Palliative Stenting With or Without Radiotherapy for Inoperable Esophageal Carcinoma

Yaldiera Utami, Achmad Fauzi***

*Department of Internal Medicine, Faculty of Medicine
University of Indonesia/Dr. Cipto Mangunkusumo General National Hospital, Jakarta
**Division of Gastroenterology, Department of Internal Medicine, Faculty of Medicine
University of Indonesia/ Dr. Cipto Mangunkusumo General National Hospital, Jakarta

Corresponding author:
Achmad Fauzi. Division of Gastroenterology, Department of Internal Medicine, Dr. Cipto Mangunkusumo General National Hospital. Jl. Diponegoro No.71 Jakarta Indonesia. Phone: +62-21-3153957; Facsimile: +62-21-3142454. E-mail: ppfauzidrgm@gmail.com

ABSTRACT

Aim: *to evaluate the comparison of palliative treatment using esophageal stenting alone or in combination with radiotherapy.*

Method: *Patient/problem, intervention, comparison, and outcome (PICO) system were used. We conduct a searching in PubMed site. The next process was selection by reading all articles (10 articles). There were 9 articles excluded from analysis. We finally choose one randomized trial study written by Javed A, Pal S, Dash NR, Ahuja V, Mohanti BK, Vishnubhatla S, et al goes to the critical appraisal step.*

Results: *The result of this study showed that dysphagia scores improved significantly in both groups, in patients with inoperable esophageal cancer treated with esophageal stenting alone (group I) and a combination of esophageal stenting and radiotherapy (group II) following stent insertion. However, dysphagia relief was more sustained in group II than in group I (7 vs. 3 months, p = 0.002).*

Conclusion: *In this evidence-based case report (EBCR), we reported a man who suffered from dysphagia caused by inoperable esophageal carcinoma. Based on the critical appraisal of the randomized trial collected previously from PubMed with specific criterias, we conclude that a combination of esophageal stent and radiotherapy effectively prolongs duration of dysphagia relief and improves the overall survival, without increasing the incidence of complications.*

Keywords: *palliative stenting, radiotherapy, inoperable esophageal cancer*

ABSTRAK

Tujuan: *Untuk mengevaluasi perbandingan pengobatan paliatif menggunakan stenting saja atau dikombinasikan dengan radioterapi.*

Metode: *Sistem patient/problem, intervention, comparison, and outcome (PICO) digunakan. Dilakukan pencarian di situs PubMed. Proses berikutnya adalah memilih dan membaca seluruh artikel (10 artikel). Ada 9 artikel yang dikeluarkan dari analisis. Akhirnya dipilih salah satu penelitian percobaan acak yang ditulis oleh Javed A, Pal S, Dash NR, Ahuja V, Mohanty BK, Vishnubhatla S, et al dan lanjut pada langkah penilaian kritis.*

Hasil: *Penelitian ini menunjukkan bahwa skor disfagia meningkat secara signifikan pada kedua kelompok, yaitu pada pasien kanker esofagus yang dioperasi dan cukup diobati dengan esofagus stenting saja (kelompok I) dan pasien kanker esofagus yang dioperasi dan diobati dengan kombinasi stenting esofagus dan radioterapi*

(kelompok II) berikut pemasangan stent. Namun, pemulihan disfagia lebih baik pada grup II daripada grup I (7 vs. 3 bulan, p = 0,002).

Simpulan: *Dalam laporan kasus berbasis bukti ini, dilaporkan seorang pria yang menderita disfagia disebabkan oleh kanker esofagus yang tidak bisa diatasi dengan operasi. Berdasarkan penilaian kritis dari uji coba acak yang dikumpulkan dari PubMed dengan kriteria tertentu, disimpulkan bahwa kombinasi stenting esofagus dan radioterapi efektif memperpanjang durasi pemulihan disfagia dan meningkatkan kelangsungan hidup secara keseluruhan, tanpa meningkatkan kejadian komplikasi.*

Kata kunci: *stenting paliatif, radioterapi, kanker esofagus inoperable*

INTRODUCTION

Esophageal cancer is an aggressive gastrointestinal malignancy with a poor prognosis.[1] It is diagnosed in about 400,000 patients each year worldwide, and its incidence is increasing.[2] Due to the lack of widespread screening methods, its insidious symptomatology, a late clinical presentation, and rapid progression, diagnosis is usually made at advanced stages.[1,3] Therefore the 5-year survival rate of patients with esophageal cancer is less than 20%. Most patients already present with locally advanced, unresectable or metastatic disease and only suitable for palliative therapy.[3] The predominant symptom of advanced esophageal cancer is dysphagia with 80–90% of all patients having some difficulty in swallowing.[1] It is one of the most distressing and debilitating symptoms in patients with cancer-related esophageal obstruction. Dysphagia leads to nutritional compromise, pain, and deterioration of quality of life.[3] As the quality of life, and to some extent the quantity of life remaining to these patients depends to a large degree on their ability to swallow, the relief of dysphagia is therefore a priority for any palliative treatment of patients suffering from esophageal cancer.[1,3]

Several treatment modalities are used for the palliative care of dysphagia in patients with inoperable esophageal cancer, including radiotherapy (endoluminal and external-beam), endoscopic ablation (for example, by laser, cryotherapy, photodynamic therapy), endoluminal plastic and metallic stents, and resection or bypass surgery. Of those approaches, endoluminal stenting and radiation therapy are the ones most commonly used.[4]

In the past there have been attempts to combine radiotherapy with stent placement in patients with esophageal cancer. These efforts are based on the premise that radiotherapy and stenting complement each other. Stents provide rapid relief of dysphagia and maintain nutrition during radiotherapy. Radiotherapy, in turn, provides lasting dysphagia relief by retarding tumor growth and, possibly, improves survival.[1] This paper was aimed to evaluate the comparison of palliative treatment using esophageal stenting alone or in combination with radiotherapy.

CLINICAL QUESTION

A 48 year-old man came with the chief complain of black stool since 2 days before admission. The history of his disease has started since a year ago. At first, he suddenly had difficulty in swallowing food. Pain in the throat or fever were denied. He was still able to eat solid food, but gradually he can only consume liquid food or just drink milk. This patient already went to other hospital and underwent esophagogastroduodenoscopy (EGD). The doctor said that there was a tumor in his esophagus, but the biopsy results were never conclusive although it has been done for seven times. The deployment of esophageal stent has been carried out in this patient at that time because there was already constricture at his esophagus. At 2 days before the admission, the patient started to pass firm black stool three times a day in small quantities. It also became more difficult for him to swallow food. There was loss of appetite but nausea and vomiting were denied. He also suffered from weight loss, approximately 10 kg in the last 3 months. Any other symptoms were denied. He has no history of chronic diseases such as diabetes mellitus, hypertension, heart disease, kidney disease, pulmonary disease, asthma, or allergies. He also did not admit for alcohol consumption or smoking. There is no history of similar disease or other chronic disease such as malignancy in the family.

From a complete physical examination, stable hemodynamic was found. Abdominal examination showed palpable liver approximately 2 cm below processus xyphoideus. On rectal touché, black stool were found. No other abnormalities were found. From the laboratory examination at emergency ward, we found normocytic normochrome anemia (Hb 8.43 mg/dL, MCV 82.7 fl, MCH 26.1 pg) and slightly

leukocytosis (Leu 10.600/uL). Electrolytes were normal (Sodium 137/Potassium 4.0/Chloride 104 mEq/L) and also no elevation of transaminases (AST 20/ALT 10 u/L) nor ureum/creatinine level (21.5/1.0 mg/dL). Later on we also checked on the fecal occult blood test and the result was positive. Serologic markers for hepatitis B, C, and HIV infections showed negative result. The level of LDH was slightly increased (331 u/L) and AFP level was normal (0.9 IU/mL). Hemostasis were normal with no prolonged PT nor aPTT. Chest X-Ray and electrocardiography showed no abnormalities.

Before the admission, this patient already underwent several examination at other hospital. Chest CT-scan showed esophagogastric tumor with stent deployed suspect malignancy and no abnormalities in the heart and lung. Esophagogastroduodenoscopy showed esophageal tumor with stent deployed and covered by tumor growth. The biopsy result showed reflux esophagitis with ulceration. OMD showed irregularity at gastroesophageal junction with stent deployed and narrowing lumen. Abdominal ultrasound showed distal esophageal tumor infiltrated to left lobes of the liver. Abdominal CT-scan showed solid tumor at distal esophageal spread through cardia and fundus of stomach, no infiltration to adjacent vascular, and coeliacus truncus lymphadenopathy.

Based on anamnesis, physical examination, laboratory and other supports, we conclude the list of problems in this patient are: (1) melena et cause GI bleeding dd/ tumor bleeding; (2) esophageal tumor et cause suspected malignancy with tumor bleeding and metastasis to the liver; (3) normocytic normochrome anemia et cause tumor bleeding dd/ anemia of chronic disorder. The patient was treated using the nasogastric tube to evaluate the bleeding and was started to be given liquid food 1700 kkal per day as soon as the bleeding stopped. Other treatment were intravenous Normal saline and Triofusin 500 mL, PPI 2 x 40 mg iv, Sucralfate 3x15 mL po, Vitamin K 3x10 mg iv, Transamin 3x500 mg iv, Lactulax 3x15 ml, Curcuma 3x200 mg, and PRC transfusion with targeted Hb 10 mg/dL.

During the treatment at our hospital, this patient underwent another EGD procedure and biopsy of the esophagus tissue. He was confirmed to have esophageal squamous cell carcinoma spread to the stomach and also liver metastases. While deciding the next step of treatment, the difficulty of swallowing food in this patient is getting more serious. Sometimes he said that he is not even able to swallow liquid food. Apparently the use of esophageal stent may not be as effective as expected.

Does a combination of esophageal stent and radiotherapy give the best outcome for the relief of dysphagia in patients with inoperable esophageal carcinoma compare to esophageal stenting alone?

METHOD

In order to answer the clinical question above, we need to start by first systematically clarifying the question with PICO system, understanding what type of clinical question it is, and what type of study design is appropriate in searching the most relevant clinical evidence. By using PICO, a clinical question will have 4 elements which are Patient/Problem, Intervention, Comparison, and Outcome. The following table shows PICO for our question:

Table 1. PICO model for the clinical question of this case

PICO	Case
Patient/Problem	Inoperable esophageal carcinoma
Intervention	Esophageal stent
Comparison	Esophageal stent combine with radiotherapy
Outcome	Relief of dysphagia

We conduct a searching in PubMed site by using three keywords; they are “inoperable esophageal carcinoma” AND “esophageal stent” AND “radiotherapy” on June 5th 2013. The searching detail is ((inoperable[All Fields] AND esophageal[All Fields] AND ("carcinoma"[MeSH Terms] OR "carcinoma"[All Fields])) AND (esophageal[All Fields] AND ("stents"[MeSH Terms] OR "stents"[All Fields] OR "stent"[All Fields]))) AND ("radiotherapy"[Subheading] OR "radiotherapy"[All Fields] OR "radiotherapy"[MeSH Terms]). Based on this search strategy, we found 32 articles matched the keywords. From these 32 articles, only 10 articles were published in the last 5 years. Thus, from the searching step, there were 10 articles that go to the next process.

The next process was selection by reading all articles (10 articles). The articles which were included in this EBCR consist of study which compare combination of esophageal stent and radiotherapy directly with esophageal stent alone. There were 9 articles excluded from analysis because it did not compare those modalities directly. The following figure showed the selection process for the most relevant clinical evidence in this EBCR:

Figure 1. Selection process of articles for critical appraisal

We finally choose one randomized trial study written by Javed A, Pal S, Dash NR, Ahuja V, Mohanti BK, Vishnubhatla S, et al goes to the critical appraisal step. In appraising the scientific evidence of the article, we use the guidance of critical appraisal of a randomized controlled trial written by Guyatt et al in Critical Appraisal Skills Programme. Details of the article is described in the following table:

Table 2. Details of the article

Paper details	
Authors	Javed A, Pal S, Dash NR, Ahuja V, Mohanti BK, Vishnubhatla S, et al
Title	Palliative Stenting With or Without Radiotherapy for Inoperable Esophageal Carcinoma: A Randomized Trial
Source	J Gastrointest 2012;43:63-9

RESULTS

In this EBCR, one prospective, randomized study is collected and compares directly the duration of relief of dysphagia in patients with inoperable esophageal cancer treated with esophageal stenting alone (group I) or a combination of esophageal stenting and radiotherapy (group II), and to assess overall survival, treatment-related complications, and quality of life (QOL) of the patients.

The result of this study showed that dysphagia scores improved significantly in both groups following stent insertion. The scores were assessed at baseline (before the start of therapy), 1 week after esophageal stenting, 1 week after completion of radiotherapy (in group II), and every 2 months there after until death or until completion of the study. However, dysphagia relief was more sustained in group II than in group I (7 vs. 3 months, $p = 0.002$). Overall median survival was significantly higher in group II than in group I (180 vs. 120 days, $p = 0.009$). Addition of radiotherapy following stenting prolonged the mean dysphagia-free survival (118.6 ± 55.8 vs. 96.8 ± 43.0 days, $p = 0.054$). Mean dysphagia-free survival was defined as survival with no or minimal dysphagia (dysphagia grade 0-1). There was significant improvement in all QOL parameters at 1 week after stenting. The QOL, however, significantly declined immediately after radiotherapy. There was no treatment-related mortality, and the incidence of complications was similar in the two groups.[1]

DISCUSSION

Carcinoma of the esophagus is defined as primary cancer of the esophagus. About 10% of this cancer occur in the upper third of the esophagus (cervical esophagus), 35% in the middle third, and 55% in the lower third. Squamous cell carcinoma and adenocarcinoma account for more than 90% of cases.[1,5,6] A variety of causative factors have been implicated in the development of the disease. The etiology of squamous cell esophageal cancer is related to excess alcohol consumption and/or cigarette smoking. The relative risk increases with the amount of tobacco smoked or alcohol consumed, with these factors acting synergistically.[6]

Due to the lack of widespread screening methods, its insidious symptomatology, a late clinical presentation, and rapid progression, diagnosis is usually made at advanced stages.[1,3] Progressive dysphagia and weight loss of short duration are the initial symptoms in the vast majority of patients. By the time these symptoms develop, the disease is usually incurable, since difficulty in swallowing does not occur until > 60% of the esophageal circumference is infiltrated with cancer.[6]

Dysphagia is defined as a sensation of "sticking" or obstruction of the passage of food through the mouth, pharynx, or esophagus. It may be associated with pain on swallowing (odynophagia), pain radiating to the chest and/or back, regurgitation or vomiting, and aspiration pneumonia.[6] The obstruction of the esophagus by the tumor causes progressive solid food dysphagia, often accompanied by weight loss. Weight loss > 10% body mass (at presentation) is an independent indicator of a poor prognosis. This usually occurs once the esophageal lumen diameter is less than 13 mm, which indicates advanced disease. The following table shows grades of dysphagia:[7]

Table 3. Grades of dysphagia

Grade	Description
1	Normal swallowing
2	Difficulty swallowing some hard solids but can swallow semisolids
3	Unable to swallow any solids but can swallow liquids
4	Difficulty swallowing liquids
5	Unable to swallow saliva

Dysphagia from inoperable esophageal cancer is a common and complex management problem, and there is no consensus on the ideal treatment approach.[4] The stage of neoplastic disease, general patient condition and (in consequence) life expectancy, should be taken into account in choosing a method for palliative treatment of dysphagia caused by esophageal cancer.[8] Several treatment modalities are

	Yes	Can't tell	No
A. What is this trial about and can I trust it?			
Screening questions			
1. Is the trial relevant to the needs of the enhancement project?	√		
2. Did the trial address a clearly focused issue?			
in terms of:	√		
the population studied,	√		
the intervention given,	√		
the outcomes considered?	√		
3. Was the assignment of patients to treatments randomised?	√		
4. Were all the patients who entered the trial properly accounted for at its conclusion?			√
was follow-up complete?	√		
were patients analysed in the groups to which they were randomised?			
Detailed questions			
5. Were patients, health workers and study personnel 'blind' to treatment?			
patients?			√
health workers?			√
study personnel?			√
6. Were the groups similar at the start of the trial?			
In terms of all the factors that might be relevant to the outcome:			
age, sex, social class, life style etc.	√		
7. Aside from the experimental intervention, were the groups treated equally?	√		
Is it worth continuing? Yes			
B. What did they find?			
8. How large was the treatment effect?		8. How large was the treatment effect?	
What outcomes are measured?	The overall survival, treatment-related complication, and quality of life (QOL)	What outcomes are measured?	The overall survival, treatment-related complication, and quality of life (QOL)
Take a note of the result(s) (eg odds ratio, number needed to treat) if provided.	Results: Overall survival was significantly higher in group receiving combined modalities (p = 0.009). Treatment-related complication was similar in both groups. The QOL was significantly declined immediately after radiotherapy.	Take a note of the result(s) (eg odds ratio, number needed to treat) if provided.	Results: Overall survival was significantly higher in group receiving combined modalities (p = 0.009). Treatment-related complication was similar in both groups. The QOL was significantly declined immediately after radiotherapy.
9. How precise was the estimate of the treatment effect?		9. How precise was the estimate of the treatment effect?	
What are the confidence limits?	N/A	What are the confidence limits?	N/A
Do you feel confidence in the authors' use of statistics?	Yes	Do you feel confidence in the authors' use of statistics?	Yes
C. Are the results relevant locally/to me?			
10. Can the results be applied to the local population?			
Do you think the patients covered by the trial are similar enough to your population? Consider culture, geography etc.	√		
11. Were all important outcomes considered?			
If not, does this effect the conclusion(s)?	√		
12. Is any information provided which could help you decide whether the benefits are worth the harms/costs (financial and otherwise)?	√		
13. Accept for further use as Type II evidence in the Protocol Enhancement Project?	√		

used for the palliative care of dysphagia in patients with inoperable esophageal cancer, including radiotherapy (endoluminal and external-beam), endoscopic ablation (for example, by laser, cryotherapy, photodynamic therapy), endoluminal plastic and metallic stents, and resection or bypass surgery.

Esophageal intubation for palliation has been used longer than 100 years. Symmonds in 1885 described the first successful intubation using a metallic device, since then several types of endoprosthesis have been tried. Stenting has proved to be a convenient and long lasting method of palliation for malignant dysphagia. Use of covered self expandable metallic stents (SEMS) and more recently self expandable plastic stents (SEPS) has led to an increase in the success rate in palliative management of strictures of esophagus.[8,9,10]

Since 1990, several case series, retrospective reviews, and prospective studies including more than 2,000 patients have shown that self-expandable metal stents (SEMS) are effective in relieving dysphagia and improving dysphagia scores, with immediate success rates between 96% and 100%. SEMS provide a substantial progress in the management of patients with inoperable carcinoma esophagus. It is made up of an alloy, usually nitinol or stainless steel is deployed using endoscopic and/or fluoroscopic techniques, quickly restores oral intake and reduces hospital stay and cost.[10] However its use is limited by the cost, high rate of recurrent dysphagia, frequent need of re-interventions and several complications.[1,4,8,9]

Complications associated with esophageal stents are generally classified as either early or delayed. Early complications occur immediately or within 2–4 weeks postprocedure and include chest pain, fever, bleeding, gastroesophageal reflux disease, globus sensation, perforation, and stent migration. In one study, early complications were reported in up to 32% of patients, with stent migration being the most common complaint. Delayed complications are more common than early ones and occur at least 2–4 weeks after placement of a stent. These complications include tumor ingrowth, stent migration, stent occlusion, development of esophageal fistulae, and recurrence of strictures. Delayed complications have been reported in 53–65% of patients, with a reintervention rate of up to 50%. Among both early and delayed complications, stent migration is the most common complication, occurring at a frequency of 7–75%.[8,9]

Recurrent dysphagia was caused by tumor ingrowth (22%), bolus obstruction (21%), stent migration (9%), or esophageal fistulae (9%).[8] This issue has led to the frequent need of re-intervention of the stent. Tumour ingrowth suggested that the longer the stent is in place the more tissue growth will be seen; hence, the longer time with the stent in situ, the more frequent the complications. APC was therefore the most frequent re-intervention modality in our study. In some instances, placing a second stent could have been an option, but when the stented area is lengthened, the motility is also reduced. Stent dislocation was another frequent problem. Due to the problems with tumour/tissue ingrowth, covered stents are generally preferred, but it is also known that they tend to migrate more often. To avoid migration, the use of larger diameter stents seems tempting, but studies have shown that these may cause even more complications. The survival after SEMS placement was quite short (mean 116 days) which emphazises the need for quick relief of dysphagia rather than a more prolonged effect.[11]

Radiotherapy, on the other hand, provides effective and long-term relief of dysphagia. However, the onset of its effect is slow and required up to 6 weeks for maximum benefit. Besides that radiotherapy-induced edema can actually worsen dysphagia during the early period. Stents placed before radiotherapy prevented this initial worsening of dysphagia. Patients who receive radiotherapy had a more sustained relief of dysphagia, which may have resulted from the inhibition of local tumor by radiotherapy, thereby delaying tumor overgrowth and ingrowth and keeping the stent patent for a longer duration. Besides the better relief of dysphagia, sustained improvement in nutritional status of patients who had received combination therapy might have also contributed to the improved survival in this group.[1]

The survival benefit of combined intubation and radiotherapy was first suggested by Ogilvie et al. Since then, a few studies have reported superior results for stenting followed by radiotherapy with regard to both relief of dysphagia and survival in patients with inoperable esophageal cancer.[1] A study by Yu et al showed that radiotherapy for esophageal cancer after esophageal stents placement is very helpful in treatment of advanced esophageal cancer. The stent inserted expanded the stenosis site and made it possible for brachytherapeutic treatment and radioactive source to pass easily and eventually dramatically prolonged the patients' survival period.[12] The dose of radiotherapy used in combination with stenting also need to be considered properly. Most studies have used radiotherapy in a dose range of 40–60 Gy. However, a higher dose of radiotherapy does not add to the

therapeutic value, and may increase the loco-regional toxicity.[1]

A few studies have reported a higher incidence of complications with radiotherapy after stent placement in esophageal cancer. In the present study, the overall rate of major complications was similar in the two treatment groups. This could be attributed to the use of Ultraflex stent, which exerts the least radial force, insertion of stents before radiotherapy, adequate interval between the stent placement and radiotherapy, and lower dose of radiotherapy used.[1]

Our patient underwent the deployment of esophageal stenting and showed several complications including bleeding and recurrent dysphagia which brought him to our hospital. From the anamnesis, we found out that the symptoms occurred few months after the stent deployment. We assumed that this patient suffered from delayed complication of esophageal stent caused by stent migration which shown from his imaging examination. The bleeding also occurred long time before he came to our hospital but never treated sufficiently. We assumed this was a result from stent deployment or from the fragile and easily bleed tumor tissue.

At first, we decided to place a nasogastric tube to relief the dysphagia and also given him medical therapy including vitamin K and transamin to stop the bleeding. It turned out that these treatment did not relief the dysphagia. We planned to do the re-intervention of the stent and combine it with radiotherapy to prolong the duration of dysphagia relief and improve overall survival for this patient.

CONCLUSION

In this evidence-based case report (EBCR), we reported a man who suffered from dysphagia caused by inoperable esophageal carcinoma. Based on the critical appraisal of the randomized trial collected previously from PubMed with specific criterias, we conclude that a combination of esophageal stent and radiotherapy effectively prolongs duration of dysphagia relief and improves the overall survival, without increasing the incidence of complications. We planned to do the re-intervention of the stent and combine it with radiotherapy to prolong the duration of dysphagia relief and improve overall survival for this patient.

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