SAFETY OF EARLY ORAL FEEDING AFTER TRANSHIATAL ESOPHAGECTOMY: PRELIMINARY REPORT OF A PROSPECTIVE TRIAL

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Abstract- Oral feeding is the best means of nutrition in surgical patients. There are many reports on early oral feeding after lower gastrointestinal (GI) operations but data regarding upper GI procedures is rather scant. This limited study focuses on early removal of nasogastric tube and start of oral diet after transhiatal esophagectomy. We prospectively evaluated 13 consecutive patients (8 males, 5 females) with esophageal cancer who had undergone transhiatal esophagectomy from March 2001 to September 2003. Nasogastric tube was removed on post-op day 2 and clear liquids started on day 3. Diet was advanced to soft regular in the next 5 days if the patients tolerated it. Mean age of patients was 63 years. Mean body weight and scrum albumin level were 57.9 kg and 3.73 gr/dL, respectively. Tumor pathology was squamous cell carcinoma in 12 cases and adenocarcinoma in 1. Location of tumor was at the lower third of the esophagus in 12 cases and middle third in one. All patients in the study group tolerated the protocol well. Only one patient had nausea after oral intake, without vomiting. We had one neck wound infection and one pulmonary infection. There was no anastomotic leakage or fistula. A group of 10 esophageal cancer patients undergoing transhiatal esophageetomy in the same period were used as the control group. One anastomotic leakage occurred in control group. We had no significant complication. Early nasogastric tube removal and oral feeding seems to be safe in patients with esophageal cancer undergoing transhiatal esophagectomy.

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INTRODUCTION

Nutritional support is one of the most important challenges after any surgical procedure, especially abdominal operations. Oral feeding is not only the best means of nutritional support but also helps in shortening the hospital stay.

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A. Jafarian, Department of General Surgery, Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran Tel: +98 21 66937185, Fax: +98 21 66937185 E-mail: jafarian@tums ac.ir Unfortunately, some limitations such as postoperative ileus and fear of anastomotic leakage hinder an early start of oral feeding. There are many published studies about the safety and benefits of early oral feeding after open colorectal surgery (1, 2). The innovation of minimally invasive techniques has attracted more attention to early oral feeding after abdominal operations, particularly in upper gastrointestinal (GI) procedures (3). Most reported studies, however, are about operations in which GI lumen has not been opened, for example gastric banding and fundoplication procedures. There are

few reports about early oral feeding after upper Gl operations with anastomosis (4, 5). Removal of the nasogastric (NG) tube, on the other hand, is a matter of concern for early ambulation and better pulmonary toilet.

This is a primary study that evaluates the safety of early removal of nasogastric tube followed by oral feeding after transhiatal esophagectomy with cervical esophagogastrostomy.

MATERIALS AND METHODS

Patients admitted due to esophageal cancer in three of eight surgical wards in Imam Khomeini Medical Complex, Tehran (a large referral hospital) were registered. The study was done prospectively from March 2001 to September 2003. All patients scheduled for transhiatal esophagectomy with gastric pull up and cervical esophagogastrostomy by our group were included in the study. We used our colleagues' patients with esophageal cancer in the same time period as control group, so surgeons were divided into two groups in those three wards. No selection criteria were used for allocating the patients in either group. Surgical technique was similar in both groups. Cervical anastomosis was hand sewn. It was performed by either one or two layers method according to the surgeon's preference. NG tube was inserted intraoperatively and in study group it was removed on postoperative day 2 if drainage was less than 200 cc per 24 hours. Oral feeding was started on the third post-op day with clear liquids (water and dilute tea in days 3 and 4). If liquids were tolerated and patient did not complain of nausea or vomiting, the diet was advanced to free liquids and soup (days 5 and 6) and regular soft diet (day 7). Neck wound drain (Penrose) which was routinely used, was removed whenever the surgeon decided. In control group, routine management was applied for post-op feeding. We obtained informed consent from all patients.

Endpoints were intolerance to liquids presenting by nausea or vomiting, reinsertion of NG tube, resumption of appetite, anastomotic leakage, wound infection and pulmonary problems (atlelectasis and aspiration pneumonia). Need for reinsertion of NG tube was defined as vomiting of more than 100 ml for two times or more. Routine postoperative analysesic drug was morphine, 3-5 mg every 4-6 hours, which was administered intravenously in the first few days and stopped after day 3.

Patients were excluded from the study if surgeon was not satisfied about the anastomosis especially because of tension. No other exclusion criteria were used. Data were analyzed by SPSS-10 using Student *t* test and Chi square test when appropriate.

RESULTS

During the study period, 15 patients were entered in the study group and underwent transhiatal esophagectomy. In two patients, the study protocol was not followed due to surgeon's concern about the anastomotic tension, so they were excluded from the study and 13 patients were enrolled in the "early feeding group". A group of 10 esophageal cancer patients undergoing transhiatal esophagectomy in the same period were used as the control group in whom the traditional protocols for postoperative feeding were followed.

The early feeding group included 8 male patients. The age ranged from 37 to 78 years with a mean of 63 years (SD = 13.39) in the study group. Average pre-op body weight was 58 Kg (SD = 11.6). Mean preoperative serum albumin level was 3.73 and 3.64 gr/dL in the study and control groups, respectively. These parameters were not significantly different in the two groups (Table 1).

In the study group, tumor was located in lower third of esophagus in 12 patients and in middle third in 1. There were 8 lower third and 2 middle third tumors in control group. One patient in each group had adenocarcinoma and the rest had squamous cell carcinoma.

In the early feeding group, NG tube was withdrawn on post-op day 2 in all but 2 patients in whom it kept in place for one more day. In the control group, on the other hand, NG tube was removed on day 4.5 by average (P < 0.0001). Oral liquids were started on day 3 in all study group patients. The mean time to start oral intake in the control group was 5.7 days after operation (P < 0.0001). In both groups, Penrose drain of the neck wound was removed on the 4th day post-op.

Table 1. Characteristics of patients and tumors*

	Study	Control	P	
	group	group	value	
Total	13	10		
Sex			NS	
Male	8	5		
Female	5	5		
Age (years)†	63	54.9	NS	
Body weight (kg)†	57.9	54.2	NS	
Serum albumin (g/dL) †	3.73	3.64	NS	
Tumor location				
Lower third	12	8	NS	
Middle third	i	2		
Pathology				
SCC	12	9	NS	
Adenocarcinoma	1	1		

Abbreviation: NS, non-significant.

One patient in each group developed nausea while on oral intake. No vomiting occurred in the early feeding group but one patient in control group developed vomiting on day 5 which was managed conservatively by reinsertion of NG tube and parenteral feeding. He was diagnosed as having delayed gastric emptying. This patient remained on parenteral feeding for two weeks after contrast study showed no mechanical obstruction.

Two patients had anorexia on starting oral diet in the study group which resolved after 1-2 days. No patient had anorexia in control group. Mean time for gas passage was 3.15 and 3.7 days in the early feeding and the control groups, respectively; the significant. difference was not statistically Postoperative pneumonia occurred in one patient in each group. No case of anastomotic leakage was found in the early feeding group, whereas one patient in the control group developed anastomotic leakage and cervical fistula. He had a very low serum albumin level preoperatively (2.4 gr/dL). The investigated complications are summarized in table

Average weight loss was 3.5 and 4.5 kg in the study and control groups, respectively (P value = 0.62, not significant).

Table 2. Complications of transhiatal esophagectomy with and without early oral feeding*

	Study group (n = 13)	Control group (n = 10)	<i>P</i> value
Nausea	1 (7.6)	1 (10)	NS
Vomiting	0	1 (10)	NS
Delayed gastric emptying	0	1 (10)	NS
Pulmonary infection	1 (7.6)	1 (10)	NS
Anastomotic leakage	0	1 (10)	NS
Neck wound infection	1 (7.6)	0	NS
Abdominal wound infection	3 (22.8)	1 (10)	NS

Abbreviation: NS, non-significant.

DISCUSSION

Oral feeding is certainly the best means of nutritional support. This is the most cost-effective route of giving nutrients with least side effects. After laparotomy and GI operations two specific problems arise: paralytic ileus and anastomosis. Ileus is not a constant problem and is very variable in different patients (6). Anastomotic leakage, however, could be a serious complication considering its anatomical

Traditionally, keeping the patient NPO for a period of 3 to 7 days according to the site of anastomosis was supposed to have a protective effect (7). In modern era this assumption has been questioned and research for shortening this period commenced during the past few years. This issue is well studied in lower GI surgery and now oral feeding is routinely started whenever ileus recovers, mostly in first 3 days (8-12). The basis of this plan is that GI secretions are much more limited during oral intake in first post-op days. Early feeding after laparoscopic upper GI operation without opening of the lumen is also a routine practice (13). On the other hand, early removal of NG tube has been reported to be safe and even beneficial for resuming bowel movement (14). Upper GI operations with anastomosis, especially when esophagus is one side of the anastomosis, are specific conditions. Esophagus has segmental circulation and lacks serosa. These factors make it at high risk of leakage. Leakages of esophagogastric anastomosis in thorax or esophagojejenostomy in abdominal cavity are life

^{*}Data are given as number unless specified otherwise.

[†] Mean.

^{*}Data are given as number (percent).

threatening complications that force surgeons to be more conservative in operations such as Ivor Lewis total gastrectomy (15).Transhiatal esophagectomy with cervical esophagogastrostomy, on the other hand, is a different situation. Reported risk of leakage in this kind of operation is approximately 12%, without serious complications (16). Neck fistulas almost always heal spontaneously and have favorable outcome. Traditionally, NG tube is kept-remained for several days and oral feeding starts if tube removal is tolerated well (17). Inadvertent early removal of NG tube in some patients, and experience of some of our senior colleagues who started oral liquids before NG tube removal from second day, made us to design this study. As we know, about 1500 cc saliva is secreted in 24 hours (18). This large volume passes from the anastomosis and limited oral intake is supposed to have no adverse effect (17). Keeping NG tube in place has positive effect only if it drains gastric contents. On the other hand, NG tube causes significant morbidites such as defective pulmonary toilet and limiting patient's ambulation. We removed NG tube on day 2 if drainage was less than 200 cc per day, which was the condition in all cases. Limited clear fluids were started the next day. All patients tolerated fluids and had a desire to drink. As pointed out, we had no leakage from anastomosis and no other significant morbidity. Only one neck wound infection occurred which was gas producing and the same infection developed in the abdominal wound of the patient later (2 weeks postop). Two other abdominal wound infections in the study group were diagnosed clinically. No other significant complication occurred. Another important factor associated with early oral feeding is the patient's sensation of well being when he or she is allowed to have oral intake. This feeling helps patient to pass recovery process easier and faster and makes him more cooperative. We didn't compare this feeling between the two groups, of course.

We concluded that early NG tube removal (post op day 2) and starting oral feeding (on day 3) with liquids after transhiatal esophagectomy could be a safe practice and do not put the patient at greater risk than traditional methods. This study emphasizes mainly on safety. Larger studies must be conducted

for confirmation of these findings and evaluation of the expected benefits such as shorter hospital stay and better nutritional support.

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COMPARISON OF THE EFFICACY OF TOPICAL DICLOFENAC VERSUS TOPICAL BETAMETHASONE AFTER STRABISMUS SURGERY

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Abstract- Topical corticosteroids are commonly used for decreasing inflammation after strabismus surgery. However the use of topical corticosteroids may be associated with several adverse effects. The aim of this study was to compare the relative effects of topical diclofenae with betamethasone in inflammation, wound healing and intraocular pressure following strabismus surgery. A single centre, single observer, prospective, randomized and single blind clinical trial of 43 patients undergoing strabismus surgery was carried out. Both postoperative treatments were instilled four times per day in the first week and two times per day in the second week postoperatively. Patient pain and discomfort, conjunctival chemosis, injection, conjunctival gap, and intraocular pressure were assessed at one day, one week, two weeks and four weeks after surgery. Since the first postoperative week the diclofenae group showed less discomfort and less conjunctival inflammation, edema, and conjunctival gap than the betamethasone group and these differences became statistically significant at the second week after surgery. There was not any significant difference between mean intraocular pressure of the diclofenae and the betamethasone group in any postoperative measurements. Diclofenae appears to be superior to corticosteroids in controlling the inflammatory responses and surgical wound healing after strabismus surgery. The maximal effect of diclofenae occurred at 2 weeks after surgery.

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Key words: Betamethasone, diclofenac, strabismus surgery

INTRODUCTION

Topical corticosteroids are commonly used for decreasing inflammation after strabismus surgery (1). However the use of topical corticosteroids may be associated with several adverse effects such as increased intraocular pressure (IOP), decreased wound

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healing, raised susceptibility to infections and cataract formation (2, 3).

Non-steroidal anti inflammatory drugs (NSAIDS) have been shown to be more effective than corticosteroids after cataract and strabismus surgery in several studies (4-6). In addition, they may reduce postoperative pain by decreasing prostaglandin production by a similar pathway as corticosteroids without impairment of corneal wound healing (7).

The aim of this study was to compare efficacy of topical Diclofenae and Betamethasone on the conjunctival healing process and IOP after strabismus surgery.

MATERIALS AND METHODS

The study population included 43 consecutive patients who underwent strabismus surgery at Farabi Hospital of Tehran from October 2002 through June 2003. Patients with systemic abnormalities, previous ocular surgery, intraocular pathology, family history of glaucoma, or allergic reaction to the steroidal or nonsteroidal drugs or chloramphenicol were excluded.

Written informed consent was obtained from all parents or patients. For patients undergoing bilateral surgery the right eye was randomized to receive postoperative topical treatment with Diclofenae sodium 0.1%-Chloramphenicol 0.5% aι Betamethasone sodium phosphate 0.1%-Chloramphenicol 0.5% while the left eye was assigned to the opposite group. In the participants with unilateral disorder the allocation was performed randomly.

All surgeries were performed by one surgeon under general anaesthesia. The rectus muscles were approached through a 5-6 mm limbal conjunctival incision or a conjunctival fornix incision. Conventional recession and resection was performed depending on the type of strabismus. Muscles were reattached after recession/resection with double armed 6-0 Vieryl sutures. The conjunctival incision was closed with 8-0 Vieryl absorbable sutures, two sutures at the limbus and one suture in the middle of each arm. Both postoperative treatments were instilled four times per day in the first week and two times per day in the second week postoperatively.

Patients were evaluated one day after surgery, at 1, 2 and 4 weeks postoperatively by a single masked investigator. Five parameters were measured: patient pain and discomfort, conjunctival chemosis, injection, conjunctival gap, and IOP (measured by Goldman type applanation tonometer). For the first parameter, the patients were asked to rate their pain perception any where between 0 (no pain) to 100 (extreme disabling pain). This score was then grouped in a 5point scale: total comfort = 0, 1 to 25=1, 26 to 50=2and 51 to 75=3 and 76 to 100=4. The second and third parameters were rated on a 4-point scale: no chemosis or injection = 0, in incision site only = 1, extended to the hours 6 and 12 of limbus = 2, extended to fornix or eyelids = 3. The size of the postoperative conjunctival gap was measured in millimeters with slit-lamp illumination perpendicular to the incision line.

Differences between the groups in clinical characteristics and surgical parameters statistically analyzed with t and Chi square tests as necessary. The comparison between postoperative measures of two groups was done using independent samples t test. Paired sample t test was utilized to compare postoperative IOPs with preoperative measures.

RESULTS

A total of 65 eyes (of 43 patients) were included in the study and were randomized to Diclofenac (33 eyes) and Betamethasone groups (32 eyes).

The patients' characteristics and surgical parameters are presented in table 1. There were no statistically significant differences between the groups in age, gender, number of operated eyes. The number of muscles operated in each eye was significantly more in Diclofenac group. As depicted in table 2, since the first postoperative week the diclofenac group showed less discomfort and less conjunctival inflammation, edema and conjunctival gap than the betamethasone group and these differences became statistically significant at the second week after surgery.

Table 1. Patients' characteristics*

	Diclofenac	Betamethasone
Characteristic	(n = 33)	(n = 32)
Age(yrs)	21.24 ± 9.39	21.25 ± 9.4
Male/Female†	17/16	16/16
Unilateral/Bilateral†	11/22	10/22
No. Muscles operated	1.79 ± 0.55	$1.47 \pm 0.47 \ddagger$
in each eye		
Preoperative IOP	13.59 ± 2.01	13.72 ± 1.95

[†] Number.

[‡] P = 0.02.

Table 2. Postoperative measures in diclofenae (Group 1) and betamethasone (Group 2) groups*

1 day		lay	l week		2 weeks		4 weeks	
Measures	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Pain and discomfort	40.3±10.1	39.1±10.9	18.9±6.2	20.7±6.3	4.2±2.8	7.2±4.0†	0.1±0.5	0.72±2.6
Chemosis	1.41 ± 0.46	1,30±0,44	0.68 ± 0.41	0.87±0.34	0.05±0.15	0.38±0.31†	0	0
Injection	1.94 ± 0.17	1.92 ± 0.18	1.30±0.25	1.39±0.21	0.74±0.28	0.89±0.21‡	()	0
Conjunctival gap	0.69±0.76	0.79±0.67	0.43±0.56	0.56±0,49	0.13±0.23	0.28±0.31±	0.003±0.02	0.009±0.03

^{*} Data are given as mean ± SD,

The results of the measurement of preoperative intraocular pressure are shown in table 3. The intraocular pressure was almost identical in the betamethasone groups in four postoperative time points. By contrast, it was significantly more than preoperative IOP at the first day and the fourth week after surgery in the diclofenae group. There was not any significant difference between mean IOP of the diclofenae and the betamethasone group in any postoperative measurements.

DISCUSSION

The present study showed that diclofenac is more effective than betamethasone for the treatment of pain and discomfort, for conjunctival chemosis, injection, and conjunctival gap.

The analgesic effect of topical diclofenae after ocular surgeries has been investigated in some studies. Morton *et al.* showed that diclofenae had the same

Table 3. Intraocular pressure (IOP) in study groups

Diclofenac	Betamethasone		
13.59±2.01	13.72±1.95		
14.3±1.8*	14.1±2.3		
13.4±2.1	13.4±2.0		
13.3 ± 2.1	13.6±1.8		
13.9±2.0 **	13.7±1.9		
	13.59±2.01 14.3±1.8* 13.4±2.1 13.3±2.1		

^{*}Data are given as mean ± SD,

analgesic effects as Oxybuprocain, especially in children (8). In the Snir *et al.* study, diclofenac was superior to dexamethasone in reducing pain and discomfort for a period of four weeks (6).

Like corticosteroids, diclofenae acts via decreasing the formation of the main mediators of inflammatory response such as prostaglandins and Leukotrienes by directly modulating cyclooxygenase pathway and indirectly modulating the lipoxygenase pathway. The anti-inflammatory effects of topical diclofenae have compared favorably with topical steroids following cataract surgery (6, 9, 10). Conversely, Apt et al. (5) and Dadeya (11) demonstrated no difference between diclofenae and steroids in the rate of resolution of the inflammatory response after strabismus surgery. The use of postoperative anti-inflammatory steroidal drops has been found to impair the quality and rate of wound healing. It seems that topical steroids decrease fibroblast activity and scar formation after corneal surgery (12). According to the results of the current study NSAIDS have not such inhibitory effects.

The routine use of postoperative topical corticosteroids may induce a high IOP, which becomes apparent after 3 to 8 weeks. Ohji et al. demonstrated that 82% of children under 10 years of age receiving topical dexamethasone 0.1% three times daily following strabismus surgery demonstrated significant elevations of IOP with half of the children having rises in IOP of greater than 15 mm Hg (13). In present study we did not find any significant difference in IOP between diclofenac and betamethasone group and all

 $[\]dot{\tau}P \leq 0.001$.

 $[\]stackrel{*}{\sim} P \le 0.05$ compared with betamethasone.

[†] $P \le 0.001$.

 $[\]ddagger P \le 0.05$ compared with betamethasone.

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the post operative IOP measures were within normal range. Less increase in IOP in betamethasone group compared with the previous studies may be due to shorter treatment period in our study (5, 6, 11).

In conclusion, diclofenae appears to be superior to corticosteroids in controlling the inflammatory responses and surgical wound healing after strabismus surgery. The maximal effect of diclofenae occurred at 2 weeks after surgery.

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