Original Article

Impact of early dysphagia intervention on swallowing function and quality of life in head and neck cancer patients treated with intensity-modulated radiation therapy or image guided radiation therapy with or without surgery/chemotherapy

ABSTRACT

Introduction: Dysphagia is a very common problem associated with head and neck cancer patients. Inspite of best of technologies like Intensity Modulated Radiotherapy (IMRT) or Image Guided Radiotherapy (IGRT), Dysphagia remains a major problem in locally advanced head and neck cancer patients.

Materials and Methods: We randomized 50 head and neck cancer patients, including all sites and stages into two groups, 25 patients in each group. In Group-A dysphagia prevention exercises were done from the day of the onset of radiation therapy and continued till 6 months, while in Group-B no dysphagia interventions were given. We analyzed rate of dysphagia, aspiration rate and its impact on quality of life. We used M.D. Anderson Dysphagia Inventory (MDADI) which is a validated and reliable questionnaire designed specifically for evaluating impact of dysphagia on quality of life (QOL) in head and neck cancer patients. American Speech language Hearing Association (ASHA) scale was used for assessing swallowing function. Penetration Aspiration Scale (PAS) was used to assess aspiration during swallowing with the help of Fiberoptic Endoscopic Evaluation of Swallowing (FEES).

Results: Quality of life was significantly better in dysphagia preventive exercise arm (group - A). There was significant improvement in the MDADI score, from the baseline to 6 months in exercise arm (14 versus 7.76, p= 0.017). Swallowing function score was also in favour of exercise arm (6.44 versus 5.8, p=0.002). Patients in exercise arm were able to swallow much better by the end of 6 months post radiotherapy. Risk of silent aspiration as evaluated by PAS score at the end of three months was 36% (Group A = 16%, Group B = 20%). At the end of six months, it improved to 24% (Group A = 8%, Group B = 16%). There was a trend towards lesser incidence of aspiration in exercise arm, although it was not statistically significant (p=0.21).

Conclusion: Results from this study demonstrated that swallowing exercises, if administered from first week of chemo-radiation and continued till 6 months, results in significant improvement in swallowing function and quality of life. Use of FEES helps in detection of silent aspiration at an early stage and reduces aspiration related morbidities.

Key words: Aspiration; dysphagia; head and neck cancer; preventive exercises; quality of life.

Introduction

Dysphagia is a very common problem associated with head and neck cancer patients. In spite of best of technologies like intensity modulated radiotherapy (IMRT) or image guided radiotherapy (IGRT), dysphagia remains a major problem in the locally advanced head and neck cancer patients. It can be due to the primary disease affecting the organ of swallowing or due to the treatment related sequelae.[1] Surgery or radiation therapy

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with or without concurrent chemotherapy are the mainstays of treatment for head and neck cancer. Swallowing problems after head and neck surgery depends on the extent of resection, specific structures resected and type of reconstruction.[2-4] It has been postulated that high radiation doses received by dysphagia and aspiration related structures (DARS) leads to swallowing muscle dysfunction and fibrosis, which appears to be the primary reason for swallowing dysfunction after radiotherapy. Common treatment-related sequelae are dysphagia, aspiration pneumonia, respiratory complications, malnutrition, change in voice and poor quality of life (QOL). Despite organ preservation through chemo-radiation, swallowing dysfunction is seen in more than 50% of patients. There is evidence of continued deterioration of swallowing function after chemo-radiation due to fibrosis in swallowing musculature. More than 50% patients have posttreatment dysphagia; 23–43% will have chronic dysphagia. Similarly, 20–40% of patients will have silent aspiration leading to pneumonia and repeated hospitalization.[5-13] Available data in the literature indicate that swallowing rehabilitation can improve outcomes and it also depicts that early intervention appears to be superior to delayed intervention.[14-16] We searched the available literature to find some other ways to reduce the rate of dysphagia. We found few publications mentioning some exercises which help in the improvement of swallowing function. We combined additionally these dysphagia exercises in one of the treatments arm (Group-A) to see their impact on chronic dysphagia, the risk of aspiration and QOL.

Materials and Methods

This study was carried out at the Department of Radiation Oncology jointly with Department of Physiotherapy and Rehabilitation (dysphagia unit) and Department of Ear, Nose, Throat (E.N.T.). The study was approved by the scientific committee and Institutional Ethics Committee. It has been registered at Clinical Trials Registry India.

This is a prospective randomized controlled trial conducted with the help of Department of Research and Statistics and was monitored by an independent monitoring committee to rule out any bias. Head and neck cancer patients, including all subsites and all stages (I–IV) with proven biopsy or histopathology reports were taken into this study after informed consent. Of 50 patients, 24 patients underwent surgery followed by adjuvant radiation. Six patients received concurrent chemotherapy also in this group. Radical radiotherapy with concurrent chemotherapy was given in 23 patients, and radical radiotherapy alone was given in 3 patients. Concurrent chemotherapy was given on weekly basis, single drug either cisplatin or carboplatin where indicated. In this study, we treated all our patients with modern conformal techniques like IMRT/IGRT with constraints to DARS, as mentioned by Eisbruch *et al*. in their various publications.[13] Patients were treated with a dose of at 60–64 Gy; 66–68 Gy and 70 Gy in postoperative, radical RT along with concurrent chemotherapy or without chemotherapy respectively with conventional fractionation of 1.8–2 Gy/fraction, 5 days a week. All patients were treated on a linear accelerator (6 MV) with IMRT technique.

We randomized these 50 head and neck cancer patients, treated at Max Cancer Centre between August 2012 and January 2014 into two groups, 25 patients in Group-A and 25 in Group-B. Randomization charts were computer generated tables, provided by the Department of Research and Statistical analysis. After informed consent, patients were randomized into two groups. In Group-A, dysphagia interventions were provided from the day of the onset of radiation therapy and continued until 6 months whereas in Group-B no dysphagia interventions were given. Dysphagia intervention consisted of following exercises which were provided by a certified, designated dysphagia and occupational therapist: (1) Jaw exercise (2) tongue exercise, (3) the Mendelsohn maneuver, (4) shaker exercises, (5) supraglottic exercises (6) tongue hold, (7) mouth opening exercise, (8) range of motion (ROM) exercises. Patients were trained for these exercises and instructed to do at least twice a day, ten repetitions of each, from the 1st week of radiation and to continue for a period of 6 months, after completion of radiation therapy. Patients demographics and treatment details are given in Table 1.

Dysphagia assessment along with the outcome measures was done for all patients. We used M.D. Anderson Dysphagia

Table 1: Patient demographics and treatment details

Patient characteristics	Total Number	Group-A	Groq>-B
Nurrber	50	25	25
Male	38	19	19
Female	12	6	6
Strgery fo llowed by Radiation alone	18	9	9
Strgery fo llowed by Radiation and chemotherapy	6	3	3
Radical Radiation w th cherroth..-apy	23	I I	12
Radical radiation abne	3	2	I
Site			
Nasq>harynx	2	I	I
Ora Icavity	23	II	1 2
Oropharynx	II	6	5
Hypq>harynx	9	4	5
Larynx	5	3	2
Stage			
I	I	0	I II
III	23	I I	12
IV	20	10	10

Inventory (MDADI) which is a validated and reliable questionnaire designed specifically for evaluating the impact of dysphagia on QOL in head and neck cancer patients. American Speech-language Hearing Association (ASHA) scale was used for assessing swallowing function. Penetration aspiration scale (PAS) was used to assess aspiration during swallowing with the help of fiberoptic endoscopic evaluation of swallowing (FEES). This was done by E.N.T. surgeon. After informed consent and assessment, the patients in Group-A were taught swallowing exercises and baseline score of ASHA, MDADI and PAS were assessed. Patients were asked to come at the end of 3rd and 6th month for follow-up in which again detailed dysphagia assessment with the score of ASHA, MDADI, PAS were assessed and exercises were reviewed. Group-B patients were also called at the end of 3rd and 6th months, but only dysphagia assessment and score of ASHA, MDADI, and PAS were recorded without any exercises.

Fiberoptic endoscopic evaluation of swallowing

FEES is a state of the art nonradioactive method of evaluation done by the E.N.T. surgeon. This exam allows direct assessment of the motor and sensory aspects of swallowing, thus giving us precise guidance for the dietary and behavioral management of patients with swallowing disorder to reduce the risk of aspiration pneumonia. Fiberoptic flexible endoscope with video attachment was introduced transnasally with the patient in functional feeding position to visualize oropharynx, hypopharynx, and larynx. Tip of the endoscope was kept at the level of the uvula. Velopharyngeal closure, base tongue anatomy, hypopharynx, vocal cord movements, laryngo-pharyngeal secretions/sensations, any abnormality like a residual disease, edema, pooling of secretions, penetration and silent aspiration into larynx were noted. Thereafter, food items of different consistencies, e.g. liquid, nectar thick liquid, pudding, soft food and solid food were introduced orally, and the behavior of food with the structures were observed and recorded. Patients were assessed based on PAS and ASHA scale for swallowing function [Table 2].

Dysphagia prevention exercises

Dysphagia and aspiration may be eliminated by the use of postures, maneuvers and by putting Ryle s/percutaneous endoscopic gastrostomy (PEG) tube. However, a patient will need all these things until swallowing physiology improves.

Table 2: Penetration aspiration scale

	Score	Description
NEITHER PEN NOR ASP	1	Material does not enter airway
PENETRATION	2	Material enters airway, but remains above vocal folds; Ejected from airway; no stasis
	3	Material remains above vocal folds; visible stasis remains
	4	Material contacts vocal folds, but is ejected; no stasis
	5	Material contacts vocal folds, and is not ejected; visible stasis remains
ASPIRATION	6	Material passes glottis, but is ejected from airway; No visible subglottic stasis
	7	Material passes glottis, but is not ejected from airway; visible Subglottic stasis despite patient's response
	8	Material passes glottis, and is not ejected; visible subglottic stasis; Absent patient response

Intervention includes ROM exercises for the lips, jaw, oral tongue, tongue base, larynx, and hyoid-related musculature. Although the optimal frequency and duration of ROM exercises is not yet determined, 5–10 repetitions of each exercise per day are generally recommended.[17]

There are various exercises which help in improving swallowing function.[18-22]

- Jaw exercises - Jaw strengthening exercises and ROM exercises
- Tongue exercises - movement of tongue in all possible directions, e.g., extension, lateralization, elevation, tongue cupping, retraction, and protrusion. Retraction of tongue backward as far as possible will exercise base of tongue, another exercise for the base of the tongue is to pretend like doing gargle or yawn
- Pharyngeal and laryngeal exercises - reduced laryngeal movement after surgery or radiation has a major impact on swallowing and aspiration. So, laryngeal exercises are very important. Mendelsohn maneuver is a laryngeal exercise in which patient holds larynx at the midpoint of a swallow, therefore, increases the duration of larynx elevation and cricopharyngeal opening. Shaker exercise helps patients with cricopharyngeal dysfunction. In this exercise the patient lies supine, raises his head above and holds for few seconds. This exercise strengthens suprahyoid musculature including hyoid bone and larynx.

Statistical analysis

The sample size was calculated based on previously published literature about the role of preventive exercises on QOL and swallowing function, by our Department of Scientific Research and Statistics. There were mostly retrospective studies with small number of patients,[15-31] so we have taken 50 patients in our study based on estimation that it would provide 80% power at the 5% (two-tailed) significance level. Comparison of variables was done using Levene's test for equality of variance and independent-sample *t*-tests were performed to determine whether differences between the two treatment groups were statistically significant. $P \geq 0.05$ was considered as statistically significant.

Results

Acute mucositis was the commonest acute toxicity which necessitated Ryle's tube or PEG insertion in 15 patients (30%). 17 patients (34%) had an interruption in their radiation requiring hospitalization for a median of 3 days (range: 1–8 days). QOL was assessed using MDADI score. It was significantly better in exercise arm (Group-A). Patients had better QOL in terms of social eating, interaction with family members regarding eating habits

and better self-esteem. MDADI score of each patient was noted at baseline and 6 months after treatment. Then mean value of each group was compared using independent samples test (Levene's test and *t*-test for equality of means). The MDADI score showed significant improvement from the baseline to 6 months in exercise arm, that is, Group-A (14 vs. 7.76, $P = 0.017$) [Figure 1].

ASHA scale was used to assess how much nutritional needs were fulfilled by oral eating. Does patient needs some supervision while swallowing, whether any special technique or modification in food habits is required. ASHA score of each patient was noted at 6 months after treatment. Then mean value of each group was compared using independent samples test (Levene's test and *t*-test for equality of means). ASHA score also recorded statistical significance in favor of exercise arm (6.44 vs. 5.8, $P = 0.002$) [Figure 2]. Patients in Group-A were able to swallow almost normally by the end of 6 months. Patients in Group-B were able to meet their nutritional needs but required occasional support or modifications in their dietary habits (soft diet or liquids with solid food items) [Figure 2].

Penetration and aspiration were evaluated during swallowing with the help of a fiberoptic endoscope. During initial workup, we found that six patients (12%) were having PAS score two, suggesting the risk of silent aspiration [Figure 3]. These patients were advised not to eat orally and were put on Ryle s/PEG tube, to minimize the risk of aspiration. The risk of silent aspiration, as evaluated by PAS score at the end of 3 months, was 36% (Group-A = 16%, Group-B = 20%). At the end of 6 months, it improved to 24% (Group-A = 8%, Group-B = 16%) [Table 3]. There was a trend toward lesser incidence of aspiration in exercise arm, but it was not statistically significant ($P = 0.21$) as shown in Figure 4. The risk of aspiration can be reduced by feeding tubes. However, prolonged tube feeding may induce severe psychological distress because it causes discomfort and distorts patient's self-image.[23]

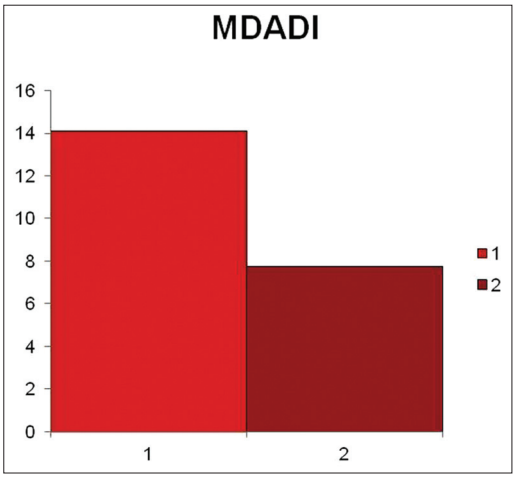

Figure 1: The M.D. Anderson Dysphagia Inventory score showed significant improvement from the baseline to 6 months in Group-A as compared to Group-B (14 vs. 7.76, *P* = 0.017)

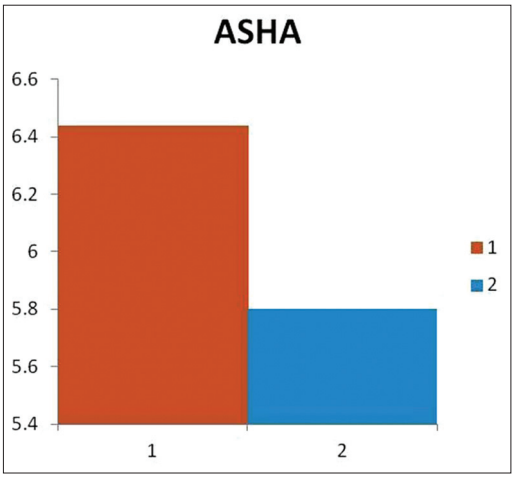

Figure 2: American Speech Language Hearing Association score showing statistical significance in favor of exercise arm that is, Group-A (6.44 vs. 5.8, *P* = 0.002)

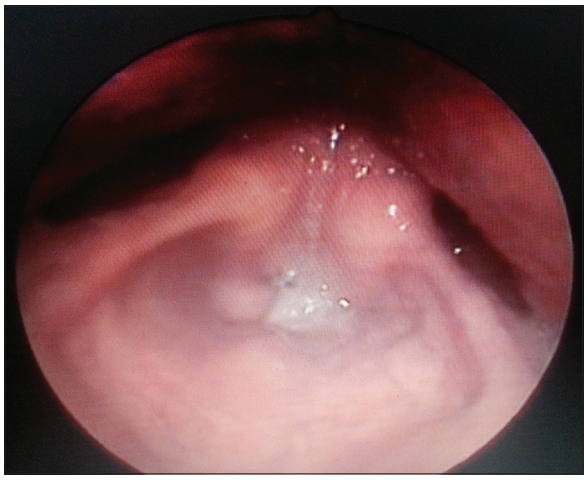

Figure 3: Fiberoptic endoscopic evaluation of swallowing showing penetration aspiration scale score = 2 with risk of aspiration

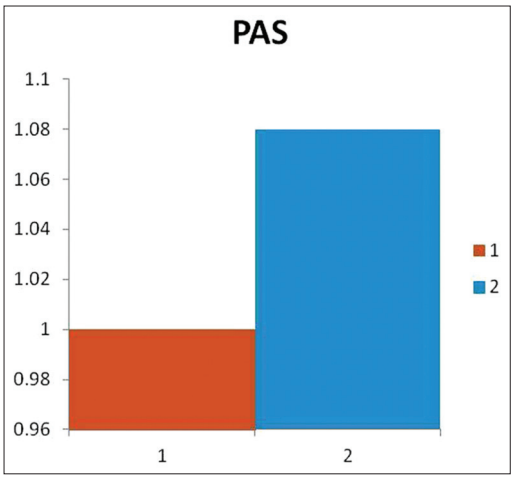

Figure 4: Lesser "aspiration" in exercise arm, but statistically not significant (*P* = 0.21)

Patients in exercise arm were able to swallow more variety of food items; there were lesser dysphagia, better cough reflex and lesser incidences of aspiration at 6 months.

Discussion

After the encouraging results from this study, we have made a policy to send all head and neck cancer patients for dysphagia assessment and training for dysphagia prevention exercises within 1st week of starting radiotherapy. In a patient having the slightest doubt about the risk of aspiration we advise for upfront NG tube or PEG tube placement. We encourage these patients to do regular dysphagia aspiration prevention exercises throughout the course of radiation therapy. In our study we found six patients (12%) to have risk for silent aspiration upfront, which increased to 36% at the end of 3 months posttreatment, at the end of 6 months it improved to 24%. We analyzed aspiration risk in exercise arm versus standard treatment arm, there was a trend toward lesser aspiration risk in exercise arm at 6 months (8% vs. 16%, $P = 0.21$) [Table 3]. There are various studies showing aspiration rate in head and neck cancer patients in the range of 15–80%[24-27] [Table 4].

Nguyen *et al*.[12] have reported 17% aspiration rate at the baseline evaluation, which increased to 59% posttreatment. 9% patient had sepsis and severe pneumonia and ultimately died. If you remove patients with baseline aspiration due to the disease itself, even then around 42% patient developed aspiration pneumonia posttreatment. Similarly, Stenson *et al*.[28] have reported aspiration rate in the range of 30–67% in their patients with head and neck cancer.

Dysphagia quality of life

In all cultures, meal time is a social event, at which sharing symbolizes friendship, closeness, and warmth. Therefore, the inability to eat represents a social handicap affecting not only our physical but also mental wellness.[29] Ekberg *et al*.[30] observed social isolation among those affected with dysphagia. Malnutrition leads to decreased physical activity, weight loss, and lethargy. These patients have feeling of frustration, anger, lack of self-esteem and confidence. These patients usually take more time to finish their meal leading to embarrassment with other family members. In addition, excessive scar formation and edema in the neck leads to the feeling of disfigurement and low self-esteem. These patients sometimes require good counseling, anxiolytics or antidepressive medications.[31,32] In our study, patiently showed statistically better QOL in exercise arm as compared to the standard treatment arm. In exercise arm, the patient had lesser fibrosis in their swallowing musculature,

Table 3: Risk of aspiration at baseline, 3 months and 6 months posttreatment

	Aspiration Risk at Baseline (%)	Aspiration Risk at 3 months (%)	Aspiration Risk at 6 months (%)
Group-A (n=25)	3 (6%)	8 (16%)	4 (8%)
Group-B (n=25)	3 (6%)	10 (20%)	8 (16%)
Total patients (n=50)	6 (12%)	18 (36%)	14 (24%)

Table 4: Rate of aspiration in various studies

AUTHORS	Year of publication	NUMBER OF PATIENTS	ASPIRATION RATE (%)
Machtay et al (24)	2002	53	4
Eisbruch et al (25)	2002	25	68
Nguyen et al (12)	2004	63	59
Pauloski et al (26)	2002	132	22
Kenneth Jensen et al (27)	2007	35	18
Present study	-	50	24

they were able to chew more variety of food items leading to a feeling of satisfaction and better self-esteem. Mouth opening, swallowing time was much better in these patients. There was much less dependency on alternative ways of feeding.

Advantage of doing fiberoptic endoscopic evaluation of swallowing as a routine

In our routine practice, we use direct laryngoscope or naso-pharyngoscope for assessing disease extent in most of head and neck patients. It gives good anatomical information but cannot assess functional swallowing status. With FEES, one can assess the anatomical extent of disease as well as assess swallowing function in the same sitting.[33-35] The ROMs of the oropharyngeal, hypopharyngeal and laryngeal structures can be assessed in real time under direct visualization. The major advantage of the procedure is it being cost effective, portability, no radiation, quick testing and immediate results. The ability to protect airway, prompt swallow, timing and direction of bolus, ability to clear secretions, pooling of secretions/food particle and sensations of the pharyngeal and laryngeal structures can be objectively studied and evaluated. In all patients, who were having a penetration of secretions or food into vocal cords, they were at high risk for developing aspiration. Managing dysphagia and aspiration in an immuno-compromised patient post chemo-radiation is not an easy task.[36-39] It involves a lot of financial aspects, morbidity, and mortality, which is highly under-reported in the management of head and neck cancer patients, especially in the developing countries.

Conclusion

Results from this study demonstrated that swallowing exercise, if administered from 1st week of chemo-radiation and continued until 6 months, results in significant improvement in swallowing function and QOL. It can prevent much dysphagia-related complications and repeated hospitalization in head and neck cancer patients. Although longer follow-up with number of patients is required.

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Conflicts of interest
There are no conflicts of interest.

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