

Potential of Absorption, Capillary Effect and Sponge-Effect in Endoscopic-Assisted Therapy for Leaks and Fistulas

KH Fuchs^{1*}, B Sudarevic¹ and Meining A^{1,2}

¹Laboratory for Interventional and Experimental Endoscopy, University of Würzburg, 97080 Würzburg, Germany

²University of Würzburg, Zentrum Innere Medizin, Head of Gastroenterology, 97080 Würzburg, Germany

***Corresponding author:**

Karl-Hermann Fuchs,
Senior Professor: Laboratory for Interventional and
Experimental Endoscopy University of Würzburg,
Gastroenterology Grombühlstr.1297080 Würzburg,
Germany, E-mail: Karl-Hermann.Fuchs@gmx.de

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1. Abstract

1.1. Introduction: Anastomotic leaks and fistulas as well as perforations do lead to increased morbidity and mortality. Several interventional endoscopic techniques such as stents, clips, endoscopic suturing and endoscopic vacuum therapy, can help in reducing an unfavorable outcome of these patients, using a differentiated management of leakages. An important feature of these therapeutic options is the continuous removal of fluid from the fistula or abscess cavity in order to heal the defect and prevent subsequent complications. The objective of this study is the investigation of technical and conceptual modifications of the established Endo-sponge therapy and their feasibility.

1.2. Methods: 1-explore and find solutions for optimization of absorbing fluids from the cavity. 2-explore and find solutions for optimization of draining fluids from the cavity using the capillary effect. 3-explore and find solutions to optimize the endoscopic placement of a sponge or drain or both in the leak cavity in the esophageal wall.

1.3. Results: The results of the absorption tests showed a rather quick disappearance of the water volumes, but an insufficient capacity of the absorber bags and packs in that only 4m-6ml of fluid could be absorbed, before the bags and packs disintegrated. The potential of the capillary-effect in treatment of abscesses without the effect of suction in the dry tests was completely insufficient. The results show that only one technique using a forceful grasper over an external shaft outside the endoscope has substantial advantages over the other techniques.

1.4. Conclusions: The investigations in the potential of super-ab-

sorbing agents and the capillary effect of films was disappointing. The maneuverability of external steerable and flexible endoscopic instruments next to an endoscope in the lumen for precise positioning of sponges or films carries a high potential of being advantageous for endoscopic therapy.

2. Introduction

Anastomotic leaks and fistulas as well as perforations do lead to increased morbidity and mortality [1-3]. These complications may cause severe problems for the patients such as mediastinitis, empyema, pneumonia, sepsis, multiorgan failure and death. Currently, several techniques of interventional endoscopy such as stents, clips, endoscopic suturing and endoscopic vacuum therapy, can help in reducing an unfavorable outcome of these patients, using a differentiated management of leakages [4-15]. An important feature of these therapeutic options is the continuous removal of fluid from the fistula or abscess cavity in order to heal the defect and prevent subsequent complications.

A conventional surgical option is the surgical revision with an attempt of closure and a sufficient drainage of the abscess outside the body. One recent endoscopic related option is the application of a sponge in the cavity and vacuum therapy technique [16-21]. The placement of a sponge in the gut-lumen at the leak and/or its cavity associated with vacuum therapy will create a drainage of fluid, providing a chance to develop granulation in the leak and start a healing process. Reviewing the literature, it seems important to combine sponge-placement with the application of suction by continuous vacuum therapy [16-21]. The necessity of a persistent drainage usu-

ally through the nasopharynx is an annoying option for the patients, since the disturbing irritation in the nose and the inability to eat and drink regular meals creates frustrations.

Endoscopic stent therapy is an attractive option, however, insufficient drainage and stent migration often limit the success of this method, especially in larger defects [4, 5, 8, 11, 12]. Recently, successful therapy has been reported in esophageal leaks using endoscopic sponge therapy with internal drainage without suction [22-24]. More technical modifications may be possible to improve this intriguing therapeutic concept.

The objective of this study is the investigation of technical and conceptual modifications of the established Endo-sponge therapy and their feasibility. One option is the exploration of the potential of the absorption-effect of certain substances to be more effective in withdrawal of fluids. Another option is evaluation of the capillary-effect of small spaces to drain fluids from unfavorable places such as abscesses. In addition, a more precise endoscopic placement of the sponge in the leak cavity reaching all corners of the involved area, may be more effective. The aim of this project is the evaluation of these different options as to their feasibility and their potential to address the needs in fluid drainage.

3. Material and Methods

3.1. Design and Open Questions

- explore and find solutions for optimization of absorbing fluids from the cavity
- explore and find solutions for optimization of draining fluids from the cavity using the capillary effect



Figure 1: potential of absorption with super-absorbers:
 (a) below superabsorber sachet or bag and above sewn-in pack;
 (b) fragile sachet bursts after excessive fluid absorption;
 (c) sewn-in superabsorber-pack with sachet after absorption still intact.

3.3. Test for Assessment of Capillary Effect of Sponge, Foil and Drain, Assembled for an Internal Drainage-System of The Leak Cavity Without Suction

The capillary effects of small caliber drains and foils in fluid can be used to treat fluid collections in the body. This principle was investigated by other authors in the past years, however they used additional suction [21, 25, 26]. Therefore, we performed test-series following the described methods, however, our aim was to explore the potential of fluid drainage based on capillary effect [21, 25, 26]. In the in-vitro test the water-volume drainage and time duration was measured and documented.

- explore and find solutions to optimize the endoscopic placement of a sponge or drain or both in the leak cavity in the esophageal wall
- provide interpretations and conclusions for future clinical use

3.2. Exploration of the Potential of Enhanced Fluid-Absorption

In this first evaluation, a “super-absorber” (granulat: Diamonds™ ConvaTec Ltd, UK, gelling sachets) was tested in a dry model to explore a potential increase of the effectivity of fluid-absorption in an abscess cavity (Figure 1). The commercially available little paper bag was exposed to a defined volume of water and the time of absorption until total disappearance of the provided water-volume was measured. Several volumes were tested in 5 tests each to gain a representative result. It was noticed during testing that the paper bags of the sachets were quite fragile and would dissolve rather quickly, resulting in local spread of the granulat within the location (Figure 1). In addition, the paper bags disrupted, when wet, as soon as there were tried to be manipulated by an endoscopic grasping device.

As a consequence, in a second test series the “super-absorber” granulat sachets were sewn in a surrounding textile-sponge in order to protect the outside cover from disrupting as well as being able to be manipulated by an endoscopic grasper (Figure1).

The absorption abilities of these “absorber-packs” were assessed by exposing the packs to increasing volumes of water (2ml; 4ml; 20ml) and measuring time in seconds/minutes until full absorption of the given water-volume.

Initial tests (capillary test 1) were performed with a polyurethan sponge (Endo-SPONGE™ B. Braun Melsungen AG, Melsungen, Germany), which is an open-pore drainage (OPD) (Figure 2). The sponge was cut to an adequate size and then fixed to the tip of a drainage with surgical sutures. Similarly, a film-connected drainage was created by using a Suprasorb™ CNP drainage film (Lohmann & Rauscher GmbH & Co.KG, Neuwied, Germany), which was rolled around a drain and again fixed with a surgical suture on the drain, thus resulting in an open-pore-film-drainage (OFD) (capillary test 2). A third option is a combination of the previous techniques, using both a small foam and a film, wrapped around the foam and fixed

by sutures on the drain as an open-pore-film-wrapped polyurethane foam drain (OPFD) (capillary test 3) (Figure 2). All drains were small caliber Redon-drains.

In a next series, the capillary effect of the folie-film alone was evalu-

ated, spreading a film-folie in a small water basin with 5ml and elevating over a height of 1,5cm to flat positioned paper (capillary test 4) (Figure 3). A last test for capillary effect was performed using just the film-material connected to an applicator-tip to introduce it into smaller fistula-openings (capillary test 5).

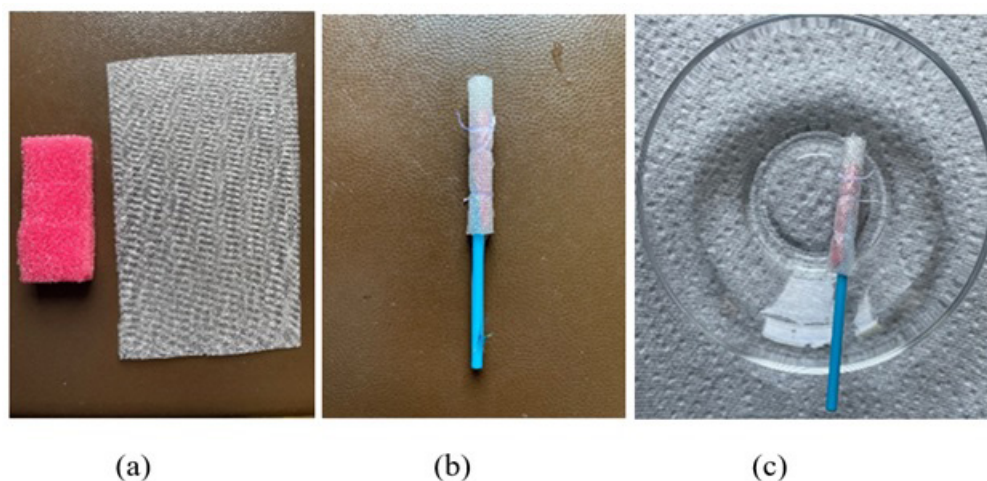


Figure 2: tests of different sponges, drains and films for fluid transport by capillary effect:

(a) Sponge and film as material to create an OPD (open-pore-drainage)

(b) Down-sized Sponge, rolled and drainage combined as OPFD (open-pore-film-wrapped polyurethane foam drain)

(c) OPFD exposed to water and tested for capillary effect with a 1cm elevation.



Figure 3: test for capillary effect from a water-basin without suction over a height of 1,0cm:

(a) a single film-folie is used to record the capillary effect

(b) the film is shaped and wrapped around an applicator-tip for improved endoscopic placement

3.4. Endoscopic Placement of Sponge and Drain System

A more precise endoscopic placement of the sponge-system in the leak cavity reaching all corners of the involved area, may be more effective. A model for evaluating different endoscopic assisted systems was established (Figure 4). A Styrofoam-model of the esophagus was created with a leak (diameter 2cm) in the middle of the esophagus, connecting the esophageal lumen with a lower abscess cavity (LAC) as well as an upper abscess cavity (UAC). A porcine-explant of an esophagus and stomach was used, provided from a local butcher, and placed in the Styrofoam model for testing (Figure 4). The simulation-leak was created and placed at the opening towards the cavities in the model.

Subsequently, different instrument combinations were used and test-

ed in this model. In these test-series, the technical feasibility of positioning a sponge or a drain-system precisely into the LAC was tested using different technical options.

As a baseline test, the well-established original Endo-Sponge™ application system (Braun Melsungen, Germany) was used, measuring the duration of the procedure with the plastic applicator system and pusher (Figure 5).

In the second positioning-test, the manipulation of a sponge was performed with a regular commercially available endoscopic grasping forceps through the working channel of the scope, fixing the sponge with the grasper prior to entering with the scope into the pharynx, subsequently pushing the sponge and endoscope forward until reaching the level of the esophageal leak. Then, the grasper

together with the sponge, is pushed further through the leak in the cavity (Figure 6). Manipulations of the sponge and optimizing its position were performed with the endoscopic grasper.

In the third positioning-test-series, the placement of the sponge, connected to a short drain, was assessed by using a guidewire, which was initially placed under endoscopic vision into the LAC (Figure 7). Then, the endoscope was removed and the sponge in combination with the drain was mounted on the guidewire and advanced into the LAC. Further manipulation was limited, once the guidewire was withdrawn. An endoscopic inspection of the sponge and drain position was performed to control the result.

A fourth positioning-test was performed using an external indepen-

dent instrument such as a larger grasper (diameter 5cm), which allows for more robust traction and pushing force to manipulate the sponge and improve its position in the cavity (Figure 4). The external independent grasper also enables the positioning of the sponge in the UAC (Figure 8).

The feasibility of all these different technical options was evaluated. Major and inhibiting handling problems had to be recorded by the participants. The participants consisted of a mixed group of individuals, employees of our laboratory, with an engineering background, surgery and gastroenterology. All participants had some experience in endoscope handling.

All data were recorded prospectively and documented, and if applicable, compared with a t-test for statistical evaluation.

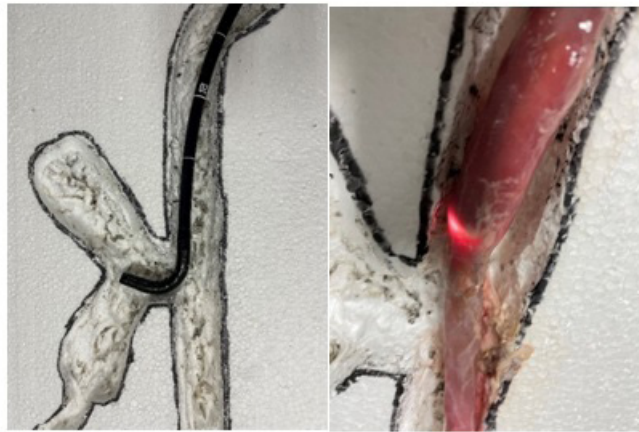


Figure 4: Styrofoam model for dry test of instruments, simulating an esophageal leak and fistula in the mid-esophagus with an upper and a lower abscess-cavity



Figure 5: Commercial sponge with external drainage for vacuum therapy (Endo-Sponge™ application system, Braun Melsungen, Germany) was used, measuring the duration of the procedure with the plastic applicator system and pusher.

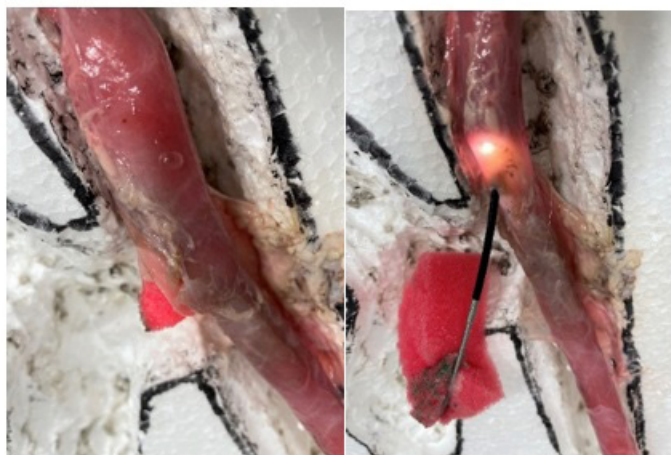


Figure 6: In the in-vitro model, the sponge is transported into the esophagus by pushing the sponge in the abscess cavity with some regular endoscopic forceps through the working-channel

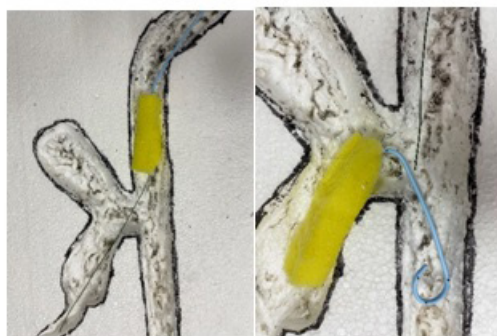


Figure 7: (a) placement of sponge via guidewire and (b) internal drainage without suction

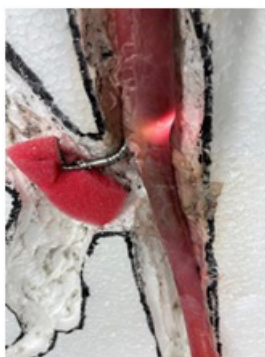


Figure 8: Positioning of sponge via external independent articulating instrument, which has a steering function and a 5mm caliber, allowing for a forceful positioning of the sponge.

4. Results

The results of the absorption tests showed a rather quick disappearance of the water volumes, but an insufficient capacity of the absorber bags and packs in that only 4m-6ml of fluid could be absorbed, before the bags and packs disintegrated. Table 1 demonstrates the data overview.

Another drawback was the fact that the bags were fragile, thus, relocating the bags by endoscopic graspers was not possible since the super-absorber bags did disintegrate.

After sewing the bags in a textile pack did improve the handling issue. The packs were more stable and could be transported or withdrawn

from their initial location by endoscopic graspers. However, the absorption function did not reach a sufficient clinical level. Since in clinical practice a daily production of pus and fluid reaches around 50-120 ml, the absorption capacity of the superabsorber-packs were at a level of about 20-25 ml. This is not sufficient for clinical use. Table 2 demonstrates the time frame and the fluid capacity as shown in our tests. As a summary of these tests it became evident that the super-absorber cannot be used in this context.

The potential of the capillary-effect in treatment of abscesses and fistulas could not be evaluated in a satisfactory way. Without the effect of suction, the dry tests for the application of sponges in

combination with drains and films regarding the capillary effect was completely insufficient, since no substantial fluid transport could be demonstrated. None of the various tests showed any substantial fluid transfer.

The third option of potential improvement concerned the optimization of endoscopic positioning of a sponge in the abscess cavity by various endoscopic tools and techniques. Table 3 shows the results of the different techniques regarding the duration of sponge placement. The results show that only one technique using a forceful grasper over an external shaft outside the endoscope has substantial

advantages over the other techniques. When the duration of positioning is compared with each other, the procedure with external FMX-grasper is faster than any other technique ($p < 0,0001$) (Table 3). The commercial sponge application system is also faster as the regular grasper ($p = 0,0366$) and also the guidewire-supported system ($p = 0,0015$).

Therefore, the potential of optimizing the current available endoscopic-assisted techniques in the management of draining and eventually healing esophageal abscesses and fistulas by enhanced fluid absorption and using the capillary effect are limited. An improved placement of a sponge-system seems technically realistic.

Table 1: absorption-test 1: Water absorption with superabsorber-bags and -packs: Time duration until full fluid absorption in seconds.

Absorption-tests	1	2	3	4	5	6	7	median
Super-absorber bag (2ml)	40	60	25	30	25	30	40	30
Super-absorber bag (4ml)	80	130	110	90	100	110	100	100
Super-absorber-pack (4ml)	60	40	70	60	50	50	60	60

Table 2: absorption-test 2: absorber-pack (sewn-in super-absorber-bag) exposed to increasing volume of water until disintegration (time in seconds)

ml of water	4	8	12	16	20	24
Time in seconds	60	160	340	480	660	Disintegration of pack

5. Discussion

This report focused on the exploration of several technical options around the clinical problem of esophageal leaks and their management. In the past decades, endoscopic technology and procedures have definitely advanced the therapeutic spectrum to help these patients. However, the limitations of the currently available endoscopic techniques such as stent migration, necessity of suction in sponge therapy, limited accuracy in sponge-placement especially in smaller fistulas, the necessity to limit oral fluid and food intake for the patients during the weeks of treatment should stimulate further research in this field.

Unfortunately, the ability of super-absorber-agents to quickly absorb fluid volumes is based on a fairly large amount of absorber-substance, which enlarges during the process in size, and therefore, is not a practical solution for intraluminal and leak problems, because again to many endoscopic visits are necessary, limiting the satisfaction for patients and payers.

We were unable to demonstrate and really evaluate the capillary effect in several dry-lab conditions. One could conclude from our experimental experience that the capillary effect without any support by suction using the different options of sponge, drains and films, is just not sufficient to improve the clinical problem. However, in our experimental setting, the tests were far from any clinical condition, and therefore, may be not realistic. It is interesting that the large experience with endoscopic placed internal drainage-systems by Donatelli et al. show a very beneficial effect regarding healing of the leak [22-24]. Despite the lack of external suction, these internal drains between the leak-track or the leak-cavity cause a stepwise healing and closure of these defects. One can speculate that intrathoracic pressure conditions and changes as well as respiratory movements

and their influence on pressure within the leak cavities may cause leak drainage without external suction. This requires further research to learn more about the mechanisms involved.

A more precise endoscopic placement of the sponge-system in the leak cavity reaching all corners of the involved area, may be more effective. The currently available sponge and drain systems usually have an applicator, which may have a guidewire system. However, most are not associated with a placement under endoscopic vision, which may lack the necessary accuracy. On the other hand, accurate position of the sponge and drainage-system seems to be an important issue regarding successful cleaning of the area of the anastomotic insufficiency and abscess drainage. If the sponge can only be placed in the esophageal lumen, a thorough cleaning of the cavity may be limited, because the suction effect of the intraluminal sponge may not reach the corners of the abscess cavity. The latter may result in excessive number of procedures until improvement of the patient, associated with more suffering of the patients and high treatment costs for the payers [25, 26].

As a consequence, we were surging for an endoscopic procedure combined with the transport and placement of a sponge-drain-system under endoscopic control into the site of interest. During the developments of transluminal endoscopic techniques, several innovations regarding endoscopic platforms with more precise maneuverability emerged [27-29]. A prerequisite is a flexible grasper with the necessary strength and maneuverability to move around corners as necessary. A new flexible grasping system was used, which has been recently published and serves the necessary needs in this situation [29].

6. Conclusions

The investigations in the potential of super-absorbing agents and

the capillary effect of films was disappointing. The maneuverability of external steerable and flexible endoscopic instruments next to an endoscope in the lumen for precise positioning of sponges or films carries a high potential of being advantageous for endoscopic therapy. Thus, clinical testing of the latter should be planned.

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