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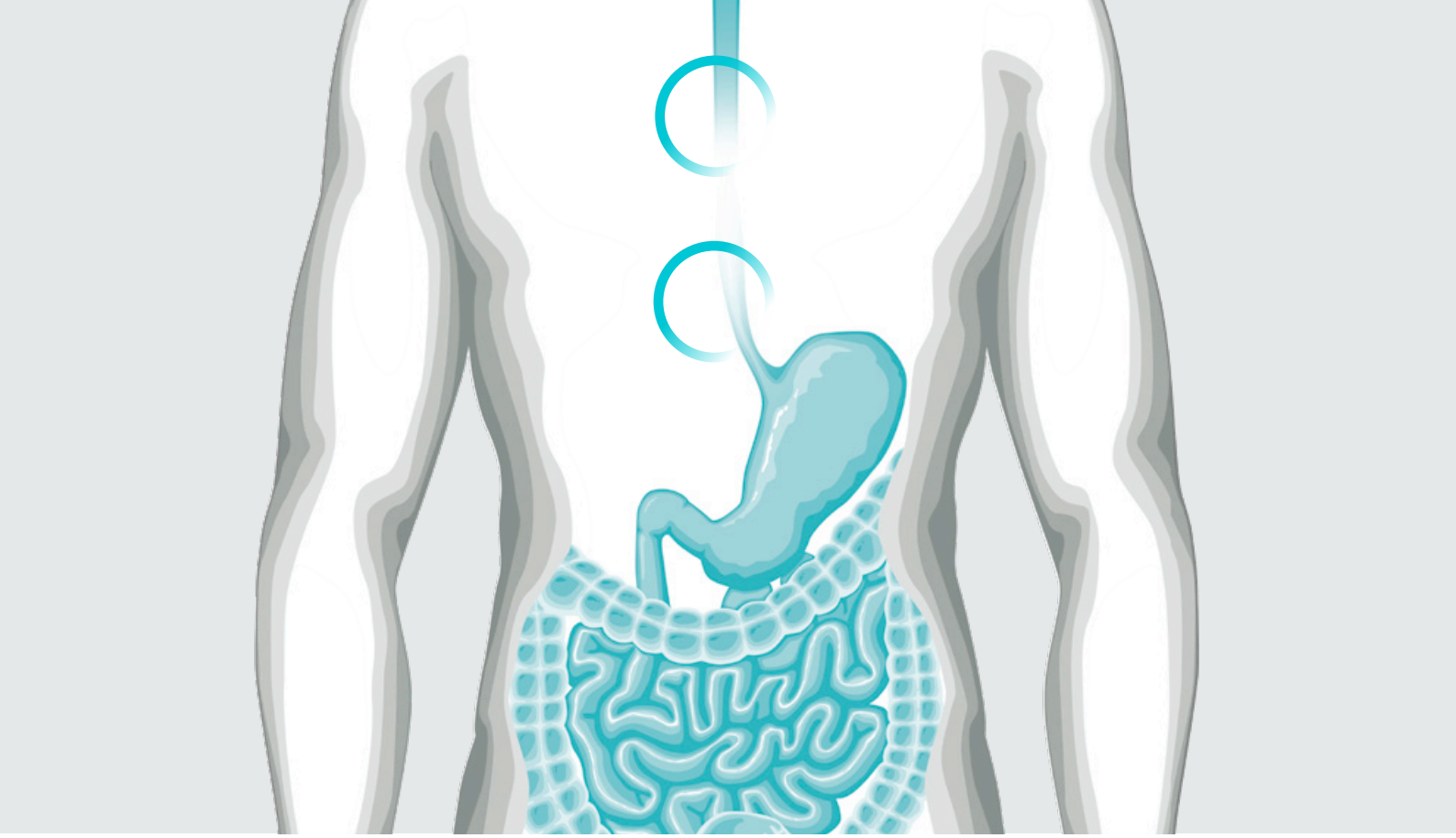
Clinical evidence Eso-SPONGE™

Endoluminal vacuum therapy for the treatment and oesophageal of anastomotic leakages

RATIONALE

According to the Robert Koch Institute (RKI), the number of new cases suffering of a esophageal carcinoma has doubled since 1990 in Germany. The older age groups were more affected. Taking into account an unchanged morbidity rate and survival rate a further increase of 10-year prevalence rate is expected in the coming years to 10.500 patients. In contrast to esophageal cancer, the incidence of gastric cancer is declining since 1990. When adopting consistent incidence and survival rates, the RKI counted with a 10-year prevalence of 56.000 gastric cancer patients for the next years[1]. Both the esophageal resection and the gastrectomy is accompanied with a high complication rate[2].



The most serious complication is an anastomosis leakage. In the literature insufficiency rates up to 30 % have been reported after esophagectomy[3]. An anastomosis leakage rate up to 10 % is recorded after gastrectomy and distal esophagectomy[4]. For large intrathoracic or intra-abdominal insufficiencies, mortality rates of up to 50 % have been observed[5]. The most responsible factor that leading to death after anastomosis leakage and perforation is the development of the mediastinitis. Next to the surgical revision and endoscopic stent system nowadays the endoluminal vacuum sponge therapy is available for the treatment of anastomosis insufficiencies. The surgical intervention consists of the surgical debridement, the closure of the dehiscence and the new construction of the anastomosis with adequate drainage. The conservative treatment is the endoscopic closure by clips or the injection of fibrin glue or endoscopic stent application or the endoluminal vacuum sponge drainage[6-9].

So far, several case series that include up to 30 patients, have been carried out using homemade endoluminal vacuum sponge systems to treat anastomosis insufficiencies in the upper gastrointestinal tract (GIT)[10]. Within these case series the sponge is endoscopic applied either intraluminal or intracavitary and the sponge is connected to a negative pressure of 125 mmHg via a drainage hose. The drainage hose is diverted transnasal. The size of the sponge is adapted to the cavity. The sponges are changed every 48-72 hours until granulated tissue has been developed. The therapy is stopped as far as the defect reached a size which is to small for a further sponge insertion or until the cavity is completely closed or collapsed. The enteral nutrition of the patient is usually performed with a feeding tube, or percutaneous endoscopic gastrostomy (PEG) or orally.

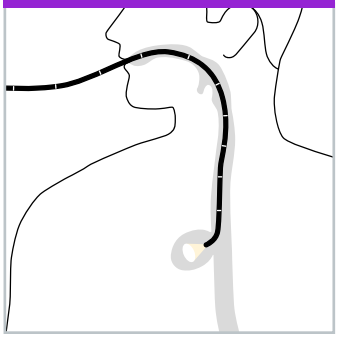
RATIONALE

The published clinical results are promising. Thus, the mortality rate lies between 0-16.7 % in these pilot studies which is well below the mortality rates described for other treatment methods[10-17]. Two authors have compared the endoscopic stent insertion with the endoluminal vacuum therapy and indicated that the stent endoluminal vacuum therapy was superior in comparison to the stent application[16,17]. Brangewitz et al.[16] could showed that the healing rate was obviously higher in patients treated with the vacuum sponge therapy compared to patients receiving stent application (84.4 % vs. 53.8 %). A higher esophageal stricture rate after stent therapy was seen as well (28.2 % vs. 9.4 %). In addition Schniewind et al.[17] observed a higher mortality rate in the stent group as in the endoluminal vacuum therapy group (50 % vs. 12 %). Possible complications after endoluminal vacuum therapy are bleedings from blood vessels erosions or the development of esophageal fistulas. Potential risks which are mentioned for the endoscopic stent applications are as follows: stent stenosis, stent migration, stent dislocation, ingrowth of the stent, perforations induced by the stent and a lacking sealing[16-17]. In most of the performed case series the endoluminal vacuum therapy is described as a safe and simple minimal invasive approach leading to low mortality rate with a excellent clinical outcome.[11,13,15,18]

Since July 2014 the first commercially purchasable endoluminal vacuum sponge system (Eso-SPONGE™) of Boston Scientific is available for the conservative endoscopic treatment of anastomosis insufficiency within the upper GIT. Eso-SPONGE is CE certified and already used in many hospitals for the treatment of perforations and anastomotic leaks. To evaluate the performance of Eso-SPONGE in the upper gastrointestinal tract (GIT), a multicenter, prospective, web-based online registry was initiated in collaboration with the University Schleswig Holstein, Department of General, Visceral, Thoracic, Transplantation and Pediatric Surgery, Prof. C. Schafmayer. The registry is used for the systematic collection of clinical data for Eso-SPONGE used in clinical routine. The registry allows the detailed documentation of the anamnesis, the outcome of endoluminal vacuum treatment and possible complications occurring during therapy. A detailed description of the Eso-SPONGE registry can be found in Clinical Evidence chapter of this brochure.

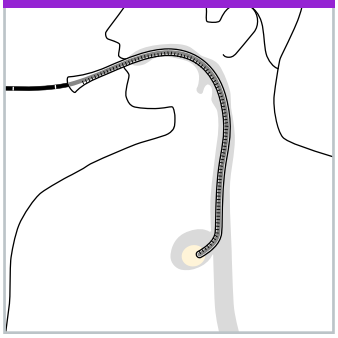
FIGURE 1: SCHEMA ESO-SPONGE™ TREATMENT

STEP 1



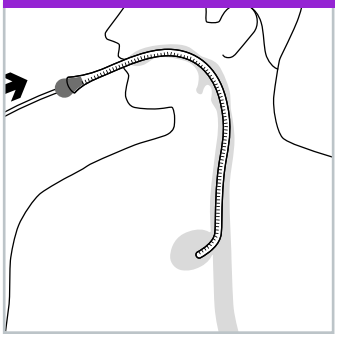
BEFORE USE:
Investigate and measure the wound cavity with a flexible endoscope.

STEP 2



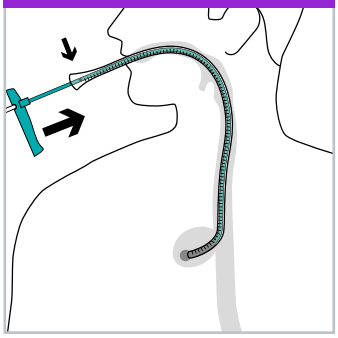
Introduce the overtube under visual control into the insufficiency hole. The endoscope can be used as a guide rail here.

STEP 3



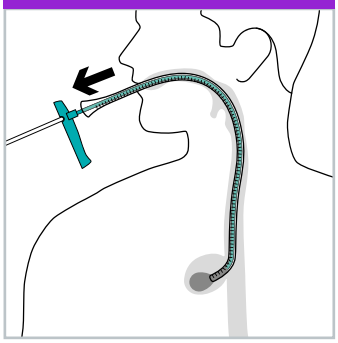
Cover the appropriate, tailored Eso-SPONGE, with sterile hydrogel (glycerol based) and introduce it into the overtube.

STEP 4



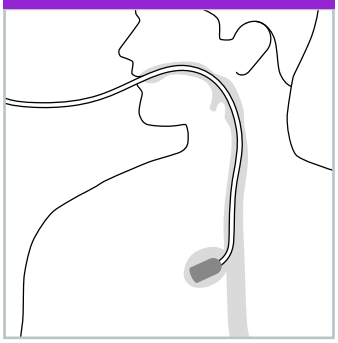
Push the Eso-SPONGE to the mark with the pusher. The sponge is now at the end of the overtube.

STEP 5



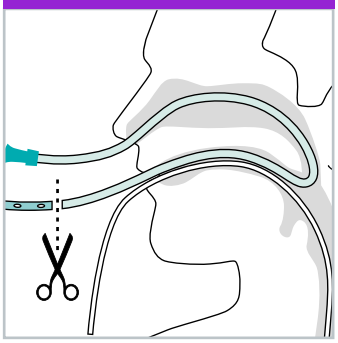
Hold the pusher in place and pull the overtube out as far as the handle of the pusher. The sponge will unfold in the insufficiency hole; the overtube and pusher can be removed together.

STEP 6



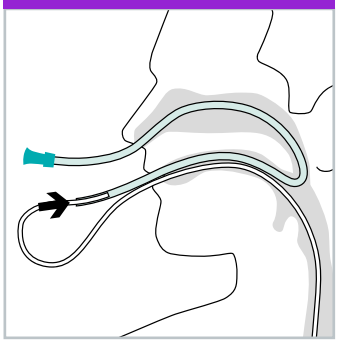
Endoscopic position control of the sponge and appropriate correction by means of endoscopic grasping forceps.

STEP 7



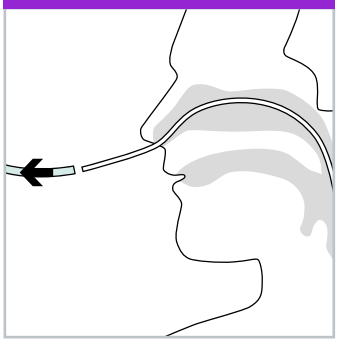
Transnasal channelling:
Insert stomach tube CH 16 (not included in the set) through the nose and bring it out through the mouth. Cut off the atraumatic tip.

STEP 8



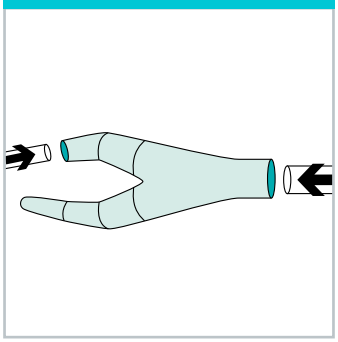
Connect the drain with the stomach tube outside the mouth. Pull the stomach tube together with the drain back through the nose.

STEP 9



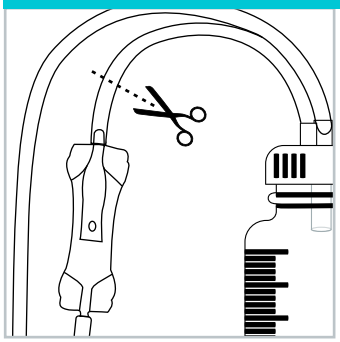
The drain is now transnasally channelled.

A

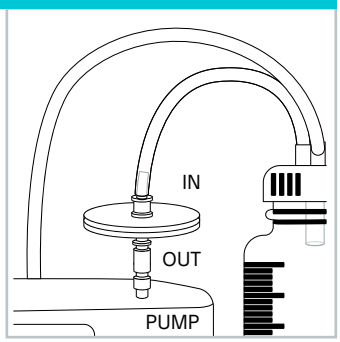


Connect the drain by means of the y-piece to the hose of an adjustable, medical pump with sufficient suction performance.* Activate the pump, where necessary keeping endoscopic visual control of the sponge.

B



When using the MV 1 pump (MTG Germany): Cut off the secret valve from the secretion cylinder hose.



Connect the filters using a Luer Lock to the pump and attach the cylinder hose to the filter.

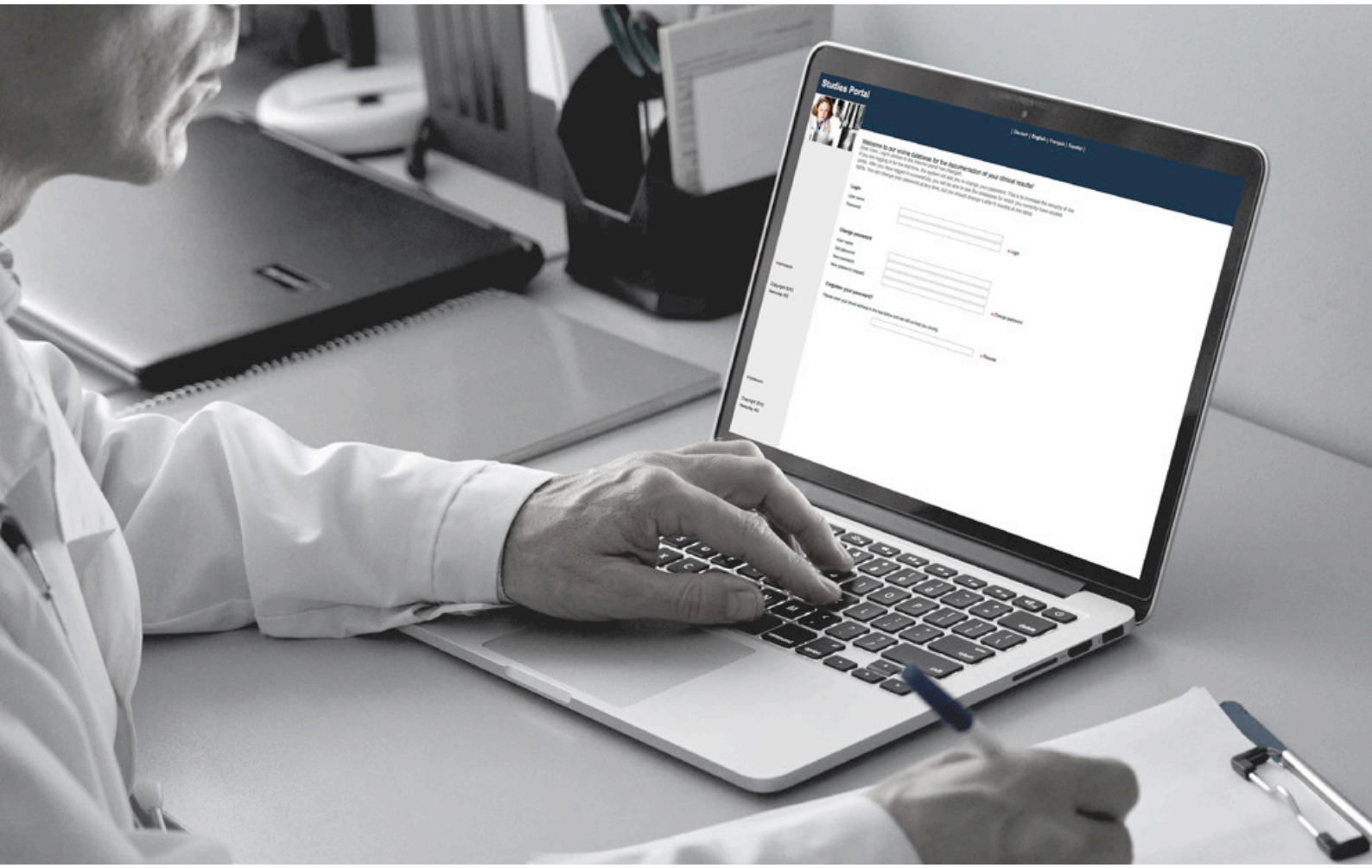
* Use an adjustable, medical pump with a suction of between 50 and a maximum of 125 mmHg. Regular checking of the system is mandatory. The system must be changed every 48-72 hours and, where appropriate, a new sponge inserted.

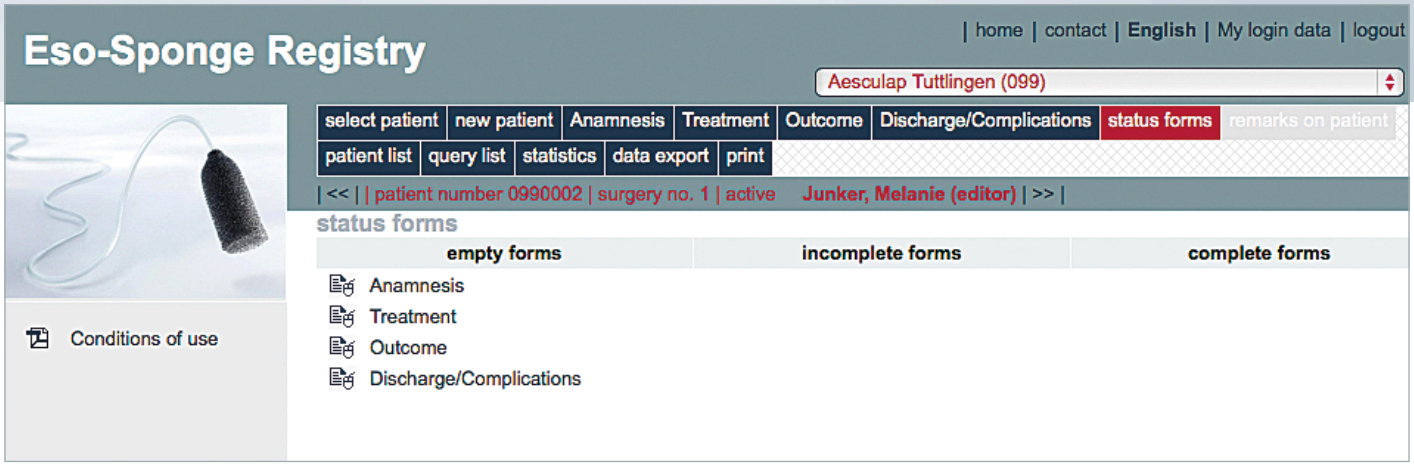
CLINICAL EVIDENCE

COHORT STUDIES – ENDOLUMINAL VACUUM THERAPY FOR THE TREATMENT OF ANASTOMOSIS INSUFFICIENCY OR PERFORATION WITHIN THE UPPER GIT.

The clinical effectiveness of the product Eso-SPONGE™ for the treatment of perforations and anastomosis insufficiencies within the upper GIT is currently evaluated in a registry (Eso-SPONGE Registry).
In November 2014, the ethics approval of the committee of the Christian Albrechts University in Kiel was obtained for the implementation of the registry.

Aim of the registry is the systematic collection of clinical data on the performance of Eso-SPONGE under daily clinical routine.
In collaboration with the University Hospital Schleswig-Holstein, Department of General, Visceral, Thoracic, Transplantation and Pediatric Surgery, Prof. C. Schafmayer a multicenter, prospective, web-based online registry was established.





Numerous clinics located in Germany have expressed their interest for participation. The Eso-SPONGE™ registry is registered (NCT02662777) at www.clinicaltrials.gov. The presentation of the first data was held by Prof. Schafmayer and Dr. Heits in Berlin on the German Surgeons Congress in April 2016. It is aimed to publish the multicentre data in a peer-reviewed journal after the inclusion of about 100 patients.

KUEHN ET AL.[10] PUBLISHED THEIR 4 YEARS EXPERIENCE OF ENDOSCOPIC VACUUM SPONGE THERAPY FOR ESOPHAGEAL ANASTOMOTIC LEAKAGES. SINCE NOVEMBER 2014 THE AUTHORS USED ESO-SPONGE FOR E-VAC.

CLINICAL EVIDENCE

Between 2011–2015 in total 21 patients were treated with the E-VAC therapy. Eleven patients suffered from an esophageal anastomotic leak and 10 had a perforation. The distance of defects were 32 cm [min. 18 cm – max. 44 cm] located away from the dental arch. The leaks were diagnosed on an average of 8 days postoperatively [min. 1 – max. 18 days] whereas most of the perforation were detected within 24 h. In eleven patients the sponges were placed intraluminal and 10 patients received an intracavitary placement. The E-VAC was applied for a median duration of 15 days [min. 3 – max. 46 days] with an average number of 5 sponges insertion [min. 1 – max. 14] per patient. In total 126 sponges were inserted in 21 patients. The sponges were changed after 3 days [min. 2 – max. 4 days] and 19/21 (90.3 %) patients could be successfully treated. Success rate of anastomotic leaks was 82 % and for the perforation 100 %. Failure of the treatment was in one case a necrosis with a severe mediastinitis. Another patient died to due fulminant sepsis followed by multi-organ failure 27 days postoperatively. During a follow-up period of 17 months [min. 4 – max. 45 months] one stenosis was seen (5.0 %) which was solved by endoscopic balloon dilatation.

The authors assessed the E-VAC therapy as a promising tool to treat various defects within the upper GIT. It can be used as an isolated treatment concept or can be combined with surgical interventions. The endoscopic vacuum sponge therapy has become the first choice treatment for perforations and anastomotic leaks within the upper GIT in this center. Since November 2014 they are using the E-VAC System “Eso-SPONGE™”.

TABLE 1: PUBLICATIONS USING ENDO-VAC TO TREAT DEFECTS IN THE UPPER GIT.

AUTHOR	Eso-SPONGE™ Register Schafmayer	Kuehn et al.[10]
YEAR	Status April 2016	2016
NUMBER OF PATIENTS	N = 29	N = 21
TYPE OF DEFECT (AI,IP,O) • (N,N,N)	25, 4, 0	11, 10, 0
APPLICATION OF THE SPONGE (IL, IC, IL/IC) • (N,N,N)	2, 19, 8	11, 10, 0
AGE OF THE PATIENTS (YEARS) [MIN. – MAX.]	64 [48-83]	72 [49-80]
NUMBER OF SPONGE [MIN. – MAX.]	9 [1-27]	5 [1-14]
MEDIAN TREATMENT DURATION (DAYS) [MIN. – MAX.]	24.5 days [4-85]	15 [3-46]
SUCCESS RATE	27/29 93 %	19/21 90.5 %
MORTALITY RATE	2/29 7 %	

Legend: NA: not applied, IL: intraluminal, IC: intracavitary, AI: anastomotic insufficiency, IP: iatrogenic perforation, O: other genese

CONCLUSION

Since its introduction into the market in 2015, clinical investigations have been performed using endoluminal vacuum therapy (E-VAC) to treat anastomotic leakages occurring after oesophageal cancer resection. The authors assessed the endoscopic endoluminal vacuum treatment as a safe and high efficient minimal invasive option. This approach is well tolerated by the patient and associated with a low complication rate. After diagnosis of the esophageal anastomotic leak the endoscopic vacuum sponge treatment should be started immediately because early treatment is more effective as late treatment regarding the clinical outcome. A longer hospital stay and a higher mortality rate has been published when the E-VAC therapy was started later than 24 hours after diagnosis of the esophageal defect. In comparison to stent placement E-VAC significantly reduces the mortality rate and significantly lowers the stricture rate. Furthermore, a higher closure rate and a shorter treatment duration has been observed using E-VAC in compared to stent placement. If needed the E-VAC therapy can be combined with stent placement or with surgical intervention. A success rate of 84 % has been reported in the literature for this minimal invasive approach after esophageal anastomotic leaks and esophageal perforation treatment.

KEY MESSAGES

- Promotes debridement, quick cleaning of the wound cavity.[10-20, 22, 24, 26]
- Promotes of granulation tissue ingrowth[10-20, 22, 24-26, 28-30]
- Mechanical reduction of the wound cavity[10-20, 22, 24-26, 29]
- Contributes significantly to the reduction of morbidity and mortality of the patients[14-20, 22, 29]
- Early treatment is likely to achieve faster healing, shorter duration of treatment/hospital stay and less complications[10, 14-17, 19]
- Likely to be superior to stent treatment and reduced need for surgical revision, and with less strictures[15, 17-18, 23]
- If necessary, Eso-SPONGE™ can be combined with stent placement or operative revision for better control of the septic focus.[10, 14-20, 22, 24, 27, 29]
- The average rate of successful treatment with Eso-SPONGE has been reported to occur in 84% of patients[10, 14-22]
- The mean treatment duration reported is less than 30 days[10, 14, 16-17, 19-21, 23-26, 28-30]

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