	-	+	-	7	11	2.8
2	+	+	+	+	-	7	13	3.6
3	+	-	-	-	-	7	11.6	3.6
4	-	+	-	+	-	7	12.8	3.2
5	-	-	-	-	-	6	9.6	2.8
6	+	+	+	+	+	8	11.2	3.8
7	-	+	-	-	-	7	12	3.0
8	-	-	-	-	-	8	12	3.9
9	-	+	-	-	-	7	11.8	3.6
10	-	+	+	+	+	9	10.9	3.4

Table 3 P value

	A	**B**	**P value**
Seroma	5/6	4/10	0.1451
Erythema	6/6	7/10	0.25
Pus discharge	5/6	3/10	0.1189
Flap margin necrosis	6/6	5/10	0.3069
Wound Dehiscence	5/6	2/10	0.035

DISCUSSION

Surgical practice often includes the use of local antimicrobial agents applied to the operative site to minimize post-operative surgical infections, especially SSI. Compared with systemic antibiotic therapy, local delivery of an antibiotic has many potential advantages, as well as some disadvantages, The benefits of local application, include high and sustained concentrations at the site of infection where local physiological changes may hinder the efficacy of systemic antibiotics[8]. Other benefits include the limited potential for systemic absorption and toxicity, reduced volumes of antibiotic use, and, possibly, less potential for the development of antibiotic resistance (as there is likely to be less of an effect on, e.g. bowel flora).

While local hypersensitivity or reactions and interference with local wound healing may be problematic, a major disadvantage of local antibiotics is that there are no specific efficacy criteria. Antibiotics may be delivered locally in the form of intraoperative washes or injections, locally applied lotions, solutions, powders, gels, creams or ointments, and antibiotic-impregnated beads or collagen implants[9,10]. The more commonly used antibiotics include cephalosporins, aminoglycosides, glycopeptides, chloramphenicol, and bacitracin.

The pharmacodynamic/pharmacokinetic profiles vary depending on the antibiotic, the dose and the method of delivery. Consequently, it is difficult to establish which antibiotic to use, as well as how much, for how long and in what form, for prophylaxis in a particular type of surgery. Comparisons of studies of local antibiotics in certain surgical settings may also be difficult given the variation in agent, dose, and formulation. For this and other reasons, local antibiotics at the surgical site have received very limited approval in any of the surgical prophylaxis consensus guidelines that we are aware of.Ceftriaxone is a third-generation cephalosporin and its bactericidal activity results from the inhibition of cell wall synthesis that is mediated through Ceftriaxone binding to penicillin-binding proteins (PBPs).It has a very long half-life and high penetrability. Ceftriaxone has in vitro activity against gram-positive and gram-negative aerobic and anaerobic bacteria. Ceftriaxone is stable against hydrolysis by a variety of beta-lactamases, including penicillinases, and cephalosporinases and extended spectrum beta-lactamase.

GELFOAM is a compressed sponge, sterile, pliable water-insoluble, off-white, nonelastic, porous, surgical sponge prepared from specially treated, purified pork Skin Gelatin and capable of absorbing and holding within its meshes many times its weight in whole blood. Foreign body reaction has been proposed in some studies.

In this prospective study, we anticipated better flap survival in group A patient due to the improved local antibiotic delivery system. however contrary to our belief in group A patient experienced one major complication and higher proportions of minor complications. Further increased seroma formation lead to delayed drain removal. All these untoward incidences are reported in the literature and attributed to the foreign body reaction either due to gel foam or excessively high concentration of antibiotic in between the two paddles. Further, the use of this local antibiotic delivery system in patients who received pre operative radiotherapy compounded the complication suggesting us to conclude that such form of local measures should be avoided in post radiotherapy patients.

CONCLUSION

Our study shows that the use of local antibiotic in between the two paddles of PMMC flap slightly increases the rate of wound infection.

Conflict of Interest

The authors declare that they have no conflict of interest.

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